UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2018

OR

☐ **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 ☒ No ☐

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 ☒ No ☐

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of July 31, 2018, there were 139,180,559 shares of Class A common stock outstanding and 13,976,855 shares of Class B common stock outstanding.

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 statements, but the 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® and DUZALLO® by us in the U.S.;
- the timing and execution of the launches and commercialization of CONSTELLA® in Europe and LINZESS in Japan;
- the timing, investment and associated activities involved in developing, obtaining regulatory approval for, launching, and commercializing our products and product candidates by us and our partners worldwide;
- our ability and the ability of our partners to secure and maintain adequate reimbursement for our products;
- our ability and the ability of our partners and third parties 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, as well as Abbreviated New Drug Applications filed by generic drug manufacturers and potential U.S. Food and Drug Administration approval thereof, and associated patent infringement suits that we have filed or may file, or other action that we may take against such companies, and the timing and resolution 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, as well as partnering arrangements, 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, real estate needs and concentration of voting control, as well as the timing and drivers thereof, and internal control over financial reporting;
- 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 or impairments of intangible assets and estimates and assumptions related thereto;
- 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;
- the proposed separation of the Company's operations into two independent, publicly traded companies, including the completion and timing of the separation, the business and operations of each company and any benefits or costs of the separation, including the tax treatment;
- the timing and benefits and costs associated with the termination of the lesinurad license agreement and the transition of the lesinurad franchise to AstraZeneca; 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® and DUZALLO® are trademarks 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.

IRONWOOD PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED June 30, 2018
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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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 145,415	$ 125,736
Available-for-sale securities	35,831	95,680
Accounts receivable, net	6,748	3,190
Related party accounts receivable, net	73,771	78,967
Inventory, net	1,099	735
Prepaid expenses and other current assets	16,678	7,288
Total current assets	279,542	311,596
Restricted cash	8,306	7,056
Property and equipment, net	16,335	17,274
Convertible note hedges	159,526	108,188
Intangible assets, net	152,953	159,905
Goodwill	785	785
Other assets	771	870
Total assets	$ 618,218	$ 605,674
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and related party accounts payable, net	$ 23,786	$ 15,958
Accrued research and development costs	5,378	7,313
Accrued expenses and other current liabilities	37,829	38,237
Current portion of capital lease obligations	2,465	4,077
Current portion of deferred rent	242	195
Current portion of 2026 Notes	24,861	—
Current portion of contingent consideration	423	247
Total current liabilities	94,984	66,027
Deferred rent, net of current portion	6,058	5,449
Contingent consideration, net of current portion	33,228	31,011
Note hedge warrants	143,019	92,188
Convertible senior notes	257,206	249,193
2026 Notes, net of current portion	122,614	146,898
Other liabilities	5,060	5,060
Commitments and contingencies		
Stockholders' (deficit) 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 138,860,929 and 136,465,526 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	139	137
Class B common stock, $0.001 par value, 100,000,000 shares authorized and 13,992,491 shares issued and outstanding at June 30, 2018 and 13,983,762 shares issued outstanding at December 31, 2017	14	14
Additional paid-in capital	1,357,224	1,318,536
Accumulated deficit	(1,401,284)	(1,308,760)
Accumulated other comprehensive loss	(44)	(79)
Total stockholders' (deficit) equity	(43,951)	9,848
Total liabilities and stockholders' (deficit) equity	$ 618,218	$ 605,674

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

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,	
	2018	2017	2018	2017
Revenues:				
Collaborative arrangements revenue	$ 71,207	$ 58,640	$ 134,293	$ 110,504
Product revenue, net	1,096	465	1,731	754
Sale of active pharmaceutical ingredient	8,803	5,972	14,237	5,985
Total revenues	81,106	65,077	150,261	117,243
Cost and expenses:				
Cost of revenues, excluding amortization of acquired intangible assets	4,065	3,502	6,672	4,033
Write-down of commercial supply and inventory to net realizable value and loss on non-cancellable purchase commitments	1,836	96	1,836	96
Research and development	38,932	37,344	75,437	71,046
Selling, general and administrative	68,363	57,792	127,864	113,396
Amortization of acquired intangible assets	3,476	421	6,952	841
Loss on fair value remeasurement of contingent consideration	1,962	6,933	2,474	8,547
Restructuring expenses	2,392	—	4,814	—
Total cost and expenses	121,026	106,088	226,049	197,959
Loss from operations	(39,920)	(41,011)	(75,788)	(80,716)
Other (expense) income:				
Interest expense	(9,383)	(9,046)	(18,656)	(18,029)
Interest and investment income	732	496	1,413	891
(Loss) gain on derivatives	(809)	5,337	507	3,138
Loss on extinguishment of debt	—	—	—	(2,009)
Other expense, net	(9,460)	(3,213)	(16,736)	(16,009)
Net loss	$ (49,380)	$ (44,224)	$ (92,524)	$ (96,725)
Net loss per share—basic and diluted	$ (0.32)	$ (0.30)	$ (0.61)	$ (0.65)
Weighted average number of common shares used in net loss per share—basic and diluted:	152,163	148,778	151,591	148,285

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

Ironwood Pharmaceuticals, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	$(49,380)	$(44,224)	$(92,524)	$(96,725)
Other comprehensive loss:				
Unrealized gains (losses) on available-for-sale securities	47	17	35	(17)
Total other comprehensive income (loss)	47	17	35	(17)
Comprehensive loss	$(49,333)	$(44,207)	$(92,489)	$(96,742)

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

Ironwood Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (92,524)	$ (96,725)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,461	4,838
Amortization of acquired intangible assets	6,952	841
(Gain) loss on disposal of property and equipment	(275)	135
Share-based compensation expense	19,794	16,419
Change in fair value of note hedge warrants	50,831	36,221
Change in fair value of convertible note hedges	(51,338)	(39,359)
Write-down of commercial supply and inventory to net realizable value and loss on non-cancellable purchase commitments	1,836	96
Write-down of excess non-cancellable ZURAMPIC and DUZALLO sample purchase commitments	390	1,353
Gain on facility subleases	—	(1,579)
Accretion of discount/premium on investment securities	(138)	111
Non-cash interest expense	8,591	7,849
Non-cash change in fair value of contingent consideration	2,474	8,547
Loss on extinguishment of debt	—	2,009
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	1,638	4,497
Prepaid expenses and other current assets	(9,373)	703
Inventory, net	(992)	1,081
Other assets	99	246
Accounts payable, related party accounts payable and accrued expenses	6,276	(5,345)
Accrued research and development costs	(1,935)	517
Deferred revenue	—	225
Deferred rent	656	(2,977)
Net cash used in operating activities	(53,577)	(60,297)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(2,491)	(90,706)
Sales and maturities of available-for-sale securities	62,512	251,027
Purchases of property and equipment	(3,200)	(1,746)
Proceeds from sale of property and equipment	272	79
Net cash provided by investing activities	57,093	158,654
Cash flows from financing activities:		
Proceeds from issuance of 2026 Notes, net of discount to lender	—	146,250
Costs associated with issuance of 2026 Notes	—	(235)
Proceeds from exercise of stock options and employee stock purchase plan	19,044	18,473
Payments on capital leases	(1,510)	(1,593)
Principal payments on PhaRMA notes	—	(134,258)
Payments on contingent purchase price consideration	(121)	(56)
Net cash provided by financing activities	17,413	28,581
Net increase in cash, cash equivalents and restricted cash	20,929	126,938
Cash, cash equivalents and restricted cash, beginning of period	132,792	62,251
Cash, cash equivalents and restricted cash, end of period	$ 153,721	$ 189,189
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 145,415	$ 182,132
Restricted cash	8,306	7,057
Total cash, cash equivalents, and restricted cash	$ 153,721	$ 189,189

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 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, based upon the Company's target-to-disease approach to development and leveraging the Company's core areas of expertise in gastrointestinal ("GI") and primary care, as well as in guanylate cyclase ("GC") pathways.

The Company's first commercial product, linaclotide, is available to adult men and women suffering from irritable bowel syndrome with constipation ("IBS-C"), or chronic idiopathic constipation ("CIC"), in certain countries around the world. Linaclotide is available under the trademarked name LINZESS® to adult men and women suffering from IBS-C or CIC in the United States (the "U.S.") and Mexico, and to adult men and women suffering from IBS-C in Japan. Linaclotide is available under the trademarked name CONSTELLA® to adult men and women suffering from IBS-C or CIC in Canada, and to adult men and women suffering from IBS-C in certain European countries.

The Company and its 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. Allergan also has an exclusive license from the Company to develop and commercialize linaclotide in all countries other than China, Hong Kong, Macau, Japan and the countries and territories of North America (the "Allergan License Territory"). On a country-by-country and product-by-product basis in the Allergan License Territory, Allergan pays the Company a royalty as a percentage of net sales of products containing linaclotide as an active ingredient. In addition, Allergan has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and in Mexico as LINZESS.

Astellas Pharma Inc. ("Astellas"), the Company's partner in Japan, has an exclusive license to develop and commercialize linaclotide in Japan. In March 2017, Astellas began commercializing LINZESS for the treatment of adults with IBS-C in Japan, and in September 2017, Astellas submitted a supplemental new drug application for approval of LINZESS for the treatment of adults with chronic constipation in Japan. The Company has 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 ("CFDA") to market linaclotide in China.

The Company's and Allergan's linaclotide life cycle management strategy in the U.S. includes the objective of strengthening the clinical profile of linaclotide by obtaining additional abdominal symptom claims and expanding the clinical utility of linaclotide by demonstrating the pain-relieving effect of a delayed release formulation, through the advancement of linaclotide delayed release in all forms of IBS. The Company and Allergan are also continuing to explore ways to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. In July 2018, the Company announced the initiation of a Phase IIIb trial evaluating the efficacy and safety of linaclotide 290 mcg on multiple abdominal symptoms in addition to pain, including bloating and discomfort, in adult patients with IBS-C.

The Company is advancing another GI development program, IW-3718, a gastric retentive formulation of a bile acid sequestrant for the potential treatment of persistent gastroesophageal reflux disease ("GERD"). The Company's clinical research has demonstrated that reflux of bile from the intestine into the stomach and esophagus plays a key role in the ongoing symptoms of persistent GERD. IW-3718 is a novel formulation of a bile acid sequestrant designed to release in the stomach over an extended period of time, bind to bile that refluxes into the stomach, and potentially provide symptomatic relief in patients with persistent GERD. In June 2018, the Company initiated two Phase III clinical trials evaluating the safety and efficacy of IW-3718 in patients with persistent GERD.

In June 2016, the Company closed a transaction with AstraZeneca (the "Lesinurad Transaction") pursuant to which the Company received an exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient (the "Lesinurad License"), including ZURAMPIC® and DUZALLO®. 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 for the treatment of hyperuricemia associated with uncontrolled gout ("uncontrolled gout"). In October 2016, the Company began commercializing ZURAMPIC in the U.S. The FDA approved DUZALLO, a fixed-dose combination product of lesinurad and allopurinol in August 2017 for the treatment of hyperuricemia associated with gout in patients who have not achieved goal serum uric acid levels with a medically appropriate daily dose of allopurinol alone. In October 2017, the Company began commercializing DUZALLO in the U.S. In January 2018, the Company commenced an initiative to evaluate the optimal mix of investments for the lesinurad franchise for uncontrolled gout, including DUZALLO and ZURAMPIC. As part of this effort, in 2018, the Company began re-allocating resources within the lesinurad franchise to systematically explore a more comprehensive marketing mix in select test markets (with paired controls), while continuing to build market presence for the lesinurad franchise across the country. In July 2018, the Company obtained and analyzed the results from the lesinurad franchise test markets. Data from the test markets did not meet expectations. In connection with the results, the Company's Board of Directors determined on July 31, 2018 to terminate the lesinurad license agreement (Note 14).

The Company is also leveraging its pharmacological expertise in GC pathways gained through the discovery and development of linaclotide, a GC-C agonist, to develop and advance a pipeline of sGC stimulators, including praliciguat and olinciguat. The Company is advancing praliciguat, its lead clinical sGC stimulator, in Phase II trials, for the potential treatment of diabetic nephropathy and for the potential treatment of heart failure with preserved ejection fraction ("HFpEF"). The Company's second clinical sGC stimulator, olinciguat, is being advanced in Phase II trials for the potential treatment of achalasia and for the potential treatment of sickle cell disease. In June 2018, the FDA granted Orphan Drug Designation to olinciguat for the treatment of patients with sickle cell disease.

In May 2018, the Company announced its intent, as authorized by its Board of Directors, to separate its sGC business from its commercial and GI business, resulting in two independent, publicly traded companies, Ironwood and a new company ("R&D Co"). Following the separation, Ironwood is expected to focus on accelerating growth of its in-market products, including LINZESS, and advance development programs targeting treatments for GI diseases, uncontrolled gout, and abdominal pain. The separated R&D Co. is expected to focus on the sGC pipeline development programs for the treatment of serious and orphan diseases. The separation is expected to be completed in the first half of 2019 and is anticipated to be tax-free. In June 2018, the Company announced certain planned future management changes in connection with, and contingent upon the successful completion of, the separation, as well as determined the initial organizational designs of the two new businesses, including employees' roles and responsibilities.

The Company has periodically entered into co-promotion agreements to maximize its salesforce productivity. As part of this strategy, 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"). In January 2017, the Company and Allergan entered into a commercial agreement under which adjustments to the Company's or Allergan's share of the net profits under the share adjustment provision of the collaboration agreement for linaclotide in North America are eliminated, in full, in 2018 and all subsequent years. As part of this agreement, Allergan appointed the Company, on a non-exclusive basis, to promote CANASA® (mesalamine), approved for the treatment of ulcerative proctitis, and DELZICOL® (mesalamine), approved for the treatment of ulcerative colitis, in the U.S. for approximately two years. In December 2017, this agreement was amended to include and extend the promotion of VIBERZI through December 31, 2018 and discontinue the promotion of DELZICOL effective January 1, 2018.

These agreements are more fully described in Note 3, *Goodwill and Intangible Assets,* and Note 4, *Collaboration, License, Co-Promotion and Other Commercial Agreements,* to these condensed consolidated financial statements.

In September 2016, the Company closed a direct private placement, pursuant to which the Company issued $150.0 million in aggregate principal amount of 8.375% notes due 2026 (the "2026 Notes") on January 5, 2017 (the "Funding Date"). The Company received net proceeds of approximately $11.2 million from the 2026 Notes, after redemption of the PhaRMA Notes outstanding balance and accrued interest of approximately $135.1 million and deducting fees and expenses of approximately $3.7 million. The proceeds from the issuance of the 2026 Notes were used to redeem the outstanding principal balance of the 11% PhaRMA Notes due 2024 (the "PhaRMA Notes") on the Funding Date. These transactions are more fully described in Note 9, *Notes Payable*, to these condensed consolidated financial statements.

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, 2017, which was filed with the Securities and Exchange Commission on February 22, 2018 (the "2017 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, 2018, and the results of its operations for the three and six months ended June 30, 2018 and 2017, and its cash flows for the six months ended June 30, 2018 and 2017. The results of operations for the three and six months ended June 30, 2018 and 2017 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.

Reclassifications and Revisions to Prior Period Financial Statements

Certain prior period financial statement items, such as Sale of Active Pharmaceutical Ingredient and Restricted Cash, have been reclassified to conform to current period presentation.

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 on-going 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, including returns, rebates, and other pricing adjustments; available-for-sale securities; inventory valuation, and related reserves; impairment of long-lived assets, including its acquired intangible assets and goodwill; 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; contingent consideration; 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.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, *Summary of Significant Accounting Policies*, in the 2017 Annual Report on Form 10-K. During the six months ended June 30, 2018, the Company adopted the following additional significant accounting policies:

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606") using the modified retrospective transition method. The adoption of ASC 606 represents a change in accounting principle that aims to more closely align revenue recognition with the delivery of the Company's services and will provide financial statement readers with enhanced disclosures. In accordance with ASC 606, the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration which the Company expects to receive in exchange for the good or service. The reported results for the three and six months ended June 30, 2018 reflect the application of ASC 606 guidance, while the reported results for prior periods were prepared in accordance with ASC 605, *Revenue Recognition* ("ASC 605"). Upon adoption of ASC 606, the Company concluded that no cumulative adjustment to the accumulated deficit as of January 1, 2018 was necessary. There were no remaining or ongoing deliverables or unrecognized consideration as of December 31, 2017 that required an adjustment to accumulated deficit. The adoption of ASC 606 had no impact on the Company's statement of operations, balance sheets, or statement of cash flows.

As part of the ASC 606 adoption, the Company has utilized certain practical expedients outlined in the guidance. These practical expedients include:

- Expensing as incurred incremental costs of obtaining a contract, such as sales commissions, if the amortization period of the asset would be less than one year.
- Recognizing revenue in the amount that the Company has the right to invoice, when consideration from the customer corresponds directly with the value to the customer of the Company's performance completed to date.
- For contracts that were modified before the beginning of the earliest reporting period presented in accordance with the pending content that links to this paragraph, an entity need not retrospectively restate the contract for those contract modifications in accordance with paragraphs ASC 606-10-25-12 through 25-13. Instead, an entity shall reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented in accordance with the pending content that links to this paragraph when: a. Identifying the satisfied and unsatisfied performance obligations b. Determining the transaction price and c. Allocating the transaction price to the satisfied and unsatisfied performance obligations.

Prior to the adoption of ASC 606, the Company recognized revenue when there was persuasive evidence that an arrangement existed, services had been rendered or delivery had occurred, the price was fixed or determinable, and collection was reasonably assured.

The Company's revenues are generated primarily through collaborative arrangements and license agreements related to the research and development and commercialization of linaclotide, as well as co-promotion arrangements in the U.S. and product revenue related to the commercial sale of ZURAMPIC and DUZALLO in the U.S. The terms of the collaborative research and development, license, co-promotion and other agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, including participation on joint steering committees, (iii) the manufacture of finished drug product, active pharmaceutical ingredient ("API"), or development materials for a partner, which are reimbursed at a contractually determined rate, and (iv) co-promotion activities by the Company's clinical sales specialists. Non-refundable payments to the Company under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API, or development materials, (iv) payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives, and (vi) royalties on product sales. Additionally, the Company may receive its share of the net profits or bear its share of the net losses from the sale of linaclotide in the U.S. and for China, Hong Kong and Macau through its collaborations with Allergan and AstraZeneca, respectively. The Company has adopted a policy to recognize revenue net of tax withholdings, as applicable.

Revenue recognition under ASC 606

Upon executing a revenue generating arrangement, the Company assesses whether it is probable the Company will collect consideration in exchange for the good or service it transfers to the customer. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. The Company must develop assumptions that require significant judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The assumptions that are used to determine the stand-alone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Collaboration, License, Co-Promotion and Other Commercial Agreements

Upon licensing intellectual property to a customer, the Company determines if the license is distinct from the other performance obligations identified in the arrangement. The Company recognizes revenues from the transaction price, including non-refundable, up-front fees allocated to the license when the license is transferred to the customer if the license has distinct benefit to the customer. For licenses that are combined with other promises, the Company assesses the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. For performance obligations that are satisfied over time, the Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company's license and collaboration agreements include milestone payments, such as development and other milestones. The Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method at the inception of the agreement. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. The Company re-evaluates the probability of achievement of such milestones and any related constraint at each reporting period, and any adjustments are recorded on a cumulative catch-up basis.

Agreements that include the supply API or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide a material right to its partner, and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded as revenue when the customer obtains control of the goods, which is typically upon shipment for sales of API and upon delivery for sales of drug product.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception under ASC 606-10-55-65.

Net Profit or Net Loss Sharing

In accordance with ASC 808 Topic, Collaborative Arrangements ("ASC 808"), the Company considered the nature and contractual terms of the arrangement and the nature of the Company's business operations to determine the classification of payments under the Company's collaboration agreements. While ASC 808 provides guidance on classification, the standard is silent on matters of separation, initial measurement, and recognition. Therefore, the Company, consistent with its accounting policies prior to the adoption of ASC 606, applies the separation, initial measurement, and recognition principles of ASC 606 to its collaboration agreements.

The Company's collaborative arrangements revenues generated from sales of LINZESS in the U.S. are considered akin to sales-based royalties. In accordance with the sales-based royalty exception, the Company recognizes its share of the pre-tax commercial net profit or net loss generated from the sales of LINZESS in the U.S. in the period the product sales are earned, as reported by Allergan, and related cost of goods sold and selling, general and administrative expenses are incurred by the Company and its collaboration partner. These amounts are partially determined based on amounts provided by Allergan and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and contractual rebates, wholesaler fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. The Company is highly dependent on Allergan for timely and accurate information regarding any net revenues realized from sales of LINZESS in the U.S. in accordance with both ASC 808 and ASC 606, and the costs incurred in selling it, in order to accurately report its results of operations. If the Company does not receive timely and accurate information or incorrectly estimates activity levels associated with the collaboration at a given point in time, the Company could be required to record adjustments in future periods.

In accordance with ASC 606-10-55, Principal Agent Considerations, the Company records revenue transactions as net product revenue in its condensed consolidated statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor, retaining inventory risk, and control over pricing. Given that the Company is not the primary obligor and does not have the inventory risks in the collaboration agreement with Allergan for North America, it records its share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and presents the settlement payments to and from Allergan as collaboration expense or collaborative arrangements revenue, as applicable. The Company and Allergan settle the cost sharing quarterly, such that the Company's statement of operations reflects 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

Product revenue, net

Net product revenue is derived from sales of ZURAMPIC and DUZALLO ("the Lesinurad Products") in the U.S. The Company sells the Lesinurad Products principally to a limited number of national wholesalers and selected regional wholesalers (the "Distributors"). The Distributors resell the Lesinurad Products to retail pharmacies and healthcare providers, who then sell to patients.

Net product revenue is recognized when the Distributor obtains control of the Company's product, which occurs at a point in time, typically upon shipment of Lesinurad Products to the Distributor. When the Company performs shipping and handling activities after the transfer of control to the Distributor (e.g., when control transfers prior to delivery), they are considered as fulfillment activities, and accordingly, the costs are accrued for when the related revenue is recognized. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less.

The Company evaluates the creditworthiness of each of its Distributors to determine whether it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur. The Company calculates its net product revenue based on the wholesale acquisition cost that the Company charges its Distributors for the Lesinurad Products less variable consideration. The product revenue variable consideration consists of estimates relating to (i) trade discounts and allowances, such as invoice discounts for prompt payment and distributor fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (iii) reserves for expected product returns and (iv) estimated costs of incentives offered to certain indirect customers including patients. These estimates could be adjusted based on actual results in the period such variances become known.

Trade Discounts and Allowances: The Company generally provides invoice discounts on sales of Lesinurad Products to its Distributors for prompt payment and pays fees for distribution services and for certain data that Distributors provide to the Company. Consistent with historical industry practice, the Company expects its Distributors to earn these discounts and fees, and accordingly deducts the full amount of these discounts and fees from its gross product revenues at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: The Company contracts with Medicaid, other government agencies and various private organizations ("Third-party Payors") to allow for eligible purchases of the Lesinurad Products at partial or full reimbursement from such Third-party Payors. The Company estimates the rebates, chargebacks and discounts it will be obligated to provide to Third-party Payors and deducts these estimated amounts from its gross product revenue at the time the revenue is recognized. Based upon (i) the Company's contracts with these Third-party Payors, (ii) the government-mandated discounts applicable to government-funded programs, (iii) information obtained from the Company's Distributors and third-parties regarding the payor mix for Lesinurad Products and (iv) historical industry information regarding the payor mix for analog products, the Company estimates the rebates, chargebacks and discounts that it will be obligated to provide to Third-party Payors.

Product Returns: The Company estimates the amount of Lesinurad Products that will be returned and deducts these estimated amounts from its gross revenue at the time the revenue is recognized. The Company's Distributors have the right to return unopened, unprescribed Lesinurad Products beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for the Lesinurad Products is at least 24 months after it has been converted into tablet form, which is the last step in the manufacturing process for Lesinurad Products and generally occurs within a few months before Lesinurad Products are delivered to the Company. The Company currently estimates product returns based on data provided to the Company by its Distributors and by other third parties, historical industry information regarding rates for similar pharmaceutical products, the estimated remaining shelf life of the Lesinurad Products previously shipped and currently being shipped to Distributors, and contractual agreements with the Company's Distributors intended to limit the amount of inventory they maintain. Reporting from the Distributors includes Distributor sales and inventory held by Distributors, which provides the Company with visibility into the distribution channel in order to determine which products, if any, were eligible to be returned.

Other Incentives: Incentives that the Company offers include voluntary patient assistance programs, such as co-pay assistance programs which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue.

Product revenue is recorded net of the trade discounts, allowances, rebates, chargebacks, discounts, product returns, and other incentives. Certain of these adjustments are recorded as an accounts receivable reserve.

Other

The Company produces linaclotide finished drug product, API and development materials for certain of its partners.

The Company recognizes revenue on linaclotide finished drug product, API and development materials when control have transferred to the partner, which generally occurs upon shipment for sales of API and upon delivery for sales of drug product, after the material has passed all quality testing required for collaborator acceptance. As it relates to development materials and API produced for Astellas, the Company is reimbursed at a contracted rate. Such reimbursements are considered as part of revenue generated pursuant to the Astellas license agreement and are presented as collaborative arrangements revenue. Any linaclotide finished drug product, API and development materials currently produced for Allergan for the U.S. or AstraZeneca for China, Hong Kong and Macau are recognized in accordance with the cost-sharing provisions of the Allergan and AstraZeneca collaboration agreements, respectively.

Revenue recognition prior to the adoption of ASC 606

Agreements Entered into Prior to January 1, 2011

For arrangements that include multiple deliverables and were entered into prior to January 1, 2011, the Company followed the provisions of ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* (''ASC 605-25''), in accounting for these agreements. Under ASC 605-25, the Company was required to identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting. Collaborative research and development and licensing agreements that contained multiple deliverables were divided into separate units of accounting when the following criteria were met:

- Delivered element(s) had value to the collaborator on a standalone basis,
- There was objective and reliable evidence of the fair value of the undelivered obligation(s), and
- If the arrangement included a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) was considered probable and substantially within the Company's control.

The Company allocated arrangement consideration among the separate units of accounting either on the basis of each unit's respective fair value or using the residual method, and applied the applicable revenue recognition criteria to each of the separate units. If the separation criteria were not met, revenue of the combined unit of accounting was recorded based on the method appropriate for the last delivered item.

Agreements Entered into or Materially Modified on or after January 1, 2011 and prior to January 1, 2018

The Company evaluated revenue from multiple element agreements entered into on or after January 1, 2011 under ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13"), or ASC 605, until the adoption of ASC 606. The Company also evaluated whether amendments to its multiple element arrangements were considered material modifications that were subject to the application of ASU 2009-13. This evaluation required management to assess all relevant facts and circumstances and to make subjective determinations and judgments.

When evaluating multiple element arrangements under ASU 2009-13, the Company considered whether the deliverables under the arrangement represented separate units of accounting. This evaluation required subjective determinations and required management to make judgments about the individual deliverables and whether such deliverables were separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluated certain criteria, including whether the deliverables had standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination included the research, manufacturing and commercialization capabilities of the partner and the availability of relevant research and manufacturing expertise in the general marketplace. In addition, the Company considered whether the collaborator can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, and whether the value of the deliverable was dependent on the undelivered items and whether there were other vendors that could provide the undelivered items.

The consideration received was allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria were applied to each of the separate units.

The Company determined the estimated selling price for deliverables using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE was not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE was available.

Up-Front License Fees prior to January 1, 2018

When management believed the license to its intellectual property had stand-alone value, the Company generally recognized revenue attributed to the license upon delivery. When management believed the license to its intellectual property did not have stand-alone value from the other deliverables to be provided in the arrangement, it was combined with other deliverables and the revenue of the combined unit of accounting was recorded based on the method appropriate for the last delivered item.

Milestones prior to January 1, 2018

At the inception of each arrangement that included pre-commercial milestone payments, the Company evaluated whether each pre-commercial milestone was substantive, in accordance with ASU No. 2010-17, *Revenue Recognition—Milestone Method* ("ASU 2010-17"), prior to the adoption of ASC 606. This evaluation included an assessment of whether (a) the consideration was commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluated factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. At December 31, 2017, the Company had no pre-commercial milestones that were deemed substantive.

Commercial milestones were accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Net Profit or Net Loss Sharing prior to January 1, 2018

In accordance with ASC 808 Topic, *Collaborative Arrangements*, and ASC 605-45, *Principal Agent Considerations*, the Company considered the nature and contractual terms of the arrangement and the nature of the Company's business operations to determine the classification of the transactions under the Company's collaboration agreements. The Company recorded revenue transactions gross in the condensed consolidated statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

The Company recognized its share of the pre-tax commercial net profit or net loss generated from the sales of LINZESS in the U.S. in the period the product sales are reported by Allergan and related cost of goods sold and selling, general and administrative expenses are incurred by the Company and its collaboration partner. These amounts were partially determined based on amounts provided by Allergan and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and contractual rebates, wholesaler fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results. For the periods covered in the condensed consolidated financial statements presented, there have been no material changes to prior period estimates of revenues, cost of goods sold or selling, general and administrative expenses associated with the sales of LINZESS in the U.S.

The Company records its share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and presents the settlement payments to and from Allergan as collaboration expense or collaborative arrangements revenue, as applicable, as the Company is not the primary obligor and does not have the risks and rewards of ownership in the collaboration agreement with Allergan for North America. The Company and Allergan settle the cost sharing quarterly, such that the Company's statement of operations reflects 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

Royalties on Product Sales prior to January 1, 2018

The Company received royalty revenues under certain of the Company's license or collaboration agreements. The Company recorded these revenues as earned.

Product Revenue, Net prior to January 1, 2018

As noted above, net product revenue is derived from sales of the Lesinurad Products in the U.S.

The Company recognized net product revenue from sales of the Lesinurad Products in accordance with ASC 605, when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has passed to the customer, the price is fixed or determinable, and collection from the customer has been reasonably assured. ASC 605 required, among other criteria, that future returns could be reasonably estimated in order to recognize revenue.

The Company began commercializing ZURAMPIC in October 2016 and DUZALLO in October 2017 in the U.S. Initially, upon the product launch of each of the Lesinurad Products, the Company determined that it was not able to reliably make certain estimates, including returns, necessary to recognize product revenue upon delivery to Distributors. As a result, through September 30, 2017, the Company recorded net product revenue for the Lesinurad Products using a deferred revenue recognition model (sell-through). Under the deferred revenue model, the Company did not recognize revenue until the respective product was prescribed to an end-user. Accordingly, the Company recognized net product revenue when the Lesinurad Products were prescribed to the end-user, using estimated prescription demand and pharmacy demand from third party sources and the Company's analysis of third party market research data, as well as other third-party information through September 30, 2017.

During the three months ended December 31, 2017, the Company concluded it had sufficient volume of historical activity and visibility into the distribution channel, in order to reasonably make all estimates required under ASC 605 to recognize product revenue upon delivery to the Distributor. During the three months and year ended December 31, 2017, product revenue is recognized upon delivery of the Lesinurad Products to the Distributors. The Company evaluated the creditworthiness of each of its Distributors to determine whether revenue can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition was required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenue from the sales to Distributors and (ii) reasonably estimate its net product revenue. The Company calculated gross product revenue based on the wholesale acquisition cost that the Company charged its Distributors for ZURAMPIC and DUZALLO. The Company estimated its net product revenue by deducting from its gross product revenue (i) trade discounts and allowances, such as invoice discounts for prompt payment and distributor fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (iii) reserves for expected product returns and (iv) estimated costs of incentives offered to certain indirect customers including patients. These estimates could be adjusted based on actual results in the period such variances become known.

Other

The Company supplies linaclotide finished drug product, API and development materials for certain of its partners.

The Company recognized revenue on linaclotide finished drug product, API and development materials when the material had passed all quality testing required for collaborator acceptance, delivery had occurred, title and risk of loss had transferred to the partner, the price was fixed or determinable, and collection was reasonably assured.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Except as set forth below, the Company did not adopt any new accounting pronouncements during the three and six months ended June 30, 2018 and 2017 that had a material effect on its condensed consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes the revenue recognition requirements in ASC 605, 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. 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. The Company adopted these ASUs using the modified retrospective transition approach effective January 1, 2018. The adoption of these ASUs did not have a material impact on the Company's financial position or results of operations as of and for the six months ended June 30, 2018; however, adoption did result in significant changes to the Company's financial statement disclosures.

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 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 condensed 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 the adoption of ASU 2016-02 may have on the Company's financial position and results of operations. The Company's analysis includes, but is not limited to, reviewing existing leases, reviewing other service agreements for embedded leases, evaluating potential system implementations, establishing policies and procedures, assessing potential disclosures and evaluating the impact of adoption on the Company's condensed consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, *Accounting for Income Taxes: Intra-Entity Asset Transfers of Assets Other than Inventory* ("ASU 2016-16"). ASU 2016-16 eliminates the ability to defer the tax expense related to intra-entity asset transfers other than Inventory. Under the new standard, entities should recognize the income tax consequences on an intra-entity transfer of an asset other than inventory when the transfer occurs. ASU 2016-16 is effective for fiscal periods beginning after December 15, 2018. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-16 to have a material impact on the Company's financial position or results of operations.

In October 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash* ("ASU 2016-18"), which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and restricted cash or restricted cash equivalents. Therefore, amounts described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017, and interim periods within those years. The Company adopted this standard during the three months ended March 31, 2018. Adoption of this standard did not have a material impact on the Company's financial position or results of operations for the three months ended and as of March 31, 2018.

As a result of adopting ASU 2016-18, the Company adjusted the condensed consolidated statements of cash flows from previously reported amounts as follows:

	Six Months Ended June 30, 2017		
	As previously reported	Adjustments	As adjusted
Cash flows from Operating Activities:			
Net decrease in restricted cash related to lease obligations	$ 1,190	$ (1,190)	$ —
Net cash flows used in operating activities	(59,107)	(1,190)	(60,297)
Net change in cash, cash equivalents, and restricted cash	128,128	(1,190)	126,938
Cash, cash equivalents, and restricted cash, beginning of period	54,004	8,247	62,251
Cash, cash equivalents, and restricted cash, end of period	$ 182,132	$ 7,057	$ 189,189

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"), to clarify the definition of a business by adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets versus businesses. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted this standard during the three months ended March 31, 2018. The adoption of this standard did not have a material impact on the Company's financial position or results of operations.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other (Topic 350)* ("ASU 2017-04") to simplify the accounting for goodwill impairment by removing Step 2 of the goodwill impairment test. ASU 2017-04 is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is evaluating the potential impact that the adoption of ASU 2017-04 may have on the Company's financial position and results of operations.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 708) Scope of Modification Accounting ("ASU 2017-09") which provides guidance that clarifies when changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. Adoption of ASU 2017-09 is required for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted this standard during the three months ended March 31, 2018. The adoption of this standard did not have a material impact on the Company's financial position and results of operations.

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 and/or 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, is greater than the conversion price of the 2022 Notes (Note 9). 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 9). 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,	
	2018	2017
Options to purchase common stock	22,056	21,621
Shares subject to repurchase	130	125
Restricted stock units	3,207	2,270
Note hedge warrants	20,250	20,250
2022 Notes	20,250	20,250
	65,893	64,516

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. Goodwill and Intangible Assets

The Company closed the Lesinurad Transaction on June 2, 2016 (the "Acquisition Date") with AstraZeneca pursuant to which the Company received an exclusive license to develop, manufacture and commercialize in the U.S. products containing lesinurad as an active ingredient, including ZURAMPIC and DUZALLO. In connection with the Lesinurad License, the Company is required to perform certain post-marketing activities required by the FDA. These post-marketing requirements for lesinurad are estimated to be less than $100.0 million over up to ten years from the Acquisition Date.

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 have been recorded at fair value, with the remaining purchase price recorded as goodwill.

The purchase price consisted of the up-front payment to AstraZeneca of $100.0 million, which was made in June 2016, and the fair value of contingent consideration of approximately $67.9 million. In addition to the up-front payment, 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 Lesinurad License. During the year ended December 31, 2017, the Company paid a $15.0 million milestone to AstraZeneca related to the approval of DUZALLO by the FDA.

The final allocation of the purchase price for the Lesinurad Transaction as of the Acquisition Date, including the contingent consideration, is summarized in the following tables (in thousands):

As of the Acquisition Date:	
Cash portion of consideration	$ 100,000
Contingent consideration	67,885
Total purchase consideration	$ 167,885

As of the Acquisition Date:	
Developed technology — ZURAMPIC	$ 22,000
IPR&D — DUZALLO	145,100
Goodwill	785
Net assets acquired	$ 167,885

In August 2017, DUZALLO was approved by the FDA for commercialization in the U.S. As a result, the Company reclassified the IPR&D – DUZALLO asset from indefinite-lived to finite-lived as development activities were completed. The amount allocated to the finite-lived intangible asset, developed technology – DUZALLO, totaled approximately $145.1 million. Developed technology – DUZALLO is being amortized on a straight-line basis to amortization of acquired intangible assets within the Company's condensed consolidated statement of operations over its estimated useful life of approximately 12 years, the period of estimated future cash flows from the approval date. The Company believes that the straight-line method of amortization represents the pattern in which the economic benefits of the asset are consumed. As of June 30, 2018, the Company recognized accumulated amortization of approximately $10.6 million with respect to the developed technology – DUZALLO intangible asset.

The Company considers the developed technology – ZURAMPIC intangible asset acquired to be developed technology, as it was approved by the FDA for commercialization as of the Acquisition Date. The developed technology – ZURAMPIC intangible asset is finite lived. The amount allocated to the developed technology – ZURAMPIC intangible asset is being 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 approximately 13 years, the period of estimated future cash flows from the Acquisition Date. 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, 2018, the Company recognized accumulated amortization of approximately $3.5 million with respect to the developed technology – ZURAMPIC intangible asset.

The estimated future amortization of developed technology – ZURAMPIC and developed technology – DUZALLO intangible assets are expected to be as follows (in thousands):

	As of June 30, 2018
2018[(1)]	$ 6,953
2019	13,905
2020	13,905
2021	13,905
2022 and thereafter	104,285
Total	$ 152,953

(1) For the six months ending December 31, 2018.

The Company tests its goodwill for impairment annually as of October 1st, or more frequently if events or changes in circumstances indicate an impairment may have occurred. Additionally, the Company evaluates its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate the reduction in the fair value below their respective carrying amounts. In connection with each impairment assessment in which indicators of impairment have been identified, the Company compares the fair value of the asset or asset group as of the date of the assessment with the carrying value of the asset or asset group on the Company's condensed consolidated balance sheet. The value of the Company's finite-lived intangible assets are based on the future expected net cash flows related to the Lesinurad Products, which include significant assumptions around future net sales and the respective investment to support these products. The Company believes that the following factors, among others, could trigger an impairment review: significant underperformance relative to historical or projected future operating results; significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business; approval of competitive products; significant negative industry or economic trends, the Company's ability to establish, maintain and/or expand the sales, marketing, distribution and market-access capabilities, or enter into and maintain agreements necessary for commercialization with payers and third-party providers on acceptable terms. If the estimates and assumptions about these products change significantly, including with respect to their commercial performance, the finite-lived intangible assets may become impaired and the Company may be required to recognize a material write-down in the period in which the impairment occurs. As of June 30, 2018, there was no impairment of goodwill or intangible assets (Note 14).

4. Collaboration, License, Co-Promotion and Other Commercial Agreements

For the three and six months ended June 30, 2018, 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 Astellas for Japan and with Allergan for the Allergan License Territory. The Company also had agreements with Allergan to co-promote VIBERZI in the U.S. and to promote CANASA in the U.S. The following table provides amounts included in the Company's condensed consolidated statements of operations as collaborative arrangements revenue and sale of API attributable to transactions from these arrangements (in thousands):

	Collaborative Arrangements Revenue			
	Three Months Ended June 30,		Six Months Ended June 30,	
Collaborative Arrangements Revenue	**2018**	**2017**	**2018**	**2017**
Linaclotide Agreements:				
Allergan (North America)	$69,810	$56,742	$131,408	$106,693
Allergan (Europe and other)	304	109	576	218
AstraZeneca (China, Hong Kong and Macau)	—	—	—	208
Co-Promotion and Other Agreements:				
Exact Sciences (Cologuard) [1]	—	1,297	—	2,436
Allergan (VIBERZI)	750	489	1,500	946
Other	343	3	809	3
Total collaborative arrangements revenue	$71,207	$58,640	$134,293	$110,504
Sale of API				
Linaclotide Agreements:				
Astellas (Japan)	$ 8,803	$ 5,972	$ 14,237	$ 5,985
Total sale of API	$ 8,803	$ 5,972	$ 14,237	$ 5,985

(1) In August 2016, the Company terminated the Exact Sciences Co-Promotion Agreement for Cologuard. Under the terms of the agreement, the Company continued to receive royalty payments through July 2017.

Accounts receivable, net and related party accounts receivable, net totaled approximately $80.0 million related to collaborative arrangements revenue and sale of API as of June 30, 2018, net of approximately $3.6 million related to related party accounts payable.

As of June 30, 2018, there were no impairment indicators for the accounts receivable recorded. During the three and six months ended June 30, 2018, there was no significant unusual activity in accounts receivable.

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 receives non-refundable, upfront licensing fees and 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. 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 those countries 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. At June 30, 2018, $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 11). 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 when it is probable that a significant reversal of revenue would not occur and the associated constraints have been lifted.

As a result of the research and development cost-sharing provisions of the linaclotide collaboration for North America, the Company offset approximately $1.9 million and offset approximately $3.3 million in incremental research and development costs during the three and six months ended June 30, 2018, respectively, and recognized an insignificant amount and approximately $0.5 million in research and development costs during the three and six months ended June 30, 2017, respectively, to reflect the obligations of each party under the collaboration to bear half of the development costs incurred.

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. 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. If either party provided fewer calls on physicians in a particular year than it was contractually required to provide, such party's share of the net profits would be adjusted as set forth in the collaboration agreement for North America. During the year ended December 31, 2017, these adjustments to the share of the net profits were 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 *Agreement with Allergan for VIBERZI*. Additionally, these adjustments to the share of the net profits are eliminated, in full, in 2018 and all subsequent years under the terms of the Company's commercial agreement with Allergan entered into in January 2017 under which the Company promotes Allergan's CANASA product, as described below in *Commercial Agreement with Allergan*. In May 2014, CONSTELLA became commercially available in Canada and in June 2014, LINZESS became commercially available in Mexico.

The Company evaluated this collaboration arrangement under ASC 606 and concluded that all development-period performance obligations had been satisfied as of September 2012. However, the Company has determined that there are three remaining commercial-period performance obligations, which include the sales detailing of LINZESS, participation in the joint commercialization committee, and approved additional trials. The consideration remaining includes cost reimbursements in the U.S., as well as commercial sales-based milestones and net profit and loss sharing payments based on net sales in the U.S. Additionally, the Company receives royalties in the mid-teens percent based on net sales in Canada and Mexico. Royalties, commercial sales-based milestones, and net profit and loss sharing payments will be recorded as collaborative arrangements revenue or expense in the period earned, in accordance with the sales-based royalty exception, as these payments relate predominately to the license granted to Allergan. The Company records royalty revenue in the period earned based on royalty reports from its partner, if available, or based on the projected sales and historical trends. The cost reimbursements received from Allergan during the commercialization period will be recognized as billed in accordance with the right-to-invoice exemption, as the Company's right to consideration corresponds directly with the value of the services transferred during the commercialization period.

The Company recognized collaborative arrangements revenue from the Allergan collaboration agreement for North America during the three and six months ended June 30, 2018 and 2017 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaborative arrangements revenue related to sales of LINZESS in the U.S.	$ 69,264	$ 56,307	$ 130,413	$ 105,759
Royalty revenue	546	435	995	934
Total collaborative arrangements revenue	$ 69,810	$ 56,742	$ 131,408	$ 106,693

The collaborative arrangements revenue recognized in the three and six months ended June 30, 2018 and 2017 primarily represents the Company's share of the net profits and net losses on the sale of LINZESS in the U.S.

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, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Collaborative arrangements revenue related to sales of LINZESS in the U.S.[1][2]	$ 69,264	$ 56,307	$ 130,413	$ 105,759
Selling, general and administrative costs incurred by the Company[1]	(11,713)	(12,496)	(22,641)	(23,605)
The Company's share of net profit	$ 57,551	$ 43,811	$ 107,772	$ 82,154

(1) Includes only collaborative arrangement revenue or selling, general and administrative costs attributable to the cost-sharing arrangement with Allergan for the three and six months ended June 30, 2018 and 2017.

(2) Certain of the unfavorable adjustments to the Company's share of the LINZESS net profits were reduced or eliminated during the six months ended June 30, 2017 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 *Agreement with Allergan for VIBERZI*.

In May 2014, CONSTELLA became commercially available in Canada and in June 2014, LINZESS became commercially available in Mexico. In October 2015, Almirall and Allergan terminated the sublicense arrangement with respect to Mexico, returning the exclusive rights to commercialize CONSTELLA in Mexico to Allergan. CONSTELLA continues to be available to adult IBS-C patients in Mexico. The Company records royalties on sales of CONSTELLA in Canada and LINZESS in Mexico in the period earned. The Company recognized approximately $0.6 million and approximately $1.0 million of combined royalty revenues from Canada and Mexico during the three and six months ended June 30, 2018, respectively. The Company recognized approximately $0.4 million and approximately $0.9 million of combined royalty revenues from Canada and Mexico during the three and six months ended June 30, 2017, respectively.

License Agreement with Allergan (All countries other than the countries and territories of North America, China, Hong Kong, Macau, and Japan)

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. In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to Allergan. In accordance with the European License Agreement, the Company granted Almirall a right to access its U.S. Phase III clinical trial data for the purposes of supporting European regulatory approval. Additionally, the Company was required to participate on a joint development committee during linaclotide's development period and is required to participate in a joint commercialization committee while linaclotide is commercially available.

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) certain 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 certain 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. The Company concluded that the 2015 amendment to the European License Agreement was not a modification to the linaclotide collaboration agreement with Allergan for North America.

In January 2017, concurrently with entering into the commercial agreement as described below in *Commercial Agreement with Allergan*, the Company and Allergan entered into an amendment to the European License Agreement. The European License Agreement, as amended (the "Allergan License Agreement"), extended the license to develop and commercialize linaclotide in all countries other than China, Hong Kong, Macau, Japan, and the countries and territories of North America. On a country-by-country and product-by-product basis in such additional territory, Allergan is obligated to pay the Company a royalty as a percentage of net sales of products containing linaclotide as an active ingredient in the upper-single digits for five years following the first commercial sale of a linaclotide product in a country, and in the low-double digits thereafter. The royalty rate for products in the expanded territory will decrease, on a country-by-country basis, to the lower-single digits, or cease entirely, following the occurrence of certain events. Allergan is also obligated to assume certain purchase commitments for quantities of linaclotide API under the Company's agreements with third-party API suppliers. The amendment to the European License Agreement did not modify any of the milestones or royalty terms related to Europe.

The Company concluded that the 2017 amendment was a material modification to the European License Agreement; however, this modification did not have a material impact on the Company's condensed consolidated financial statements as there was no deferred revenue associated with the European License Agreement. The Company also concluded that the 2017 amendment to the European License Agreement was not a material modification to the linaclotide collaboration agreement with Allergan for North America. The Company's conclusions on deliverables under ASC Topic 605-25, Revenue Recognition—Multiple-Element Arrangements ("ASC 605-25") are described below in *Commercial Agreement with Allergan*.

The Company evaluated the European License Agreement under ASC 606. In evaluating the terms of the 2009 European License Agreement under ASC 606, the Company determined that there are no remaining performance obligations as of September 2012. However, the Company continues to be eligible to receive consideration in the form of commercial launch milestones, sales-based milestones, and royalties.

The commercial launch milestones, sales-based milestones and royalties under the European License Agreement have historically been recognized as revenue as earned. Under ASC 606, the Company will apply the sales-based royalty exception to royalties and sales-based milestones, as these payments relate predominantly to the license granted to Allergan (formerly Almirall). Accordingly, the royalties and sales-based milestones will be recorded as revenue in the period earned. The Company records royalties on sales of CONSTELLA in Europe in the period earned based on royalty reports from its partner, if available, or the projected sales and historical trends. The commercial launch milestones will be recognized as revenue when it is probable that a significant reversal of revenue would not occur and the associated constraint has been lifted.

Additionally, the Company evaluated the terms of the January 2017 amendment under ASC 606 and determined that it would be treated as a separate contract given that it adds a distinct good or service at an amount that reflects standalone selling price. The Company determined that all performance obligations in this amendment were satisfied in January 2017 when the license for the additional territory was transferred. The Company continues to receive royalties under this agreement, which are recorded in the period earned pursuant to the sales-based royalty exception, as they related predominantly to the license granted to Allergan.

The Company recognized approximately $0.3 million and $0.6 million of royalty revenue during the three and six months ended June 30, 2018, respectively, and an insignificant amount and approximately $0.2 million during the three and six months ended June 30, 2017, respectively.

License Agreement for Japan with Astellas

In November 2009, the Company entered into a license agreement with Astellas, as amended, 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. During the year ended December 31, 2017, the Company and Astellas entered into a commercial API supply agreement (the "Astellas Commercial Supply Agreement"). Pursuant to the Astellas Commercial Supply Agreement, the Company sells linaclotide API supply to Astellas at a contractually defined rate and recognizes related revenue as sale of API. Under the license agreement, the Company receives 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.

In 2009, Astellas paid the Company a non-refundable, up-front licensing fee of $30.0 million, which was recognized as collaborative arrangements revenue on a straight-line basis over the Company's estimate of the period over which linaclotide was developed under the license agreement in accordance with ASC 605. The development period was completed in December 2016 upon approval of LINZESS by the Japanese Ministry of Health, Labor and Welfare at which point all previously deferred revenue under the agreement was recognized.

The agreement also includes three development milestone payments that totaled up to $45.0 million, all of which were achieved and recognized as revenue through December 31, 2016 in accordance with ASC 605. 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. The second milestone payment, consisting of $15.0 million upon filing of a New Drug Application ("NDA") for linaclotide with the Japanese Ministry of Health, Labor and Welfare, was achieved in February 2016. The third development milestone payment consisting of $15.0 million upon approval of an NDA by the Japanese Ministry of Health, Labor and Welfare to market linaclotide in Japan was achieved in December 2016.

The Company has evaluated the terms of the 2009 License Agreement with Astellas under ASC 606 and has determined that there are no remaining performance obligations as of December 2016. However, there continues to be consideration in the form of royalties on sales of LINZESS in Japan under the 2009 License Agreement. Upon adoption of ASC 606, the Company concluded that the royalties on sales of LINZESS in Japan relate predominantly to the license granted to Astellas. Accordingly, the Company applies the sales-based royalty exception and records royalties on sales of LINZESS in Japan in the period earned based on royalty reports from its partner, if available, or the projected sales and historical trends.

Additionally, under the terms of the Astellas Commercial Supply Agreement, the Company continues to have an ongoing performance obligation to supply API. Upon adoption of ASC 606, product revenue is recognized when the customer obtains control of the Company's product, which occurs at a point in time, typically upon shipment of the product to the customer. This results in earlier revenue recognition than the Company's historical accounting.

The royalty on sales of LINZESS in Japan during each of the three and six months ended June 30, 2018 and June 30, 2017 relating to the quarters in arrears did not exceed the transfer price of API sold and other contractual deductions during the periods. During each of the three and six months ended June 30, 2017, the Company recognized approximately $6.0 million from the sale of API to Astellas under the license agreement and the Astellas Commercial Supply Agreement. During the three and six months ended June 30, 2018, the Company recognized approximately $8.8 million and $14.2 million, respectively, from the sale of API to Astellas under the license agreement and the Astellas Commercial Supply Agreement.

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

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

- an exclusive license to develop and commercialize linaclotide in the License Territory (the "License Deliverable") (the deliverable was completed upon execution and all associated revenue was recognized as of December 31, 2016),
- 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 deliverable was completed and all associated revenue was recognized as of December 31, 2013).

Under ASC 605, 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 performs R&D Services and JDC services, and supplies clinical trial materials during the estimated development period. All consideration allocated to such services was 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 in accordance with ASC 605. At the inception of the arrangement, the Company identified the supply of linaclotide drug product for commercial requirements and commercialization services as contingent deliverables under ASC 605 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.

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 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") which includes the $25.0 million non-refundable up-front payment and approximately $9.0 million representing 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.

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.

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. As a result of the cost-sharing arrangements under the collaboration, the Company offset an insignificant amount and approximately $0.2 million in research and development costs during the three and six months ended June 30, 2017 respectively.

In March 2017, the Company began providing supply of linaclotide drug product and certain commercialization-related services pursuant to the AstraZeneca Collaboration Agreement. During the three and six months ended June 30, 2017, the Company recognized no revenue and approximately $0.2 million, respectively, as collaborative arrangements revenue related to linaclotide drug product, as this deliverable was no longer contingent.

Upon the adoption of ASC 606, the Company reevaluated the AstraZeneca Agreements and, consistent with its conclusions under ASC 605, identified six performance obligations including the license, R&D services, JDC services, supply of clinical trial material, co-promotion services for NEXIUM, and the JCC services. The Company determined that the supply of linaclotide drug product for commercial requirements was an optional service at inception of the arrangement and did not provide a material right to AstraZeneca.

At the adoption date, the Company had fully satisfied its obligation to transfer the license and NEXIUM co-promotion services to AstraZeneca. The following remaining performance obligations are ongoing as of the June 30, 2018:

- research, development and regulatory services pursuant to the IDP, as modified from time to time (the R&D Services),
- JDC services, and
- obligation to supply clinical trial material, and
- JCC services

Under ASC 606, the Company applied the contract modification practical expedient to the August 2014 amendment, which expanded the scope of the Company's activities under the IDP and increased the development budget. This practical expedient allows an entity to reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented. The application of this practical expedient resulted in a total transaction price of approximately $34.0 million, which was allocable to the Company's performance obligations on a relative standalone selling price ("SSP") basis.

Under ASC 606, amounts of consideration allocated to the license and NEXIUM co-promotion services would have been recognized in full prior to adoption as these performance obligations were satisfied in October 2012 and December 2013, respectively. Consideration allocated to the R&D Services will be recognized as such services are provided over the performance period using an output method based on full-time employee hours incurred. Consideration allocated to the JDC services are recognized ratably over the development period using a time-based, straight-line attribution model. Revenue from the supply of clinical trial material is recognized as the clinical trial material is delivered to the customer. During each of the three and six months ended June 30, 2018, the Company offset approximately $0.7 million related to R&D Services and JDC services.

Upon commercialization, the Company's only remaining performance obligation will be JCC services. During commercialization, the Company will be entitled to receive sales-based milestone payments from AstraZeneca. Additionally, the parties will 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; from that point, profits and losses will be shared equally thereafter. Commercial sales-based milestones and net profit and loss sharing payments will be recorded as collaborative arrangements revenue or expense in the period earned, in accordance with the sales-based royalty exception, as these payments related predominately to the license granted to AstraZeneca. Any cost reimbursements received from AstraZeneca during the commercialization period will be recognized as billed in accordance with the right-to-invoice exemption, as the Company's right to consideration corresponds directly with the value of the services transferred during the commercialization period.

Co-Promotion and Other 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"). The Exact Sciences Co-Promotion Agreement was terminated by the parties in August 2016. Under the terms of the non-exclusive Exact Sciences Co-Promotion Agreement, the Company's sales team promoted and educated health care practitioners regarding Cologuard through July 2016. Exact Sciences maintained 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 was compensated primarily via royalties earned on the net sales of Cologuard generated from the healthcare practitioners on whom the Company called with such royalties payable through July 2017. There were no refund provisions in the Exact Sciences Co-Promotion Agreement.

During the three and six months ended June 30, 2017, the Company recognized approximately $1.3 million and approximately $2.4 million, respectively, as collaborative arrangements revenue related to this arrangement in accordance with ASC 605-25.

The Company determined that the Exact Sciences Co-Promotion Agreement was completed prior to the adoption of ASC 606 and accordingly did not reevaluate the terms of the agreement.

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 detailed VIBERZI to the same health care practitioners to whom they detail LINZESS. Allergan was responsible for all costs and activities relating to the commercialization of VIBERZI outside of the co-promotion. The Company's promotional efforts under the non-exclusive co-promotion began when VIBERZI became commercially available in December 2015. The VIBERZI Co-Promotion Agreement was effective through December 31, 2017.

Under the terms of the VIBERZI Co Promotion Agreement, the Company's promotional efforts were 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 provided a minimum number of VIBERZI calls on physicians. The Company provided the minimum number of VIBERZI calls on physicians pursuant to the VIBERZI Co-Promotion Agreement, and was compensated with the elimination of certain of the unfavorable adjustments to the Company's share of net profits stipulated by the linaclotide collaboration agreement with Allergan for North America for the years ending December 31, 2015, 2016 and 2017. 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 $1.1 million and approximately $2.9 million during the three and six months ended June 30, 2017, respectively. During the three and six months ended June 30, 2017, the Company recognized approximately $0.5 million and approximately $0.9 million, respectively, in collaborative arrangements revenue related to the VIBERZI Co-Promotion Agreement for the performance of medical education services.

In December 2017, the Company and Allergan entered into an amendment to the commercial agreement with Allergan (the "VIBERZI Amendment"), as described below, to include the VIBERZI promotional activities through December 31, 2018. Under the terms of the VIBERZI Amendment, the Company's clinical sales specialists will continue detailing VIBERZI in the second position to the same health care practitioners to whom they detail LINZESS in the first position and provide certain medical education services. The Company has the potential to achieve a milestone payment of up to $7.5 million based on the net sales of VIBERZI during 2018, and will be compensated approximately $3.0 million over the term of the agreement for its medical education initiatives. The Company evaluated the VIBERZI Amendment in accordance with ASC 606 and determined that it would be treated as a separate contract because it adds a distinct good or service at an amount that reflects standalone selling price. The following performance obligations under the VIBERZI Amendment were identified:

- sales detailing of VIBERZI in either first or second position, and

- medical education services

The sales-based milestone payment will be recognized as collaborative arrangements revenue when it is probable that a significant reversal of revenue would not occur and the associated constraint has been lifted. As of June 30, 2018, the Company determined the sales-based milestone payment was fully constrained. The consideration related to medical education events of approximately $3.0 million will be recognized over the period of performance that medical education services are provided. During the three and six months ended June 30, 2018, the Company recognized approximately $0.8 million and approximately $1.5 million, respectively, of collaborative arrangements revenue related to VIBERZI.

Commercial Agreement with Allergan

In January 2017, concurrently with entering into the amendment to the European License Agreement, the Company and Allergan entered into an agreement under which the adjustments to the Company's or Allergan's share of the net profits under the share adjustment provision of the collaboration agreement for linaclotide in North America relating to the contractually required calls on physicians in each year are eliminated, in full, in 2018 and all subsequent years (the "Commercial Agreement"). Pursuant to the Commercial Agreement, Allergan appointed the Company, on a non-exclusive basis, to promote CANASA, approved for the treatment of ulcerative proctitis, and DELZICOL, approved for the treatment of ulcerative colitis, in the U.S. for approximately two years through February 2019. Under the terms of the Commercial Agreement, the Company is obligated to perform third position sales details and offer samples of such products to gastroenterology prescribers who are on the then-current call panel for LINZESS to which the Company provides first or second position details. The Company purchases samples of CANASA and DELZICOL from Allergan at the actual manufacturing cost. On a product-by-product basis, Allergan pays the Company a royalty in the mid-teens on incremental sales of CANASA and DELZICOL above a mutually agreed upon sales baseline. Additionally, the Company may incur a detailing shortfall penalty if it fails to meet the annual target product detail amount in any calendar year.

In December 2017, the Company and Allergan entered into the VIBERZI Amendment to the Commercial Agreement, as described above, to include and extend the VIBERZI promotional activities through December 31, 2018 and discontinue the promotion of DELZICOL effective January 1, 2018. Accordingly, promotional activities for DELZICOL terminated on December 31, 2017 and, subject to the Company's or Allergan's rights of early termination, the promotional activities for CANASA will terminate on February 26, 2019. The share adjustment relief will, in the case of Allergan's termination for convenience and certain other specified circumstances, survive termination of the commercial agreement. Under ASC 605, the Company concluded that the commercial agreement with Allergan, as amended, was not a material modification to the linaclotide collaboration agreement with Allergan for North America.

Activities under the Commercial Agreement with Allergan and the Allergan License Agreement were evaluated in accordance with ASC 605-25 upon execution, as the agreements were entered into concurrently, to determine if they represented a multiple element revenue arrangement.

The Company identified the following deliverables:

- an exclusive license to develop and commercialize linaclotide in the Allergan License Territory, and
- sales detailing services for CANASA and DELZICOL.

The exclusive license for the Allergan License Territory is nontransferable and has certain sublicense restrictions. The Company determined that Allergan had the internal product development and commercialization capabilities that would enable Allergan to use the license for its intended purposes without the involvement of the Company and, therefore, the license had standalone value. The deliverable for the sales detailing services for CANASA and DELZICOL was deemed to have standalone value based on the nature of the services, and all deliverables met the criteria to be accounted for as separate units of accounting under ASC 605-25. There was no allocable arrangement consideration at the inception of the arrangement, as the consideration is in the form of royalties and the elimination of a contingent liability. During each of the three and six months ended June 30, 2017, the Company did not recognize royalty revenue related to the Commercial Agreement with Allergan to promote CANASA and DELZICOL.

Upon adoption of ASC 606, the Company evaluated the commercial agreement and the amendment to the European License Agreement under the contract combination and contract modification guidance in ASC 606. The Company determined that the agreements should be accounted for as separate contracts because each agreement adds distinct goods or services at an amount that reflects standalone selling price. The Company concluded that the CANASA and DELZICOL sales detailing deliverable under ASC 605 was also considered a performance obligation in accordance with ASC 606. Accordingly, the Company records royalties on sales of CANASA and any estimated detailing shortfall penalty over the period of performance for the sales details; collaborative arrangements revenue is recognized when it is probable that a significant reversal of revenue would not occur and the associated constraint has been lifted. The Company estimates sales detailing royalties based on royalty reports from its partner, if available, or the projected sales and historical trends. At the inception of the arrangement, the consideration associated with the agreement comprised of royalties and a sales detailing shortfall penalty are fully constrained. During each of the three and six months ended June 30, 2018, the Company did not recognize royalty revenue related to the Commercial Agreement with Allergan for sales of CANASA. As discussed above, the Company's obligation to perform sales detailing for DELZICOL was eliminated through the VIBERZI Amendment to the Commercial Agreement with Allergan.

The VIBERZI Amendment was effective as of January 1, 2018 and evaluated in accordance with ASC 606 as described above.

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, 2018, and $18.0 million for regulatory milestones, none of which had been paid as of June 30, 2018. 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. The Company did not record any research and development expense associated with the Company's other collaboration and license agreements during each of the three and six months ended June 30, 2018 and 2017.

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, 2018 and December 31, 2017 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 for similar instruments in active markets, 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 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 Company also invests in certain reverse repurchase agreements which are collateralized by deposits in the form of Government Securities and Obligations for an amount not less than 102% of their principal amount. The Company does not record an asset or liability for the collateral as the Company is not permitted to sell or re-pledge the collateral. The collateral has at least the prevailing credit rating of U.S. Government Treasuries and Agencies. The Company utilizes a third-party custodian to manage the exchange of funds and ensure the collateral received is maintained at 102% of the reverse repurchase agreements principal amount on a daily basis.

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, 2018	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	$ 115,951	$ 115,951	$ —	$ —
Repurchase agreements	30,000	30,000	—	—
Available-for-sale securities:				
U.S. Treasury securities	16,715	16,715	—	—
U.S. government-sponsored securities	19,116	—	19,116	—
Convertible Note Hedges	159,526	—	—	159,526
Total assets measured at fair value	$ 341,308	$ 162,666	$ 19,116	$ 159,526
Liabilities:				
Note Hedge Warrants	$ 143,019	$ —	$ —	$ 143,019
Contingent Consideration	33,651	—	—	33,651
Total liabilities measured at fair value	$ 176,670	$ —	$ —	$ 176,670

		Fair Value Measurements at Reporting Date Using		
	December 31, 2017	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	$ 44,311	$ 44,311	$ —	$ —
U.S. Treasury securities	11,991	11,991	—	—
Repurchase agreements	70,000	70,000	—	—
Available-for-sale securities:				
U.S. Treasury securities	64,343	64,343	—	—
U.S. government-sponsored securities	31,336	—	31,336	—
Convertible Note Hedges	108,188	—	—	108,188
Total assets measured at fair value	$ 330,169	$ 190,645	$ 31,336	$ 108,188
Liabilities:				
Note Hedge Warrants	$ 92,188	$ —	$ —	$ 92,188
Contingent Consideration	31,258	—	—	31,258
Total liabilities measured at fair value	$ 123,446	$ —	$ —	$ 123,446

There were no transfers between fair value measurement levels during the three and six months ended June 30, 2018 or 2017.

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 June 30, 2018 and December 31, 2017 are carried at amounts that approximate fair value due to their short-term maturities.

The non-current portion of the capital lease obligations at June 30, 2018 approximates fair value as it bears interest at a rate approximating a market interest rate.

Convertible Note Hedges and Note Hedge Warrants

The Company's Convertible Note Hedges and the Note Hedge Warrants are recorded as derivative assets and liabilities, and are classified as Level 3 under the fair value hierarchy. These derivatives are not actively traded and are valued using the Black-Scholes option-pricing model which requires the use of subjective assumptions. Significant inputs used to determine the fair value as of June 30, 2018 included the price per share of the Company's Class A common stock, time to maturity of the derivative instruments, the strike prices of the derivative instruments, the risk-free interest rate, and the volatility of the Company's Class A common stock. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock in the foreseeable future; therefore, the expected dividend yield is assumed to be zero. Changes to these inputs could materially affect the valuation of the Convertible Note Hedges and Note Hedge Warrants.

The following inputs were used in the fair market valuation of the Convertible Note Hedges and Note Hedge Warrants as of June 30, 2018 and December 31, 2017:

	Six Months Ended June 30, 2018		Year Ended December 31, 2017	
	Convertible Note Hedges	Note Hedge Warrants	Convertible Note Hedges	Note Hedge Warrants
Risk-free interest rate [1]	2.7 %	2.7 %	2.1 %	2.2 %
Time to maturity	4.0	4.5	4.5	5.0
Stock price [2]	$ 19.12	$ 19.12	$ 14.99	$ 14.99
Strike price [3]	$ 16.58	$ 21.50	$ 16.58	$ 21.50
Common stock volatility [4]	42.3 %	44.9 %	44.1 %	44.1 %
Dividend yield	— %	— %	— %	— %

(1) Based on U.S. Treasury yield curve, with terms commensurate with the terms of the Convertible Note Hedges and the Note Hedge Warrants.
(2) The closing price of the Company's Class A common stock on the last trading day of the quarter ended June 30, 2018 and December 31, 2017, respectively.
(3) As per the respective agreements for the Convertible Note Hedges and Note Hedge Warrants.
(4) Selected volatility based on historical volatility of the Company's Class A common stock.

The Convertible Note Hedges and the Note Hedge Warrants are recorded at fair value at each reporting period and changes in fair value are recorded in other expense, net within the Company's condensed consolidated statements of operations. Gains and losses for these derivative financial instruments are presented separately in the Company's condensed consolidated statements of cash flows.

The following table reflects the change in the Company's Level 3 convertible note derivatives from December 31, 2017 through June 30, 2018 (in thousands):

	Convertible Note Hedges	Note Hedge Warrants
Balance at December 31, 2017	$ 108,188	$ (92,188)
Change in fair value, recorded as a component of gain (loss) on derivatives	51,338	(50,831)
Balance at June 30, 2018	$ 159,526	$ (143,019)

Contingent Consideration

In connection with the Lesinurad Transaction, the Company recorded a liability of $67.9 million as of the Acquisition Date. This valuation was based on a Monte-Carlo simulation, which includes significant estimates related to probability weighted net cash outflow projections, primarily comprised of estimated future royalty and milestone payments to AstraZeneca, discounted using a yield curve equivalent to the Company's credit risk, which was the estimated cost of debt financing for market participants. Adjustments are recorded when there are changes in significant assumptions, including net sales projections, probability weighted net cash outflow projections, the discount rate, passage of time, and the yield curve equivalent to the Company's credit risk, which is based on the estimated cost of debt for market participants. This estimate represents the probability weighted analysis of expected future milestone and royalty payments based on net sales to be made to AstraZeneca. Changes to these inputs are re-evaluated each reporting period and could materially affect the valuation of the contingent consideration. The estimated fair value of contingent consideration was approximately $33.7 million as of June 30, 2018 (Note 14).

The following table reflects the change in the Company's Level 3 contingent consideration payable from December 31, 2017 through June 30, 2018 (in thousands):

	Contingent Consideration
Fair Value at December 31, 2017	31,258
Changes in fair value	2,474
Payments/transfers to accrued expenses and other current liabilities	(81)
Fair value at June 30, 2018	$ 33,651

2.25% Convertible Senior Notes

In June 2015, the Company issued approximately $335.7 million of its 2022 Notes. The Company separately accounted for the liability and equity components of the 2022 Notes by allocating the proceeds between the liability component and equity component (Note 9). The fair value of the 2022 Notes, which differs from their carrying value, is influenced by interest rates, the price of the Company's Class A common stock and the volatility thereof, and the prices for the 2022 Notes observed in market trading, which are Level 2 inputs. The estimated fair value of the 2022 Notes was approximately $445.6 million and approximately $392.8 million as of June 30, 2018 and December 31, 2017, respectively.

8.375% Notes Due 2026

In September 2016, the Company closed a direct private placement pursuant to which the Company issued $150.0 million in aggregate principal amount of the 2026 Notes in January 2017. The estimated fair value of the 2026 Notes was approximately $152.1 million and approximately $152.5 million as of June 30, 2018 and December 31, 2017. This valuation was calculated using a discounted cash flow estimate of expected interest and principal payments and was determined using Level 3 inputs, including significant estimates related to expected LINZESS sales and a discount rate equivalent to market participant interest rates.

6. Available-for-Sale Securities

The following tables summarize the available-for-sale securities held at June 30, 2018 and December 31, 2017 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
June 30, 2018				
U.S. Treasury securities	$ 16,731	$ —	$ (16)	$ 16,715
U.S. government-sponsored securities	19,144	—	(28)	19,116
Total	$ 35,875	$ —	$ (44)	$ 35,831

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2017				
U.S. Treasury securities	$ 64,378	$ —	$ (35)	$ 64,343
U.S. government-sponsored securities	31,384	—	(47)	31,337
Total	$ 95,762	$ —	$ (82)	$ 95,680

The contractual maturities of all securities held at June 30, 2018 are one year or less. There were 12 and 29 available-for-sale securities in an unrealized loss position at June 30, 2018 and December 31, 2017, respectively, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of these securities at June 30, 2018 and December 31, 2017 was approximately $35.8 million and approximately $95.7 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 June 30, 2018.

There were no sales of available-for-sale securities during each of the three and six months ended June 30, 2018 or 2017. Net unrealized holding gains or losses for the period that have been included in accumulated other comprehensive loss were not material to the Company's condensed consolidated results of operations.

7. Inventory

Inventory consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Raw Materials	$ 308	$ —
Work in Progress	—	—
Finished Goods	791	735
	$ 1,099	$ 735

The Company's inventory represents linaclotide API and drug product and Lesinurad Products finished goods that are available for commercial sale. The Company evaluates inventory levels quarterly and any inventory that has a cost basis in excess of its expected net realizable value, inventory that becomes obsolete, inventory in excess of expected sales requirements, inventory that fails to meet commercial sale specifications or is otherwise impaired is written down with a corresponding charge to the statement of operations in the period that the impairment is first identified. No such impairments of linaclotide API inventory were recorded during the three and six months ended June 30, 2018 or 2017.

The Company wrote down approximately $1.8 million related to lesinurad inventory and commercial supply purchase commitments during the three months ended June 30, 2018 as a result of revised demand forecasts (Note 14). The adjustment was recorded as write-down of lesinurad commercial supply to net realizable value and loss on non-cancelable purchase commitments.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Salaries	$ 3,912	$ 4,566
Accrued vacation	4,868	4,672
Accrued incentive compensation	9,338	13,403
Other employee benefits	1,410	1,305
Professional fees	2,708	1,261
Accrued interest	873	873
Workforce reduction charges	2,310	—
Other	12,410	12,157
	$ 37,829	$ 38,237

As of June 30, 2018, other accrued expenses of approximately $12.4 million includes approximately $3.3 million related to a portion of the activities associated with the Company's intent to separate into two independent publicly traded companies, approximately $2.5 million related to linaclotide excess non-cancelable purchase commitments, approximately $1.2 million related to Lesinurad Products commercial supply excess non-cancelable purchase commitments and approximately $0.4 million related to excess non-cancelable Lesinurad Products sample purchase commitments (Note 14). As of December 31, 2017, other accrued expenses of approximately $12.2 million included approximately $3.4 million related to linaclotide excess purchase commitments, approximately $1.3 million related to excess non-cancelable ZURAMPIC sample purchase commitments, and approximately $0.2 million related to ZURAMPIC finished goods inventory.

9. Notes Payable

8.375% Notes due 2026

On September 23, 2016, the Company closed a direct private placement, pursuant to which the Company issued $150.0 million in aggregate principal amount of 8.375% notes due 2026 on the Funding Date, January 5, 2017. The proceeds from the issuance of the 2026 Notes were used to redeem the outstanding principal balance of the PhaRMA Notes on the Funding Date. The Company capitalized approximately $0.5 million of debt issuance costs, which were netted against the carrying value of the 2026 Notes.

The 2026 Notes bear an annual interest rate of 8.375%, with interest payable March 15, June 15, September 15 and December 15 of each year (each an "8.375% Payment Date") which began on June 15, 2017. Principal of the 2026 Notes will be payable on the 8.375% Payment Dates beginning March 15, 2019. From March 15, 2019, the Company will make quarterly payments on the 2026 Notes equal to the greater of (i) 7.5% of net sales of linaclotide in the U.S. for the preceding quarter (the "8.375% Synthetic Royalty Amount") and (ii) accrued and unpaid interest on the 2026 Notes (the "8.375% Required Interest Amount"). Principal on the 2026 Notes will be repaid in an amount equal to the 8.375% Synthetic Royalty Amount minus the 8.375% Required Interest Amount, when this is a positive number, until the principal has been paid in full. Given the principal payments on the 2026 Notes are based on the 8.375% Synthetic Royalty Amount, which will vary from quarter to quarter, the 2026 Notes may be repaid prior to September 15, 2026, the final legal maturity date. The Company expects to pay approximately $24.9 million of the principal within twelve months following June 30, 2018.

The 2026 Notes are secured by a security interest in a segregated bank account established to receive the required quarterly payments as well as certain limited accounts receivables, payment intangibles or other rights to payment or proceeds, in each case, up to the 8.375% Synthetic Royalty Amount or estimated equivalent thereto, as applicable. Up to the amount of the required quarterly payments under the 2026 Notes, Allergan deposits its quarterly profit (loss) sharing payments due to the Company related to net sales of linaclotide in the U.S. pursuant to the collaboration agreement for North America, if any, into the segregated bank account. If the funds deposited by Allergan into the segregated bank account are insufficient to make a required payment of interest or principal on a particular 8.375% Payment Date, the Company is obligated to deposit such shortfall out of the Company's general funds into the segregated bank account.

The 2026 Notes may be redeemed at any time prior to maturity, in whole or in part, at the option of the Company. If applicable, the Company will pay a redemption price equal to the percentage of outstanding principal balance of the 2026 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 2026 Notes being redeemed):

Payment Dates	Redemption Percentage
From and including March 15, 2018 to and including March 14, 2019	108.00 %
From and including March 15, 2019 to and including March 14, 2020	105.50 %
From and including March 15, 2020 to and including March 14, 2021	102.75 %
From and including March 15, 2021 and thereafter	100.00 %

The 2026 Notes contain certain covenants related to the Company's obligations with respect to the commercialization of linaclotide and the related collaboration agreement with Allergan for North America, 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 2026 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 accounting for the 2026 Notes requires the Company to make certain estimates and assumptions about the future net sales of linaclotide in the U.S. Linaclotide has been marketed as LINZESS in the U.S. since December 2012 and the estimates of the magnitude and timing of linaclotide net sales are subject to significant variability and uncertainty. These estimates and assumptions are likely to change, which may result in future adjustments to the portion of the 2026 Notes 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.

2.25% Convertible Senior Notes due 2022

In June 2015, the Company issued approximately $335.7 million aggregate principal amount of 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. The Company used approximately $21.1 million of the net proceeds from the sale of the 2022 Notes to pay the net cost of the Convertible Note Hedges (after such cost was partially offset by the proceeds to the Company from the sale of the Note Hedge Warrants), as described below.

The 2022 Notes are governed by an indenture (the "Indenture") between the Company and U.S. Bank National Association, as the trustee. The 2022 Notes are senior unsecured obligations and bear cash interest at the annual rate of 2.25%, payable on June 15 and December 15 of each year, which began on December 15, 2015. The 2022 Notes will mature on June 15, 2022, unless earlier converted or repurchased. The Company may settle conversions of the 2022 Notes through payment or delivery, as the case may be, of cash, shares of Class A common stock of the Company or a combination of cash and shares of Class A common stock, at the Company's option (subject to, and in accordance with, the settlement provisions of the Indenture). The initial conversion rate for the 2022 Notes is 60.3209 shares of Class A common stock (subject to adjustment as provided for in the Indenture) per $1,000 principal amount of the 2022 Notes, which is equal to an initial conversion price of approximately $16.58 per share and 20,249,665 shares. Holders of the 2022 Notes may convert their 2022 Notes at their option at any time prior to the close of business on the business day immediately preceding December 15, 2021 in multiples of $1,000 principal amount, only under the following circumstances:

- during any calendar quarter commencing after the calendar quarter ending on September 30, 2015 (and only during such calendar quarter), if the last reported sale price of the Company's Class A common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the 2022 Notes on each applicable trading day;

- during the five business day period after any five consecutive trading day period (the "measurement period") in which the "trading price" (as defined in the Indenture) per $1,000 principal amount of the 2022 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's Class A common stock and the conversion rate for the 2022 Notes on each such trading day; or

- upon the occurrence of specified corporate events described in the Indenture.

On or after December 15, 2021, until the close of business on the second scheduled trading day immediately preceding June 15, 2022, holders may convert their 2022 Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

If a make-whole fundamental change, as described in the Indenture, occurs and a holder elects to convert its 2022 Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the conversion rate as described in the Indenture. The Company may not redeem the 2022 Notes prior to the maturity date and no "sinking fund" is provided for by the 2022 Notes, which means that the Company is not required to periodically redeem or retire the 2022 Notes. Upon the occurrence of certain fundamental changes involving the Company, holders of the 2022 Notes may require the Company to repurchase for cash all or part of their 2022 Notes at a repurchase price equal to 100% of the principal amount of the 2022 Notes to be repurchased, plus accrued and unpaid interest.

The Indenture does not contain any financial covenants or restrict the Company's ability to repurchase the Company's securities, pay dividends or make restricted payments in the event of a transaction that substantially increases the Company's level of indebtedness. The Indenture provides for customary events of default. In the case of an event of default with respect to the 2022 Notes arising from specified events of bankruptcy or insolvency, all outstanding 2022 Notes will become due and payable immediately without further action or notice. If any other event of default with respect to the 2022 Notes under the Indenture occurs or is continuing, the trustee or holders of at least 25% in aggregate principal amount of the then outstanding 2022 Notes may declare the principal amount of the 2022 Notes to be immediately due and payable. Notwithstanding the foregoing, the Indenture provides that, upon the Company's election, and for up to 180 days, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2022 Notes.

In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the liability and equity components of the 2022 Notes by allocating the proceeds between the liability component and the embedded conversion option, or equity component, due to the Company's ability to settle the 2022 Notes in cash, its Class A common stock, or a combination of cash and Class A common stock at the option of the Company. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible debt borrowing rate for similar debt. The equity component of the 2022 Notes was recognized as a debt discount and represents the difference between the gross proceeds from the issuance of the 2022 Notes and the fair value of the liability of the 2022 Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount, or debt discount, is amortized to interest expense using the effective interest method over seven years, or the life of the 2022 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

The Company's outstanding Convertible Note balances as of June 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Liability component:		
Principal	$ 335,699	$ 335,699
Less: unamortized debt discount	(72,980)	(80,530)
Less: unamortized debt issuance costs	(5,513)	(5,976)
Net carrying amount	$ 257,206	$ 249,193
Equity component	$ 114,199	$ 114,199

In connection with the issuance of the 2022 Notes, the Company incurred approximately $11.7 million of debt issuance costs, which primarily consisted of initial purchasers' discounts and legal and other professional fees. The Company allocated these costs to the liability and equity components based on the allocation of the proceeds. The portion of these costs allocated to the equity components totaling approximately $4.0 million were recorded as a reduction to additional paid-in capital. The portion of these costs allocated to the liability components totaling approximately $7.7 million were recorded as a reduction in the carrying value of the debt on the balance sheet and are amortized to interest expense using the effective interest method over the expected life of the 2022 Notes.

The Company determined the expected life of the 2022 Notes was equal to their seven-year term. The effective interest rate on the liability components of the 2022 Notes for the period from the date of issuance through June 30, 2018 was 9.34%. The following table sets forth total interest expense recognized related to the 2022 Notes during the three and six months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Contractual interest expense	$ 1,888	$ 1,888	$ 3,777	$ 3,777
Amortization of debt issuance costs	237	196	464	383
Amortization of debt discount	3,816	3,497	7,550	6,918
Total interest expense	$ 5,941	$ 5,581	$ 11,791	$ 11,078

Convertible Note Hedge and Warrant Transactions with Respect to 2022 Notes

To minimize the impact of potential dilution to the Company's Class A common stockholders upon conversion of the 2022 Notes, the Company entered into the Convertible Note Hedges covering 20,249,665 shares of the Company's Class A common stock in connection with the issuance of the 2022 Notes. The Convertible Note Hedges have an exercise price of approximately $16.58 per share and are exercisable when and if the 2022 Notes are converted. If upon conversion of the 2022 Notes, the price of the Company's Class A common stock is above the exercise price of the Convertible Note Hedges, the counterparties are obligated to deliver shares of the Company's Class A common stock and/or cash with an aggregate value approximately equal to the difference between the price of the Company's Class A common stock at the conversion date and the exercise price, multiplied by the number of shares of the Company's Class A common stock related to the Convertible Note Hedge being exercised.

Concurrently with entering into the Convertible Note Hedges, the Company also sold 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 strike price of the Note Hedge Warrants is initially $21.50 per share, subject to adjustment, and such warrants are exercisable over the 150 trading day period beginning on September 15, 2022. The Note Hedge Warrants could have a dilutive effect on the Class A common stock to the extent that the market price per share of the Company's Class A common stock exceeds the applicable strike price of such warrants.

The Convertible Note Hedges and the Note Hedge Warrants are separate transactions entered into by the Company and are not part of the terms of the 2022 Notes. Holders of the 2022 Notes and the Note Hedge Warrants do not have any rights with respect to the Convertible Note Hedges. The Company paid approximately $91.9 million for the Convertible Note Hedges and recorded this amount as a long-term asset on the condensed consolidated balance sheet. The Company received approximately $70.8 million for the Note Hedge Warrants and recorded this amount as a long-term liability, resulting in a net cost to the Company of approximately $21.1 million. The Convertible Note Hedges and Note Hedge Warrants are accounted for as derivative assets and liabilities, respectively, in accordance with ASC Topic 815, "Derivatives and Hedging" (Note 5).

11% PhaRMA Notes due 2024

In January 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 PhaRMA Notes were redeemed at par on the 2026 Notes' Funding Date, January 5, 2017, resulting in a loss on extinguishment of debt related to the write-off of the remaining PhaRMA Notes unamortized debt issuance costs of approximately $2.0 million.

10. Commitments and Contingencies

Lease Commitments

During the year ended December 31, 2015, the Company entered into 12-month capital leases (the "2015 Vehicle Leases") for certain vehicles within its vehicle fleet for its field-based sales force and medical science liaisons. The 2015 Vehicle Leases expire at varying times through December 2018. In accordance with the terms of the 2015 Vehicle Leases, the Company maintains a letter of credit securing its obligations under the lease agreements of $0.6 million, which is recorded as restricted cash.

During the six months ended June 30, 2018, the Company entered into new 12-month operating leases (the "2018 Vehicle Leases") for certain vehicles within its vehicle fleet for its field-based sales force and medical science liaisons. In connection with entering into the 2018 Vehicle Leases, all of the 2015 Vehicle Leases will be terminated through December 31, 2018. The 2018 Vehicle Leases expire at varying times beginning in April 2019 with an automatic one-month renewal provision. In accordance with the terms of the 2018 Vehicle Leases, the Company maintains a letter of credit securing its obligations under the lease agreements of $1.3 million, which is recorded as restricted cash.

At June 30, 2018, the weighted average interest rate on the outstanding 2018 Vehicle Lease obligations was approximately 3.4% and the weighted average interest rate on the outstanding 2015 Vehicle Lease obligations was approximately 3.5%.

11. 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 and six months ended June 30, 2018 and 2017 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	$ 3,800	$ 3,568	$ 7,122	$ 6,192
Selling, general and administrative	6,539	5,572	12,065	10,227
Restructuring expenses	413	—	607	—
	$10,752	$ 9,140	$19,794	$16,419

During the three months ended March 31, 2018, the Company reduced its field-based workforce by approximately 60 employees, primarily consisting of field-based sales representatives that promoted DUZALLO or ZURAMPIC in the first position, resulting in a modification to certain share-based payment awards. As a result of the modification, the Company recorded stock-based compensation expense of approximately $0.2 million to restructuring expenses during the three months ended March 31, 2018.

During the three months ended June 30, 2018, the Company initiated a reduction in headquarter-based workforce by approximately 40 employees associated with the Company’s intent to separate. Certain share-based payment awards were modified in connection with the reduction in workforce. As a result of the modifications, the Company recorded stock-based compensation expense of approximately $0.4 million to restructuring expenses during the three months ended June 30, 2018.

A summary of stock option activity for the six months ended June 30, 2018 is as follows:

	Number of Shares (in thousands)	Weighted-Average Fair Value
Outstanding at December 31, 2017	21,086	$ 12.90
Granted	3,041	14.74
Exercised	(1,607)	10.42
Cancelled	(464)	14.79
Outstanding at June 30, 2018	22,056	$ 13.30

The weighted-average assumptions used to estimate the fair value of the stock options using the Black-Scholes option-pricing model were as follows for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Expected volatility	44.0 %	46.1 %	43.6 %	46.1 %
Expected term (in years)	6.0	6.0	6.0	6.0
Risk-free interest rate	2.8 %	2.0 %	2.7 %	2.0 %
Expected dividend yield	— %	— %	— %	— %

The Company utilizes RSUs in addition to stock options as part of the equity compensation it provides to its employees, each RSU representing the right to receive one share of the Company's Class A Common Stock pursuant to the terms of the applicable award agreement and granted pursuant to the terms of the Company's 2010 Equity 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 estimated forfeitures, is recognized over the applicable service period.

A summary of RSU activity for the six months ended June 30, 2018 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2017	2,277	$ 15.08
Granted	1,606	$ 14.71
Vested	(488)	$ 15.19
Forfeited	(188)	$ 14.92
Unvested as of June 30, 2018	3,207	$ 14.89

12. Related Party Transactions

In September 2009, Allergan became a related party when the Company sold to Allergan 2,083,333 shares of the Company's convertible preferred stock. Amounts due to and due from Allergan 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. The Company had approximately $73.8 million and approximately $79.0 million in related party accounts receivable, net of related party accounts payable, associated with Allergan as of June 30, 2018 and December 31, 2017, respectively.

The Company has and currently obtains health insurance services for its employees from an insurance provider whose President and Chief Executive Officer became a member of the Company's Board of Directors in April 2016. The Company paid approximately $3.0 million and approximately $6.3 million in insurance premiums to this insurance provider during the three and six months ended June 30, 2018, respectively, and approximately $3.0 million and approximately $6.0 million during the three and six months ended June 30, 2017, respectively. At June 30, 2018 and

December 31, 2017, the Company had an insignificant amount and no accounts payable due to this related party, respectively.

13. Workforce Reduction

On January 30, 2018, the Company commenced an initiative to evaluate the optimal mix of investments for the lesinurad franchise. As part of this effort, the Company reduced its field-based workforce by approximately 60 employees, primarily consisting of field-based sales representatives that promoted DUZALLO or ZURAMPIC in the first position.

During the three months ended March 31, 2018, the Company substantially completed the implementation of this reduction in field-based workforce and, in accordance with ASC 420, *Exit or Disposal Activities*, recorded approximately $2.4 million of costs including employee severance, benefits and related costs. These costs are reflected in the condensed consolidated statement of operations as approximately $2.4 million in restructuring expenses.

On June 27, 2018, the Company determined the initial organizational designs of the two new businesses, including employees' roles and responsibilities, in connection with the Company's intent to separate its sGC business from its commercial and GI business. As part of this process, the Company has initiated a reduction in its headquarter-based workforce by approximately 40 employees and expects to substantially complete the reduction in its workforce during the year ending December 31, 2018. The Company anticipates total costs related to the reduction in workforce to be approximately $5.3 million and will incur substantially all expenses through the end of 2018.

During the three months ended June 30, 2018, the Company recorded approximately $2.4 million of costs, including employee severance, benefits and related costs, in connection with the reduction in workforce associated with the Company's intent to separate in accordance with ASC 420, *Exit and Disposal Activities*. These costs are reflected in the condensed consolidated statement of operations as restructuring expenses.

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the three months ended June 30, 2018 (in thousands):

Employee severance, benefits and related costs	Amounts Accrued at March 31, 2018	Charges	Amount Paid	Amounts Accrued at June 30, 2018
January 2018 Reduction	$ 1,160	$ —	$ (1,016)	$ 144
June 2018 Reduction	—	2,166	—	2,166
Total	$ 1,160	$ 2,166	$ (1,016)	$ 2,310

14. Subsequent Events

In July 2018, the Company obtained and analyzed the results from the lesinurad franchise test markets. Data from the test markets did not meet expectations. In connection with the results, the Company's Board of Directors determined on July 31, 2018 to terminate the lesinurad license agreement. On August 2, 2018, the Company delivered to AstraZeneca notice of termination of the lesinurad license agreement, which termination is made with respect to all products under the lesinurad license agreement and expected to be effective 180 days from the notice. Upon such termination the lesinurad commercial supply agreement also will terminate. The Company expects to incur costs associated with DUZALLO and ZURAMPIC until the termination of the lesinurad agreement is effective.

In connection with the analysis of the data from the test markets and subsequent notice of termination of the lesinurad license agreement, the Company has reduced its projected revenue and net cash flow assumptions associated with its developed technology – ZURAMPIC and developed technology – DUZALLO intangible assets, as well as its contingent consideration liability. Accordingly, the Company expects to record, during the three months ending September 30, 2018, a full intangible asset impairment of approximately $150.0 million and a gain on fair value remeasurement of contingent consideration of approximately $30.0 million. Additionally, in connection with the notice of termination of the lesinurad license agreement, the Company wrote down approximately $2.2 million related to lesinurad inventory and purchase commitments during the three months ended June 30, 2018 as a result of revised demand forecasts. Approximately $1.8 million of such adjustment was recorded as write-down of lesinurad commercial supply to net realizable value and loss on non-cancelable purchase commitments and approximately $0.4 million was recorded as selling, general, and administrative expense in the Company's condensed consolidated statement of operations.

As a result of the termination of the lesinurad license agreement, the Company expects to reduce its workforce by approximately 125 employees, primarily consisting of field-based sales employees. The Company estimates that it will incur aggregate charges in connection with the reduction in its workforce of approximately $9.0 million to $11.0 million for one-time employee severance and benefit costs and approximately $1.0 million to $2.0 million for termination fees and other contract-related costs, primarily in 2018, nearly all of which are expected to result in cash expenditures.

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 the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto 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 a commercial biotechnology company leveraging our proven development and commercial capabilities as we seek to bring multiple medicines to patients. We are advancing innovative product opportunities in areas of large unmet need, based upon our target-to-disease approach to development and leveraging our core areas of expertise in gastrointestinal, or GI, diseases and primary care, as well as in guanylate cyclase, or GC, pathways.

Our first commercial product, linaclotide, is available to adult men and women suffering from irritable bowel syndrome with constipation, or IBS-C, or chronic idiopathic constipation, or CIC, in certain countries around the world. Linaclotide is available under the trademarked name LINZESS® to adult men and women suffering from IBS-C or CIC in the United States, or the U.S. and Mexico, and to adult men and women suffering from IBS-C in Japan. Linaclotide is available under the trademarked name CONSTELLA® to adult men and women suffering from IBS-C or CIC in Canada, and to adult men and women suffering from IBS-C in certain European countries.

We and our partner Allergan plc (together with its affiliates), or Allergan, began commercializing LINZESS in the U.S. in December 2012. Under our 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 us and Allergan. Allergan has an exclusive license from us to develop and commercialize linaclotide in the Allergan License Territory, which is comprised of all countries other than China, Hong Kong, Macau, Japan and the countries and territories of North America. On a country-by-country and product-by-product basis in the Allergan License Territory, Allergan pays us royalties as a percentage of net sales of products containing linaclotide as an active ingredient. In addition, Allergan has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and in Mexico as LINZESS.

Astellas Pharma Inc., or Astellas, our partner in Japan, has an exclusive license to develop and commercialize linaclotide in Japan. In March 2017, Astellas began commercializing LINZESS for the treatment of adults with IBS-C in Japan, and in September 2017, Astellas submitted a supplemental new drug application for approval of LINZESS for the treatment of adult patients with chronic constipation in Japan. In October 2012, we entered into a collaboration agreement with AstraZeneca AB (together with its affiliates), 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 December 2015, we and AstraZeneca filed for approval with the China Food and Drug Administration, or CFDA, to market linaclotide in China.

Our and Allergan's linaclotide life cycle management strategy in the U.S. includes the objective of strengthening the clinical profile of linaclotide by obtaining additional abdominal symptom claims and expanding the clinical utility of linaclotide by demonstrating the pain-relieving effect of a delayed release formulation, through the advancement of linaclotide delayed release in all forms of IBS. We and Allergan are also continuing to explore ways to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. In July 2018, we announced the initiation of a Phase IIIb trial evaluating the efficacy and safety of linaclotide 290 mcg on multiple abdominal symptoms in addition to pain, including bloating and discomfort, in adult patients with IBS-C.

We are also advancing another GI development program, IW-3718, a gastric retentive formulation of a bile acid sequestrant for the potential treatment of persistent gastroesophageal reflux disease, or persistent GERD. Our clinical research has demonstrated that reflux of bile from the intestine into the stomach and esophagus plays a key role in the ongoing symptoms of persistent GERD. IW-3718 is a novel formulation of a bile acid sequestrant designed to release in the stomach over an extended period of time, bind to bile that refluxes into the stomach, and potentially provide symptomatic relief in patients with persistent GERD. In June 2018, we initiated two Phase III clinical trials evaluating the safety and efficacy of IW-3718 in patients with persistent GERD.

In June 2016, we closed a transaction with AstraZeneca, or the Lesinurad Transaction, pursuant to which we received an exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient, or the Lesinurad License, including ZURAMPIC® and DUZALLO®. Lesinurad 200mg tablets were approved as ZURAMPIC by the U.S. Food and Drug Administration, or FDA, in December 2015 for use in combination with a xanthine oxidase inhibitor, or XOI, for the treatment of hyperuricemia associated with uncontrolled gout. In October 2016, we began commercializing ZURAMPIC in the U.S. The FDA approved DUZALLO, a fixed-dose combination product of lesinurad and allopurinol, in August 2017 for the treatment of hyperuricemia associated with gout in adults who have not achieved goal serum uric acid levels with a medically appropriate daily dose of allopurinol alone. In October 2017, we began commercializing DUZALLO in the U.S. We have accounted for the Lesinurad Transaction in accordance with Accounting Standards Codification, or ASC, Topic 805, “Business Combinations”, or ASC 805, as the Lesinurad Transaction meets the requirements of a business combination. The transaction is more fully described in Note 3, *Goodwill and Intangible Assets*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. In January 2018, we commenced an initiative to evaluate the optimal mix of investments for our lesinurad franchise for uncontrolled gout, including DUZALLO and ZURAMPIC. As part of this effort, in 2018 we began re-allocating resources within our lesinurad franchise to systematically explore a more comprehensive marketing mix in select test markets (with paired controls), while continuing to build market presence for the lesinurad franchise across the country. In July 2018, we obtained and analyzed the results from the lesinurad franchise test markets. Data from the test markets did not meet expectations. In connection with the results, our Board of Directors determined on July 31, 2018 to terminate the lesinurad license agreement. These events are more fully described in Note 14, *Subsequent Events*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

We are also leveraging our pharmacological expertise in GC pathways gained through the discovery and development of linaclotide, a GC-C agonist, to develop a pipeline of soluble guanylate cyclase, or sGC, stimulators including praliciguat and olinciguat. We are advancing praliciguat, our lead clinical sGC stimulator, in Phase II trials for the potential treatment of diabetic nephropathy and for the potential treatment of heart failure with preserved ejection fraction, or HFpEF. Data supported the continued advancement of praliciguat for evaluation as a potential treatment for patients with diabetic nephropathy and patients with HFpEF. Our second clinical sGC stimulator, olinciguat, is being advanced in Phase II trials for the potential treatment of achalasia and for the potential treatment of sickle cell disease. In June 2018, the FDA granted Orphan Drug Designation to olinciguat for the treatment of patients with sickle cell disease.

As part of our strategy, we have also established development and commercial capabilities that we plan to leverage as we seek to bring multiple medicines to patients. We intend to play an active role in the development and commercialization of our products in the U.S., and to establish a strong global brand by out-licensing commercialization rights in other territories to high-performing partners.

In May 2018, we announced the intent, as authorized by our Board of Directors, to separate our sGC business from our commercial and GI business, resulting in two independent, publicly traded companies, Ironwood and a new company, or R&D Co. Following the separation, Ironwood is expected to focus on accelerating growth of its in-market products, including LINZESS, and advance development programs targeting treatments for GI diseases, uncontrolled gout, and abdominal pain. The separated R&D Co. is expected to focus on the sGC pipeline development programs for the treatment of serious and orphan diseases. The separation is expected to be completed in the first half of 2019 and is anticipated to be tax-free. In June 2018, we announced certain planned future management changes in connection with, and contingent upon the successful completion of, the separation, as well as determined the initial organizational designs of the two new businesses, including employees’ roles and responsibilities.

In August 2015, we 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, or IBS-D, which expired in December 2017. In January 2017, we and Allergan entered into a commercial agreement under which the adjustments to our or Allergan's share of the net profits under the share adjustment provision of the collaboration agreement for linaclotide in North America are eliminated, in full, in 2018 and all subsequent years. In addition, Allergan appointed us, on a non-exclusive basis, to promote CANASA® (mesalamine), approved for the treatment of ulcerative proctitis, and DELZICOL® (mesalamine), approved for the treatment of ulcerative colitis, in the U.S. for approximately two years. In December 2017, this agreement was amended to include the promotion of VIBERZI through December 31, 2018 and to discontinue the promotion of DELZICOL effective January 1, 2018. These agreements are more fully described in Note 4, *Collaboration, License, Co-Promotion and Other Commercial Agreements*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

We were incorporated in Delaware on January 5, 1998 as Microbia, Inc. On April 7, 2008, we changed our name to Ironwood Pharmaceuticals, Inc. We operate in one reportable business segment—human therapeutics.

To date, we have dedicated a majority of our activities to the research, development and commercialization of linaclotide and the commercialization of lesinurad, as well as to the research and development of our other product candidates. We have incurred significant operating losses since our inception in 1998. As of June 30, 2018, we had an accumulated deficit of approximately $1.4 billion. We are unable to predict the extent of any future losses or guarantee when, or if, our company will become cash flow positive.

Financial Overview

Revenues. Our revenues are generated primarily through our collaborative arrangements and license agreements related to research and development and commercialization of linaclotide, as well as co-promotion arrangements in the U.S. and product revenue related to the commercial sale of ZURAMPIC and DUZALLO in the U.S. Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers,* or ASC 606, using the modified retrospective transition method. The adoption of ASC 606 represents a change in accounting principle that aims to more closely align revenue recognition with the delivery of our services and will provide financial statement readers with enhanced disclosures. In accordance with ASC 606, we recognize revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration which we expect to receive in exchange for the good or service. The reported results for the three and six months ended as of June 30, 2018 reflect the application of ASC 606 guidance, while the reported results for prior periods were prepared in accordance with ASC 605, *Revenue Recognition,* or ASC 605. Upon adoption of ASC 606, we concluded that no cumulative adjustment to the accumulative deficit as of January 1, 2018 was necessary. The adoption of ASC 606 had no impact on our condensed consolidated statement of operations, condensed consolidated balance sheets, or condensed consolidated statement of cash flows.

The terms of the collaborative research and development, license and co-promotion agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, (iii) the manufacture of finished drug product, active pharmaceutical ingredient, or API, or development materials for a partner which are reimbursed at a contractually determined rate, and (iv) co-promotion activities by our clinical sales specialists. Payments to us may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API or development materials, (iv) payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives and (vi) 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.

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 to and from Allergan as collaboration expense or collaborative arrangements revenue, as applicable. Net profits or losses consist of net sales 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. Although we expect net sales to increase over time, the settlement payments between Allergan 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 the 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 or any other markets where linaclotide receives approval.

Product revenue is recognized when the Distributor obtains control of our product, which occurs at a point in time, typically upon shipment of ZURAMPIC and DUZALLO, or the Lesinurad Products, to the Distributor. When we perform shipping and handling activities after the transfer of control to the Distributor (e.g., when control transfers prior to delivery), they are considered as fulfillment activities, and accordingly, the costs are accrued for when the related revenue is recognized. Taxes collected from Customers relating to product sales and remitted to governmental authorities are excluded from revenues. We expense incremental costs of obtaining contracts with Distributors as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

We evaluate the creditworthiness of each of our Distributors to ensure it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur. We calculate our net product revenue based on the wholesale acquisition cost that we charge our Distributors for the Lesinurad Products less variable consideration. The product revenue variable consideration consists of estimates relating to (i) trade discounts and allowances, such as invoice discounts for prompt payment and distributor fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (iii) reserves for expected product returns and (iv) estimated costs of incentives offered to certain indirect customers including patients. These estimates could be adjusted based on actual results in the period such variances become known.

Cost of Revenues. Cost of revenues includes cost of collaborative arrangements revenue related to the sales of linaclotide API and drug product, as well as the cost of product revenue related to sales of the Lesinurad Products in the U.S. Cost related to the sales of linaclotide API and drug product are recognized upon shipment of linaclotide API and drug product to certain of our partners outside of the U.S. Our cost of collaborative arrangements revenue for linaclotide consists of the internal and external costs of producing such API and drug product for certain of our partners outside of the U.S. Cost of product revenue related to the sales of the Lesinurad Products in the U.S. includes the cost of producing finished goods that correspond with product revenue for the reporting period, such as third-party supply and overhead costs, as well as certain period costs related to freight, packaging, stability and quality testing, and customer acquisition.

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, as well as licensing fees for our product candidates. We charge all research and development expenses to operations as incurred. Under our linaclotide collaboration agreements with Allergan for the U.S. and AstraZeneca for China, Hong Kong and Macau, we are reimbursed for certain research and development expenses, and we net these reimbursements against our research and development expenses as incurred. Amounts owed to Allergan or AstraZeneca for such linaclotide territories are recorded as incremental research and development expense.

The core of our research and development strategy is to leverage our development capabilities, as well as our pharmacologic expertise, to bring multiple medicines to patients. We are advancing innovative product opportunities in areas of large unmet need, including IBS-C and CIC, abdominal pain associated with lower GI disorders, hyperuricemia associated with uncontrolled gout, persistent GERD, diabetic nephropathy, HFpEF and specialty diseases, including sickle cell disease and achalasia.

Linaclotide. Linaclotide is the first FDA-approved guanylate cyclase type-C, or GC-C, agonist. Linaclotide is approved and commercially available in the U.S., Japan and in a number of E.U. and other countries.

We and Allergan are exploring development opportunities in the U.S. to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. In January 2017, the FDA approved a 72 mcg dose of LINZESS for adults with CIC, which became available in the U.S. in March 2017. In July 2018, we announced the initiation of a Phase IIIb trial evaluating the efficacy and safety of linaclotide 290 mcg on multiple abdominal symptoms in addition to pain, including bloating and discomfort, in adult patients with IBS-C.

We and Allergan plan to advance linaclotide delayed release as a visceral, non-opioid, pain-relieving agent for patients suffering from all forms of IBS, and have established a plan with the FDA for clinical pediatric programs with linaclotide, as described below.

Lesinurad. Lesinurad 200mg tablets were approved as ZURAMPIC by the FDA in December 2015. In October 2016, we began commercializing ZURAMPIC in the U.S. The FDA approved DUZALLO, the fixed-dose combination product of lesinurad and allopurinol in August 2017 for the treatment of hyperuricemia associated with gout in patients who have not achieved goal serum uric acid levels with a medically appropriate daily dose of allopurinol alone. In October 2017, we began commercializing DUZALLO in the U.S.

The FDA has required a post-marketing clinical study to further evaluate the renal and cardiovascular safety of lesinurad, and has required that enrollment include patients with moderate renal impairment. The post-marketing requirements for lesinurad are estimated to be less than $100.0 million over up to ten years from June 2, 2016, or the Acquisition Date.

Development Candidates. We are advancing our persistent GERD program through the development of IW-3718, a gastric retentive formulation of a bile acid sequestrant. IW-3718 is designed to release in the stomach over an extended period of time, bind to bile that refluxes into the stomach, and potentially provide symptomatic relief in patients with persistent GERD. In June 2018, we announced the initiation of two Phase III clinical trials evaluating the safety and efficacy of IW-3718 in patients with persistent GERD.

We are currently progressing praliciguat and olinciguat, our first two sGC stimulator candidates, in clinical development. We believe both product candidates have distinct pharmacologic profiles that may be differentiating and enable opportunities in multiple indications. Praliciguat is being evaluated as a potential treatment for diabetic nephropathy and for HFpEF. Olinciguat is being evaluated as a potential treatment for sickle cell disease and achalasia. Dysregulation of the nitric oxide, or NO, pathway is believed to be linked to multiple vascular and fibrotic diseases.
By boosting NO signaling, praliciguat and olinciguat have the potential to have a multidimensional impact by addressing the underlying causes of diabetic nephropathy, HFpEF, sickle cell disease and achalasia. In June 2018, the FDA granted Orphan Drug Designation to olinciguat for the treatment of patients with sickle cell disease.

We have additional assets in early development that we continue to advance, and we are 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 pathways.

The following table sets forth our research and development expenses related to our product pipeline for the three and six months ended June 30, 2018 and 2017. These expenses relate primarily to internal compensation, benefits and other employee-related expenses and external costs associated with nonclinical studies and clinical trial costs 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Linaclotide[1]	$ 8,187	$ 8,665	$ 15,478	$ 16,916
Lesinurad[2]	1,492	4,287	3,439	9,167
Development candidates:				
GI disorders (two compounds)[3]	7,481	4,887	12,789	10,609
Vascular and fibrotic disorders (two compounds)[3]	12,900	14,210	26,000	24,215
Central nervous system disorders (one compound)[3]	3,278	2	6,560	32
Total development candidates	23,659	19,099	45,349	34,856
Discovery research	5,594	5,293	11,171	10,107
Total research and development expenses	$ 38,932	$ 37,344	$ 75,437	$ 71,046

(1) Includes linaclotide in all indications, populations and formulations.
(2) Includes lesinurad in all indications, populations and formulations.
(3) Number of compounds includes clinical-stage development candidates for the three months ended June 30, 2018.

Since 2004, the date we began tracking costs by program, we have incurred approximately $444.3 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 Allergan for the U.S. and AstraZeneca for China, Hong Kong and Macau 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.

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 connection with the FDA approval of LINZESS, 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 Allergan established a nonclinical and clinical post-marketing plan with the FDA to understand the efficacy and safety of LINZESS in pediatric patients. We and Allergan have are advancing clinical pediatric programs in IBS-C patients age seven to 17 and functional constipation patients age six to 17. We and Allergan are also exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. In October 2012, we entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China, Hong Kong and Macau, with AstraZeneca having primary responsibility for the local operational execution. 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 for other geographic markets within IBS-C and CIC, or in additional indications, populations or formulations.

In December 2015, the FDA approved ZURAMPIC for use in conjunction with an XOI for the treatment of hyperuricemia associated with uncontrolled gout. In connection with the FDA approval, the FDA has required a post-marketing clinical study to further evaluate the renal and cardiovascular safety of lesinurad, and has required that enrollment include patients with moderate renal impairment. These post-marketing requirements are estimated to be less than $100.0 million over up to ten years from the Acquisition Date. The FDA approved DUZALLO, the fixed-dose combination product containing lesinurad and allopurinol, in August 2017 for the treatment of hyperuricemia associated with gout in patients who have not achieved goal serum uric acid levels with a medically appropriate daily dose of allopurinol alone.

We are also advancing other development programs such as IW-3718, targeting persistent GERD, praliciguat targeting diabetic nephropathy and HFpEF, and olinciguat targeting sickle cell disease and achalasia.

Given the inherent uncertainties that come with the development of pharmaceutical products, we cannot estimate with any degree of certainty how our 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 within its currently approved indications; if or when linaclotide will be developed 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 intend to access externally discovered drug candidates that fit within our core strategy. In evaluating these potential assets, we apply the same investment 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 and varying 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, and, even if approved, a product may face post-approval development and regulatory requirements.
- There may be substantial costs, delays and difficulties in successfully integrating externally developed product candidates into our business operations.
- The emergence of competing technologies and products and other adverse market developments may negatively impact us.

As a result of the factors discussed above, including the factors discussed under "Risk Factors" in Item 1A of this Quarterly Report on Form 10-Q, 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.

We expect our research and development costs will be substantial for the foreseeable future. We will continue to invest in linaclotide, including the investigation of ways to enhance the clinical profile within their currently approved indications, and the exploration of its potential utility in other indications, populations and 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, insurance 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 record all selling, general and administrative expenses as incurred.

Under our AstraZeneca collaboration agreement for linaclotide, 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 Allergan's 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 Allergan as collaboration expense or collaborative arrangements revenue, respectively.

Amortization of Acquired Intangible Assets. Amortization expense is based on the economic consumption of intangible assets. Our amortization is related to the ZURAMPIC and DUZALLO intangible assets, which is amortized on a straight-line basis over the estimated useful life of the assets. We believe that the straight-line method of amortization represents the pattern in which the economic benefits of the intangible assets are consumed.

(Gain) Loss on Fair Value Remeasurement of Contingent Consideration. Our contingent consideration obligation related to the Lesinurad Transaction consists of the fair value of estimated future milestone and royalty payments. This liability is revalued at each reporting period. Changes in the fair value of our contingent consideration, other than changes due to payments, are recognized as a (gain)/loss on fair value remeasurement of contingent consideration in our condensed consolidated statement of operations. Adjustments are recorded when there are changes in significant assumptions, including net sales projections, probability weighted net cash outflow projections, the discount rate, passage of time, and the yield curve equivalent to our credit risk, which is based on the estimated cost of debt for market participants.

Restructuring Expenses. We record costs and liabilities associated with exit and disposal activities in accordance with ASC 420, *Exit or Disposal Cost Obligations*. Such costs are based on estimates of fair value in the period the liabilities are incurred. We evaluate and adjusts these costs as appropriate for changes in circumstances as additional information becomes available.

Other (Expense) Income. Interest expense consists primarily of cash and non-cash interest costs related to the 2022 Notes and the 2026 Notes. Non-cash interest expense consists of amortization of the debt discount and associated debt issuance costs associated with the 2022 Notes and 2026 Notes. We amortize these costs using the effective interest rate method over the life of the respective note agreements as interest expense in our condensed consolidated statements of operations.

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

In June 2015, in connection with the issuance of the 2022 Notes, we entered into convertible note hedge transactions, or the Convertible Note Hedges. Concurrently with entering into the Convertible Note Hedges, we also entered into certain warrant transactions in which we sold note hedge warrants, or the Note Hedge Warrants, to the Convertible Note Hedge counterparties to acquire 20,249,665 shares of our Class A common stock, subject to customary anti-dilution adjustments. Gain (loss) on derivatives consists of the change in fair value of the Convertible Note Hedges and Note Hedge Warrants, which are recorded as derivative assets and liabilities. The Convertible Note Hedges and the Note Hedge Warrants are recorded at fair value at each reporting period and changes in fair value are recorded in our condensed consolidated statements of operations.

In September 2016, we closed a direct private placement, pursuant to which we issued $150.0 million in aggregate principal amount of 8.375% notes due 2026 on January 5, 2017, or the Funding Date. The proceeds from the issuance of the 2026 Notes were used to redeem the outstanding principal balance of the PhaRMA Notes on the Funding Date. This transaction is more fully described in Note 9, *Notes Payable*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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 U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make certain estimates and assumptions that may affect the reported amounts of assets and liabilities and 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. Significant estimates and assumptions in our condensed consolidated financial statements include those related to revenue recognition including returns, rebates, and other pricing adjustments; available-for-sale securities; inventory valuation, and related reserves; impairment of long-lived assets; including our acquired intangible assets and goodwill; 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; contingent consideration; contingencies and share-based compensation. We base our estimates on our 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 our estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Except as outlined below, during the three and six months ended June 30, 2018, 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, 2017, which was filed with the Securities and Exchange Commission, or SEC, on February 22, 2018, or the 2017 Annual Report on Form 10-K.

Revenue Recognition

Effective January 1, 2018, we adopted ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606") using the modified retrospective transition method. The adoption of ASC 606 represents a change in accounting principle that aims to more closely align revenue recognition with the delivery of our services and will provide financial statement readers with enhanced disclosures. In accordance with ASC 606, we recognize revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration which we expect to receive in exchange for the good or service. The reported results for the three and six months ended as of June 30, 2018 reflect the application of ASC 606 guidance, while the reported results for prior periods were prepared in accordance with ASC 605. Upon adoption of ASC 606, we concluded that no cumulative adjustment to the accumulative deficit as of January 1, 2018 was necessary. There were no remaining or ongoing deliverables or unrecognized consideration as of December 31, 2017 that required an adjustment to accumulated deficit. The adoption of ASC 606 had no impact on our condensed consolidated statement of operations, condensed consolidated balance sheets, or condensed consolidated statement of cash flows.

As part of the ASC 606 adoption, we have utilized certain practical expedients outlined in the guidance. These practical expedients include:

- Expensing as incurred incremental costs of obtaining a contract, such as sales commissions, if the amortization period of the asset would be less than one year.
- Recognizing revenue in the amount that we have the right to invoice, when consideration from the customer corresponds directly with the value to the customer of our performance completed to date.
- For contracts that were modified before the beginning of the earliest reporting period presented in accordance with the pending content that links to this paragraph, an entity need not retrospectively restate the contract for those contract modifications in accordance with paragraphs ASC 606-10-25-12 through 25-13. Instead, an entity shall reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented in accordance with the pending content that links to this paragraph when: a. Identifying the satisfied and unsatisfied performance obligations b. Determining the transaction price and c. Allocating the transaction price to the satisfied and unsatisfied performance obligations.

Prior to the adoption of ASC 606, we recognized revenue when there was persuasive evidence that an arrangement existed, services had been rendered or delivery had occurred, the price was fixed or determinable, and collection was reasonably assured.

Our revenues are generated primarily through collaborative arrangements and license agreements related to the research and development and commercialization of linaclotide, as well as co-promotion arrangements in the U.S. and product revenue related to the commercial sale of ZURAMPIC and DUZALLO in the U.S. The terms of the collaborative research and development, license, co-promotion and other agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, including participation on joint steering committees, (iii) the manufacture of finished drug product, API, or development materials for a partner, which are reimbursed at a contractually determined rate, and (iv) co-promotion activities by our clinical sales specialists. Non-refundable payments to us under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API, or development materials, (iv) payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives, and (vi) royalties on product sales. Additionally, we may 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 for China, Hong Kong and Macau through our collaborations with Allergan and AstraZeneca, respectively. We have adopted a policy to recognize revenue net of tax withholdings, as applicable.

Revenue recognition under ASC 606

Upon executing a revenue generating arrangement, we assess whether it is probable we will collect consideration in exchange for the good or service it transfers to the customer. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations. We must develop assumptions that require significant judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The assumptions that are used to determine the stand-alone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Collaboration, License, Co-Promotion and Other Commercial Agreements

Upon licensing intellectual property, we determine if the license is distinct from the other performance obligations identified in the arrangement. We recognize revenues from the transaction price, including non-refundable, up-front fees allocated to the license when the license is transferred to the customer if the license has distinct benefit to the customer. For licenses that are combined with other promises, we assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. For performance obligations that are satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Our license and collaboration agreements include milestone payments, such as development and other milestones. We evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method at the inception of the agreement. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. We re-evaluate the probability of achievement of such milestones and any related constraint at each reporting period, and any adjustments are recorded on a cumulative catch-up basis.

Agreements that include the supply API or drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. We assess if these options provide a material right to its partner, and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded as revenue when the customer obtains control of the goods, which is typically upon shipment for sales of API and upon delivery for sales of drug product.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur in accordance with the sales-based royalty exception under ASC 606-10-55-65.

Net Profit or Net Loss Sharing

In accordance with ASC 808 Topic, Collaborative Arrangements ("ASC 808"), we considered the nature and contractual terms of the arrangement and the nature of our business operations to determine the classification of payments under our collaboration agreements. While ASC 808 provides guidance on classification, the standard is silent on matters of separation, initial measurement, and recognition. Therefore, we, consistent with our accounting policies prior to the adoption of ASC 606, apply the separation, initial measurement, and recognition principles of ASC 606 to our collaboration agreements.

Our collaborative arrangements revenue generated from sales of LINZESS in the U.S. are considered akin to sales-based royalties. In accordance with the sales-based royalty exception, we recognize our share of the pre-tax commercial net profit or net loss generated from the sales of LINZESS in the U.S. in the period the product sales are earned, as reported by Allergan, and related cost of goods sold and selling, general and administrative expenses are incurred by us and our collaboration partner. These amounts are partially determined based on amounts provided by Allergan and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and contractual rebates, wholesaler fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. We are highly dependent on Allergan for timely and accurate information regarding any net revenues realized from sales of LINZESS in the U.S. in accordance with both ASC 808 and ASC 606, and the costs incurred in selling it, in order to accurately report its results of operations. If we do not receive timely and accurate information or incorrectly estimate activity levels associated with the collaboration at a given point in time, we could be required to record adjustments in future periods.

In accordance with ASC 606-10-55, Principal Agent Considerations, we record revenue transactions as net product revenue in our condensed consolidated statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor, retaining inventory risk, and control over pricing. Given that we are not the primary obligor and do not have the inventory risks in the collaboration agreement with Allergan for North America, we record our share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and presents the settlement payments to and from Allergan as collaboration expense or collaborative arrangements revenue, as applicable. We and Allergan settle the cost sharing quarterly, such that our statement of operations reflects 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

Product revenue, net

Net product revenue is derived from sales of the Lesinurad Products in the U.S. We sell the Lesinurad Products principally to a limited number of national wholesalers and selected regional wholesalers (the "Distributors"). The Distributors resell the Lesinurad Products to retail pharmacies and healthcare providers, who then sell to patients.

Net product revenue is recognized when the Distributor obtains control of our product, which occurs at a point in time, typically upon shipment of Lesinurad Products to the Distributor. When we perform shipping and handling activities after the transfer of control to the Distributor (e.g., when control transfers prior to delivery), they are considered as fulfillment activities, and accordingly, the costs are accrued for when the related revenue is recognized. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

We evaluate the creditworthiness of each of its Distributors to determine whether it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur. We calculate our net product revenue based on the wholesale acquisition cost that we charge our Distributors for the Lesinurad Products less variable consideration. The product revenue variable consideration consists of estimates relating to (i) trade discounts and allowances, such as invoice discounts for prompt payment and distributor fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (iii) reserves for expected product returns and (iv) estimated costs of incentives offered to certain indirect customers including patients. These estimates could be adjusted based on actual results in the period such variances become known.

Trade Discounts and Allowances: We generally provide invoice discounts on sales of Lesinurad Products to our Distributors for prompt payment and pay fees for distribution services and for certain data that Distributors provide to us. Consistent with historical industry practice, we expect our Distributors to earn these discounts and fees, and accordingly deducts the full amount of these discounts and fees from our gross product revenues at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various private organizations ("Third-party Payors") to allow for eligible purchases of the Lesinurad Products at partial or full reimbursement from such Third-party Payors. We estimate the rebates, chargebacks and discounts we will be obligated to provide to Third-party Payors and deduct these estimated amounts from our gross product revenue at the time the revenue is recognized. Based upon (i) our contracts with these Third-party Payors, (ii) the government-mandated discounts applicable to government-funded programs, (iii) information obtained from our Distributors and third-parties regarding the payor mix for Lesinurad Products and (iv) historical industry information regarding the payor mix for analog products, we estimate the rebates, chargebacks and discounts that we will be obligated to provide to Third-party Payors.

Product Returns: We estimate the amount of Lesinurad Products that will be returned and deduct these estimated amounts from our gross revenue at the time the revenue is recognized. Our Distributors have the right to return unopened, unprescribed Lesinurad Products beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for the Lesinurad Products is at least 24 months after it has been converted into tablet form, which is the last step in the manufacturing process for Lesinurad Products and generally occurs within a few months before Lesinurad Products are delivered to us. We currently estimate product returns based on data provided to us by our Distributors and by other third parties, historical industry information regarding rates for similar pharmaceutical products, the estimated remaining shelf life of the Lesinurad Products previously shipped and currently being shipped to Distributors, and contractual agreements with our Distributors intended to limit the amount of inventory they maintain. Reporting from the Distributors includes Distributor sales and inventory held by Distributors, which provides us with visibility into the distribution channel in order to determine which products, if any, were eligible to be returned.

Other Incentives: Incentives that we offer include voluntary patient assistance programs, such as co-pay assistance programs which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Product revenue is recorded net of the trade discounts, allowances, rebates, chargebacks, discounts, product returns, and other incentives. Certain of these adjustments are recorded as an accounts receivable reserve.

Other

We produce linaclotide finished drug product, API and development materials for certain of our partners.

We recognize revenue on linaclotide finished drug product, API and development materials when control has transferred to the partner, which generally occurs upon shipment for sales of API and upon delivery for drug product, after the material has passed all quality testing required for collaborator acceptance. As it relates to development materials and API produced for Astellas, we are reimbursed at a contracted rate. Such reimbursements are considered as part of revenue generated pursuant to the Astellas license agreement and are presented as collaborative arrangements revenue. Any linaclotide finished drug product, API and development materials currently produced for Allergan for the U.S. or AstraZeneca for China, Hong Kong and Macau are recognized in accordance with the cost-sharing provisions of the Allergan and AstraZeneca collaboration agreements, respectively.

Revenue recognition prior to the adoption of ASC 606

Agreements Entered into Prior to January 1, 2011

For arrangements that include multiple deliverables and were entered into prior to January 1, 2011, we followed the provisions of ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*, or ASC 605-25, in accounting for these agreements. Under ASC 605-25, we were required to identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting. Collaborative research and development and licensing agreements that contained multiple deliverables were divided into separate units of accounting when the following criteria were met:

- Delivered element(s) had value to the collaborator on a standalone basis,

- There was objective and reliable evidence of the fair value of the undelivered obligation(s), and
- If the arrangement included a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) was considered probable and substantially within our control.

We allocated arrangement consideration among the separate units of accounting either on the basis of each unit's respective fair value or using the residual method, and applied the applicable revenue recognition criteria to each of the separate units. If the separation criteria were not met, revenue of the combined unit of accounting was recorded based on the method appropriate for the last delivered item.

Agreements Entered into or Materially Modified on or after January 1, 2011 and prior to January 1, 2018

We evaluated revenue from multiple element agreements entered into on or after January 1, 2011 under ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements* ("ASU 2009-13"), or ASC 605, until the adoption of ASC 606. We also evaluated whether amendments to its multiple element arrangements were considered material modifications that were subject to the application of ASU 2009-13. This evaluation required management to assess all relevant facts and circumstances and to make subjective determinations and judgments.

When evaluating multiple element arrangements under ASU 2009-13, we considered whether the deliverables under the arrangement represented separate units of accounting. This evaluation required subjective determinations and required management to make judgments about the individual deliverables and whether such deliverables were separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluated certain criteria, including whether the deliverables had standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination included the research, manufacturing and commercialization capabilities of the partner and the availability of relevant research and manufacturing expertise in the general marketplace. In addition, we considered whether the collaborator can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, and whether the value of the deliverable was dependent on the undelivered items and whether there were other vendors that could provide the undelivered items.

The consideration received was allocated among the separate units of accounting using the relative selling price method, and the applicable revenue recognition criteria were applied to each of the separate units.

We determined the estimated selling price for deliverables using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE was not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE was available.

Up-Front License Fees prior to January 1, 2018

When management believed the license to its intellectual property had stand-alone value, we generally recognized revenue attributed to the license upon delivery. When management believed the license to its intellectual property did not have stand-alone value from the other deliverables to be provided in the arrangement, it was combined with other deliverables and the revenue of the combined unit of accounting was recorded based on the method appropriate for the last delivered item.

Milestones prior to January 1, 2018

At the inception of each arrangement that included pre-commercial milestone payments, we evaluated whether each pre-commercial milestone was substantive, in accordance with ASU No. 2010-17, *Revenue Recognition—Milestone Method* ("ASU 2010-17"), prior to the adoption of ASC 606. This evaluation included an assessment of whether (a) the consideration was commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluated factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. At December 31, 2017, we had no pre-commercial milestones that were deemed substantive.

Commercial milestones were accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

Net Profit or Net Loss Sharing prior to January 1, 2018

In accordance with ASC 808 Topic, *Collaborative Arrangements*, and ASC 605-45, *Principal Agent Considerations*, we considered the nature and contractual terms of the arrangement and the nature of our business operations to determine the classification of the transactions under our collaboration agreements. We recorded revenue transactions gross in the condensed consolidated statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

We recognized our share of the pre-tax commercial net profit or net loss generated from the sales of LINZESS in the U.S. in the period the product sales are reported by Allergan and related cost of goods sold and selling, general and administrative expenses are incurred by us and our collaboration partner. These amounts were partially determined based on amounts provided by Allergan and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and contractual rebates, wholesaler fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results. For the periods covered in the condensed consolidated financial statements presented, there have been no material changes to prior period estimates of revenues, cost of goods sold or selling, general and administrative expenses associated with the sales of LINZESS in the U.S.

We record our share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and present the settlement payments to and from Allergan as collaboration expense or collaborative arrangements revenue, as applicable, as we are not the primary obligor and do not have the risks and rewards of ownership in the collaboration agreement with Allergan for North America. We and Allergan settle the cost sharing quarterly, such that our statement of operations reflects 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

Royalties on Product Sales prior to January 1, 2018

We received royalty revenues under certain of the Company's license or collaboration agreements. We recorded these revenues as earned.

Product Revenue, Net prior to January 1, 2018

As noted above, net product revenue is derived from sales of the Lesinurad Products in the U.S.

We recognized net product revenue from sales of the Lesinurad Products in accordance with ASC 605, when persuasive evidence of an arrangement exists, delivery has occurred and title of the product and associated risk of loss has passed to the customer, the price is fixed or determinable, and collection from the customer has been reasonably assured. ASC 605 required, among other criteria, that future returns could be reasonably estimated in order to recognize revenue.

We began commercializing ZURAMPIC in October 2016 and DUZALLO in October 2017 in the U.S. Initially, upon the product launch of each of the Lesinurad Products, we determined that it was not able to reliably make certain estimates, including returns, necessary to recognize product revenue upon delivery to Distributors. As a result, through September 30, 2017, we recorded net product revenue for the Lesinurad Products using a deferred revenue recognition model (sell-through). Under the deferred revenue model, we did not recognize revenue until the respective product was prescribed to an end-user. Accordingly, we recognized net product revenue when the Lesinurad Products were prescribed to the end-user, using estimated prescription demand and pharmacy demand from third party sources and the Company's analysis of third party market research data, as well as other third-party information through September 30, 2017.

During the three months ended December 31, 2017, we concluded we had sufficient volume of historical activity and visibility into the distribution channel, in order to reasonably make all estimates required under ASC 605 to recognize product revenue upon delivery to the Distributor. During the three months and year ended December 31, 2017, product revenue is recognized upon delivery of the Lesinurad Products to the Distributors. We evaluated the creditworthiness of each of its Distributors to determine whether revenue can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition was required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product revenue from the sales to Distributors and (ii) reasonably estimate our net product revenue. We calculated gross product revenue based on the wholesale acquisition cost that the Company charged its Distributors for ZURAMPIC and DUZALLO. We estimated its net product revenue by deducting from our gross product revenue (i) trade discounts and allowances, such as invoice discounts for prompt payment and distributor fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (iii) reserves for expected product returns and (iv) estimated costs of incentives offered to certain indirect customers including patients. These estimates could be adjusted based on actual results in the period such variances become known.

Other

We supply linaclotide finished drug product, API and development materials for certain of our partners.

We recognized revenue on linaclotide finished drug product, API and development materials when the material had passed all quality testing required for collaborator acceptance, delivery had occurred, title and risk of loss had transferred to the partner, the price was fixed or determinable, and collection was reasonably assured.

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands)		(in thousands)	
Revenues:				
Collaborative arrangements revenue	$ 71,207	$ 58,640	$134,293	$110,504
Product revenue, net	1,096	465	1,731	754
Sale of active pharmaceutical ingredient	8,803	5,972	14,237	5,985
Total revenues	81,106	65,077	150,261	117,243
Cost and expenses:				
Cost of revenues, excluding amortization of acquired intangible assets	4,065	3,502	6,672	4,033
Write-down of commercial supply and inventory to net realizable value and loss on non-cancellable purchase commitments	1,836	96	1,836	96
Research and development	38,932	37,344	75,437	71,046
Selling, general and administrative	68,363	57,792	127,864	113,396
Amortization of acquired intangible assets	3,476	421	6,952	841
Loss on fair value remeasurement of contingent consideration	1,962	6,933	2,474	8,547
Restructuring expenses	2,392	—	4,814	—
Total cost and expenses	121,026	106,088	226,049	197,959
Loss from operations	(39,920)	(41,011)	(75,788)	(80,716)
Other (expense) income:				
Interest expense	(9,383)	(9,046)	(18,656)	(18,029)
Interest and investment income	732	496	1,413	891
(Loss) gain on derivatives	(809)	5,337	507	3,138
Loss on extinguishment of debt	—	—	—	(2,009)
Other expense, net	(9,460)	(3,213)	(16,736)	(16,009)
Net loss	$ (49,380)	$ (44,224)	$ (92,524)	$ (96,725)

Three and Six Months Ended June 30, 2018 Compared to Three and Six Months Ended June 30, 2017

Revenues

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenues:								
Collaborative arrangements revenue	$71,207	$58,640	$12,567	21 %	$134,293	$110,504	$23,789	22 %
Product revenue, net	1,096	465	631	136 %	1,731	754	977	130 %
Sale of active pharmaceutical ingredient	8,803	5,972	2,831	47 %	14,237	5,985	8,252	138 %
Total revenues	$81,106	65,077	16,029	25 %	150,261	117,243	33,018	28 %

Collaborative Arrangements Revenue. The increase in revenue from collaborative arrangements of approximately $12.6 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 was primarily related to an approximately $13.0 million increase in our share of the net profits from the sale of LINZESS in the U.S. driven by increased prescription demand; and an approximately $0.6 million increase in royalty payments. The increases were partially offset by an approximately $1.3 million decrease attributable to the decrease in revenue under the Cologuard Co-Promotion Agreement with Exact Sciences due to the end of the royalty period.

The increase in revenue from collaborative arrangements of approximately $23.8 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was primarily related to an approximately $24.7 million increase in our share of the net profits from the sale of LINZESS in the U.S. driven by increased prescription demand; an approximately $1.2 million increase in royalty payments; and an approximately $0.6 million increase in revenue related to VIBERZI co-promotion activities. The increases were partially offset by an approximately $2.4 million decrease attributable to the decrease in revenue under the Cologuard Co-Promotion Agreement with Exact Sciences due to the end of the royalty period.

Product Revenue, net. The increase in net product revenue of approximately $0.6 million and approximately $1.0 million for the three and six months ended June 30, 2018 compared to the three and six months ended June 30, 2017, respectively, was primarily due to net product sales of DUZALLO in the U.S. in 2018. We began commercializing DUZALLO in September 2017.

Sale of active pharmaceutical ingredient. The increase in sale of API of approximately $2.8 million and approximately $8.3 for the three and six months ended June 30, 2018, compared to the three and six months ended June 30, 2017, respectively, was primarily due to increased shipments of linaclotide API to Astellas for Japan. In March 2017, Astellas began commercializing LINZESS for the treatment of adults with IBS-C in Japan.

Cost and Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(dollars in thousands)				(dollars in thousands)			
Cost and expenses:								
Cost of revenues, excluding amortization of acquired intangible assets	$ 4,065	$ 3,502	$ 563	16 %	$ 6,672	$ 4,033	$ 2,639	65 %
Write-down of commercial supply and inventory to net realizable value and loss on non-cancellable purchase commitments	1,836	96	1,740	1,813 %	1,836	96	1,740	1,813 %
Research and development	38,932	37,344	1,588	4 %	75,437	71,046	4,391	6 %
Selling, general and administrative	68,363	57,792	10,571	18 %	127,864	113,396	14,468	13 %
Amortization of acquired intangible assets	3,476	421	3,055	726 %	6,952	841	6,111	727 %
Loss on fair value remeasurement of contingent consideration	1,962	6,933	(4,971)	(72)%	2,474	8,547	(6,073)	(71)%
Restructuring expenses	2,392	—	2,392	100 %	4,814	—	4,814	100 %
Total cost and expenses	$121,026	$106,088	$14,938	14 %	$226,049	$197,959	$28,090	14 %

Cost of Revenue, excluding amortization of acquired intangible assets. The increase of approximately $0.6 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 was primarily related to an increase of approximately $1.0 million due to an increase in linaclotide API sales to Astellas in Japan. The increase of approximately $2.6 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was primarily related to an increase of approximately $3.4 million due to an increase in linaclotide API sales to Astellas in Japan, offset by approximately $0.8 million due to a decrease in one-time period related costs incurred during the six months ended June 30, 2017.

Write-down of lesinurad commercial supply to net realizable value and loss on non-cancelable purchase commitments. The increase of approximately $1.7 million in write-down of lesinurad commercial supply and loss on non-cancelable purchase commitments for each of the three and six months ended June 30, 2018 compared to the three and six months ended June 30, 2017 was due to revisions to the lesinurad commercial supply demand forecasts. For additional information refer to Note 14, *Subsequent Events*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Research and Development Expense. The increase in research and development expense of approximately $1.6 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 was primarily related to an increase of approximately $2.2 million in compensation, benefits and other employee-related expenses; an increase of approximately $1.3 million in research costs related to our early-stage pipeline candidates; and an increase of approximately $0.4 million in operating costs including facilities. These increases were partially offset by a decrease of $2.1 million related to lesinurad development.

The increase in research and development expense of approximately $4.4 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was primarily related to an increase of approximately $5.3 million in compensation, benefits and other employee-related expenses; an increase of approximately $2.8 million in research costs related to our early-stage pipeline candidates; an increase of approximately $1.7 million in operating costs including facilities; and an increase of approximately $0.9 million in professional services, including consulting and contractor expenses. These increases were partially offset by a decrease of $4.5 million related to lesinurad development; a decrease of approximately $1.7 million in external costs related to the development of linaclotide.

Selling, General and Administrative Expense. Selling, general and administrative expenses increased approximately $10.6 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 primarily as a result of an approximately $7.6 million increase in legal and consulting costs associated with the Company's intent to separate into two independent publicly traded companies; an increase of approximately $2.2 million in legal and consulting costs associated with the proxy statement; an approximately $1.8 million increase in costs associated with selling expenses and marketing programs; an increase of approximately $1.0 million in costs associated with professional services such as temporary support; and an approximately $0.9 million increase associated with post-marketing requirements related to the Lesinurad Transaction. These increases were partially offset by a decrease of an approximately $1.7 million in transitional support service costs associated with the Lesinurad Transaction, and a decrease of approximately $1.5 million in facility and operating costs.

Selling, general and administrative expenses increased approximately $14.5 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 primarily as a result of an approximately $8.0 million increase in legal and consulting costs associated with the Company's intent to separate into two independent publicly traded companies; an approximately $4.8 million increase in costs associated with selling expenses and marketing programs; an approximately $4.3 million increase in costs associated with post-marketing requirements related to the Lesinurad Transaction; an increase of approximately $2.8 million in legal and consulting costs associated with the proxy statement; an increase of approximately $2.2 million in compensation, benefits and other employee-related expenses; and an increase of approximately $1.5 million in costs associated with professional services such as temporary support. These increases were partially offset by a decrease of an approximately $6.6 million in transitional support service costs associated with the Lesinurad Transaction; a decrease of approximately $1.8 million in sample expenses; and an approximately $0.8 million decrease in costs related to facilities and operating costs.

Amortization of Acquired Intangible Assets. The increase in amortization of acquired intangible assets expense of approximately $3.1 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 and approximately $6.1 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017, was primarily due to the DUZALLO intangible asset which began amortizing in August 2017 upon FDA approval. The amount allocated to the ZURAMPIC and DUZALLO intangible assets will be amortized on a straight-line basis over their estimated useful lives of approximately 13 years from Acquisition Date and 12 years from approval date, respectively, the period of estimated future cash flows.

Loss on Fair Value remeasurement of contingent consideration. Fair value remeasurement of contingent consideration includes significant estimates related to probability weighted net cash outflow projections, discounted using a yield curve equivalent to our credit risk which estimates the probability weighted analysis of expected future milestone and royalty payments based on net sales to be made to AstraZeneca in connection with the Lesinurad Transaction. Changes to these inputs are re-evaluated each reporting period. The decrease in the loss on fair value of the contingent consideration obligation of approximately $5.0 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017, as well as the decrease of approximately $6.1 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was primarily due to revised net cash outflows projections and the passage of time.

Restructuring Expenses. The increase in restructuring expenses of approximately $2.4 million for the three months ended June 30, 2018 compared to the three months ended June 30, 2017 was due to the restructuring costs incurred in June 2018 associated with our intent to separate into two independent, publicly traded companies and the determination of the initial organizational designs of the two new businesses.

The increase in restructuring expenses of approximately $4.8 million for the six months ended June 30, 2018 compared to the six months ended June 30, 2017 was due to approximately $2.4 million of costs incurred in June 2018 associated with our intent to separate into two independent, publicly traded companies and the determination of the initial organizational designs of the two new businesses and approximately $2.4 million of costs incurred with the reduction in field-based workforce in January 2018 associated with an initiative to evaluate the optimal mix of investments for the lesinurad franchise.

Other (Expense) Income, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2018	2017	$	%	2018	2017	$	%
	(dollars in thousands)				(dollars in thousands)			
Other (expense) income:								
Interest expense	$(9,383)	$(9,046)	$ (337)	4 %	$(18,656)	$(18,029)	$ (627)	3 %
Interest and investment income	732	496	236	48 %	1,413	891	522	59 %
Gain (loss) on derivatives	(809)	5,337	(6,146)	(115) %	507	3,138	(2,631)	(84)%
Loss on extinguishment of debt	—	—	—	— %	—	(2,009)	2,009	(100)%
Total other expense, net	$(9,460)	$(3,213)	$(6,247)	194%	$(16,736)	$(16,009)	$ (727)	5 %

Interest expense increased by approximately $0.3 million during the three months ended June 30, 2018 compared to the three months ended June 30, 2017, mainly due to an increase of approximately $0.4 million in interest expense associated with the 2022 Notes. Interest expense increased by approximately $0.6 million during the six months ended June 30, 2018 compared to the six months ended June 30, 2017, mainly due to an increase of approximately $0.7 million in interest expense associated with the 2022 Notes.

Interest and investment income increased by approximately $0.2 million and approximately $0.5 million during the three and six months ended June 30, 2018 compared to the three and six months ended June 30, 2017, respectively, mainly due to an increase in higher yield return on investment securities in 2018.

For the three months ended June 30, 2018, we recorded a loss on derivatives of approximately $0.8 million resulting from an approximately $46.1 million increase in the fair value of the Convertible Note Hedges and an approximately $46.9 million increase in the fair value of the Note Hedge Warrants. For the three months ended June 30, 2017, we recorded a gain on derivatives of approximately $5.3 million resulting from an approximately $21.4 million increase in the fair value of the Convertible Note Hedges and an approximately $16.1 million increase in the fair value of the Note Hedge Warrants.

For the six months ended June 30, 2018, we recorded a gain on derivatives of approximately $0.5 million resulting from an approximately $51.3 million increase in the fair value of the Convertible Note Hedges and an approximately $50.8 million increase in the fair value of the Note Hedge Warrants. For the six months ended June 30, 2017, we recorded a gain on derivatives of approximately $3.1 million resulting from an approximately $39.3 million increase in the fair value of the Convertible Note Hedges and an approximately $36.2 million increase in the fair value of the Note Hedge Warrants.

Loss on extinguishment of debt was approximately $2.0 million during the six months ended June 30, 2017. This is due to the write-off of the remaining unamortized debt issuance costs on the PhaRMA Notes as part of the redemption in January 2017.

Liquidity and Capital Resources

At June 30, 2018, we had approximately $181.2 million of unrestricted cash, cash equivalents and available-for-sale securities. Our cash equivalents include amounts held in money market funds and repurchase agreements. 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 final maturity when purchased of less than twenty-four months, so as to primarily achieve liquidity and capital preservation.

During the six months ended June 30, 2018, our balances of cash, cash equivalents and available-for-sale securities decreased approximately $40.2 million. This decrease is primarily due to approximately $53.6 million of cash used to operate our business, including payments related to, among other things, research and development, and selling, general and administrative expenses as we continue to invest in our research pipeline and support the continued commercialization of our products. We also invested approximately $3.2 million in capital expenditures, and made payments of approximately $1.5 million on capital lease obligations. These cash outflows were partially offset by approximately $19.0 million in proceeds from the exercise of stock options.

In September 2016, we closed a direct private placement, pursuant to which we issued $150.0 million in aggregate principal amount of 8.375% notes due 2026 on January 5, 2017. The proceeds from the issuance of the 2026 Notes were used to redeem the outstanding principal balance of the PhaRMA Notes on the Funding Date. We began making interest payments on June 15, 2017. From March 15, 2019, we are obligated to make quarterly payments on the 2026 Notes. Given the principal payments on the 2026 Notes will vary from quarter to quarter, the 2026 Notes may be repaid prior to September 15, 2026, the final legal maturity date.

We may from time to time seek to retire, redeem or repurchase all or part of our outstanding debt through cash purchases and/or exchanges, in open market purchases, privately negotiated transactions, by tender offer or otherwise. Such repurchases, redemptions or exchanges, if any, will depend on prevailing market conditions, liquidity requirements, contractual restrictions and other factors, and the amounts involved may be material.

Sources of Liquidity

We have incurred losses since our inception in 1998 and, as of June 30, 2018, we had an accumulated deficit of approximately $1.4 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, royalties and our share of net profits, as well as reimbursement of certain expenses; and debt financings, including approximately $324.0 million of net proceeds from the private placement of our 2022 Notes in June 2015 and approximately $11.2 million of net proceeds, after fees and the redemption of the PhaRMA Notes, from the issuance of $150.0 million in aggregate principal amount of the 2026 Notes in January 2017.

Funding Requirements

We began commercializing LINZESS in the U.S. with our collaboration partner, Allergan, in the fourth quarter of 2012, and we currently derive substantially all of our revenue from this collaboration. Additionally, we began commercializing ZURAMPIC and DUZALLO in the U.S. for the treatment of uncontrolled gout in the fourth quarter of 2016 and the fourth quarter of 2017, respectively. We are also deploying significant resources to advance product opportunities in IBS-C and CIC, abdominal pain associated with lower GI disorders, persistent GERD, diabetic nephropathy, HFpEF, and specialty diseases, including sickle cell disease and achalasia, as well as to fulfill FDA requirements for linaclotide and lesinurad. Our goal is to become cash flow positive, driven by increased revenue generated through sales of LINZESS and financial discipline. However, we have not achieved positive cash flows from operations to date.

Under our 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 us and Allergan. Additionally, we receive royalties from Allergan based on sales of linaclotide in its licensed territories outside of the U.S. We believe revenues from our LINZESS partnership for the U.S. with Allergan will continue to constitute a significant portion of our total revenue for the foreseeable future and we cannot be certain that such revenues, as well as the revenues from our other commercial activities, will enable us to become cash flow positive, or to do so in the timeframes we expect. We also 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, develop and commercialize other products, and continue to invest in our pipeline and potentially other external opportunities. We believe that our cash on hand as of June 30, 2018 will be sufficient to meet our projected operating needs at least through the next twelve months from the issuance of these financial statements.

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 develop our product candidates and obtain regulatory approvals and the costs to commercialize linaclotide in the U.S., China and other markets, and develop and commercialize other products, as well as our goal to become cash flow positive, are forward-looking statements that involve risks and uncertainties. Our actual results could vary materially and negatively from these and other forward-looking statements 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 develop, obtain regulatory approval for, and commercialize linaclotide and our other product candidates, in each case, for all of the markets, indications, populations and formulations for which we believe each is suited. Our funding requirements will depend on many factors, including, but not limited to, the following:

- the revenue generated by sales of LINZESS, CONSTELLA, and any other products;
- the rate of progress and cost of our commercialization activities, including the expense we incur in marketing and selling LINZESS 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, as well as the timing and cost of any post-approval development and regulatory requirements;
- the success of our research and development efforts;
- the emergence of competing or complementary products;
- 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, including royalties or other payments due or payable under such agreements; and
- the acquisition of businesses, products and technologies and the impact of other strategic transactions, as well as the cost and timing of integrating any such assets into our business operations.

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 2017 Annual Report on Form 10-K. There have not been any material changes from the contractual commitments and obligations previously disclosed in our 2017 Annual Report on Form 10-K, other than a change in estimated obligations associated with our vehicle leases. This change is more fully described in Note 10, *Commitments and Contingencies*, to our condensed consolidated financial statements appearing elsewhere 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 2017 Annual Report on Form 10-K and Note 1, *Nature of Business*, appearing elsewhere in this Quarterly Report on Form 10-Q. We did not otherwise adopt any new accounting pronouncements during the three and six months ended June 30, 2018 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, collateralized reverse repurchase agreements, 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 primarily 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 obligations, 2026 Notes and 2022 Notes 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.

Equity Price Risk

2022 Notes

Our 2022 Notes include conversion and settlement provisions that are based on the price of our Class A common stock at conversion or at maturity of the 2022 Notes. The amount of cash we may be required to pay is determined by the price of our Class A common stock. The fair value of our 2022 Notes is dependent on the price and volatility of our Class A common stock and will generally increase or decrease as the market price of our Class A common stock changes.

The 2022 Notes are convertible into Class A common stock at an initial conversion rate of 60.3209 shares of Class A common stock (subject to adjustment as provided for in the indenture that governs the 2022 Notes) per $1,000 principal amount of the 2022 Notes, which is equal to an initial conversion price of approximately $16.58 per share. The 2022 Notes will mature on June 15, 2022 unless earlier converted or repurchased. The 2022 Notes bear cash interest at an annual rate of 2.25%, payable on June 15 and December 15 of each year, which began on December 15, 2015. As of June 30, 2018, the fair value of the 2022 Notes was estimated by us to be $445.6 million. The 2022 Notes are more fully described in Note 5, *Fair Value of Financial Instruments*, and Note 9, *Notes Payable,* in the accompanying notes to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Convertible Note Hedge and Warrant Transactions with Respect to 2022 Notes

To minimize the impact of potential dilution to our common stock upon conversion of the 2022 Notes, we entered into Convertible Note Hedges. Concurrently with entering into the Convertible Note Hedges, we entered into warrant transactions whereby we sold Note Hedge Warrants to acquire, subject to customary adjustments, 20,249,665 shares of our Class A common stock at an initial strike price of approximately $21.50 per share, subject to adjustment. The Convertible Note Hedges and Note Hedge Warrants are more fully described in Note 9, *Notes Payable,* in the accompanying notes to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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 and six months ended June 30, 2018 and 2017 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 officer concluded no other 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.

PART II OTHER INFORMATION

Item 1. ***Legal proceedings***

Actions in which we are the Plaintiff

LINZESS

We and Allergan have received Paragraph IV certification notice letters, or Notice Letters, regarding Abbreviated New Drug Applications, or ANDAs, submitted to the FDA by generic drug manufacturers requesting approval to engage in commercial manufacture, use, sale and offer for sale of (i) 145 mcg and 290 mcg linaclotide capsules, or the Potential Generic Products, and/or (ii) 72 mcg linaclotide capsules, or the Potential 72mcg Generic Products, each proposed generic versions of our FDA-approved drug LINZESS.

In October 2016, we received a Notice Letter relating to an ANDA that was submitted to the FDA by Teva Pharmaceuticals USA, Inc., or Teva. Teva's Notice Letter contends that United States patents for LINZESS (U.S. Patent Nos. 7,371,727, 7,704,947, 7,745,409, 8,080,526, and 8,110,553 (expiring 2024); 7,304,036 (expiring 2026); and 8,748,573, 8,802,628, and 8,933,030 (expiring 2031), or the Challenged Patents) listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, are invalid, unenforceable and/or would not be infringed by Teva's manufacture, use, sale or offer for sale of the Potential Generic Products. In September 2017, we received a second Notice Letter relating to the ANDA submitted to the FDA by Teva contending that U.S. Patent No. 9,708,371 (expiring 2033) listed in the Orange Book is invalid and/or would not be infringed by Teva's manufacture, use, sale or offer for sale of the Potential Generic Products. In December 2017, we received a Notice Letter relating to an ANDA that was submitted to the FDA by Teva, contending that U.S. Patent Nos. 7,371,727, 7,704,947, 7,745,409, 8,080,526, and 8,110,553; 7,304,036; 8,933,030; and 9,708,371, or the 72mcg Challenged Patents, are invalid, unenforceable and/or would not be infringed by Teva's manufacture, use, sale or offer for sale of the Potential 72 mcg Generic Product.

In October 2016, we received a Notice Letter relating to an ANDA that was submitted to the FDA by Aurobindo Pharma Ltd., or Aurobindo, contending that certain of the Challenged Patents (U.S. Patent Nos. 8,748,573, 8,802,628, and 8,933,030) are invalid and/or would not be infringed by Aurobindo's manufacture, use, sale or offer for

sale of the Potential Generic Products. In July 2017, we received a second Notice Letter relating to the ANDA submitted to the FDA by Aurobindo contending that the other Challenged Patents (U.S. Patent Nos. 7,371,727, 7,704,947, 7,745,409, 8,080,526, 8,110,553, and 7,304,036) are invalid and/or would not be infringed by Aurobindo's manufacture, use, sale or offer for sale of the Potential Generic Products. In March 2018, we received a third Notice Letter relating to the ANDA submitted to the FDA by Aurobindo contending that U.S. Patent No. 9,708,371 listed in the Orange Book is invalid and/or would not be infringed by Aurobindo's manufacture, use, sale or offer for sale of the Potential Generic Products.

In November 2016, we received a Notice Letter relating to an ANDA that was submitted to the FDA by Sandoz Inc., or Sandoz, contending that all of the Challenged Patents are invalid, unenforceable and/or would not be infringed by Sandoz's manufacture, use, sale or offer for sale of the Potential Generic Products. In January 2018, we received a second Notice Letter relating to the ANDA submitted to the FDA by Sandoz contending that U.S. Patent No. 9,708,371 is invalid and/or would not be infringed by Sandoz's manufacture, use, sale or offer for sale of the Potential Generic Products.

In November 2016, we received a Notice Letter relating to an ANDA that was submitted to the FDA by Mylan Pharmaceuticals Inc., or Mylan, contending that all of the Challenged Patents are invalid, unenforceable and/or would not be infringed by Mylan's manufacture, use, sale or offer for sale of the Potential Generic Products. In October 2017, we received a second Notice Letter relating to the ANDA submitted to the FDA by Mylan contending that U.S. Patent No. 9,708,371 is invalid and/or would not be infringed by Mylan's manufacture, use, sale or offer for sale of the Potential Generic Products. In February 2018, we received a Notice Letter relating to an ANDA that was submitted to the FDA by Mylan, contending that the 72mcg Challenged Patents, are invalid, unenforceable and/or would not be infringed by Mylan's manufacture, use, sale or offer for sale of the Potential 72 mcg Generic Product.

In response to the four ANDAs for which we received Notice Letters in 2016, we and Allergan filed a lawsuit against these generic drug manufacturers in Delaware District Court in November 2016. We asserted that the Challenged Patents are valid and infringed by Teva, Sandoz and Mylan, and that U.S. Patent No. 8,933,030 is valid and infringed by Aurobindo and an affiliate of Aurobindo. In August 2017, we and Allergan filed a lawsuit against Aurobindo and its affiliate in Delaware District Court, related to Aurobindo's second Notice Letter. We asserted that U.S. Patent Nos. 7,371,727, 7,704,947, 7,745,409, 8,080,526, 8,110,553, and 7,304,036 are valid and infringed by Aurobindo and its affiliate. This lawsuit has been consolidated with the lawsuit filed in November 2016. In accordance with the Hatch-Waxman Act, the timely filing of the lawsuits against the ANDA filers with respect to the Challenged Patents triggered an automatic stay of the FDA's approval of the five ANDAs until February 29, 2020 (unless there is a final court decision adverse to us and Allergan sooner). In October 2017, November 2017, and January 2018, we and Allergan filed lawsuits against Teva, Mylan, and Sandoz, respectively, each in Delaware District Court, related to each of their respective second Notice Letters. We asserted that U.S. Patent No. 9,708,371 is valid and infringed by each of Teva, Mylan and Sandoz. The lawsuits filed in October 2017, November 2017, and January 2018 against Teva, Mylan and Sandoz, respectively, have been consolidated with the lawsuit filed in November 2016.

Mylan responded to our lawsuit in December 2016, asserting defenses of, among other things, lack of subject matter and personal jurisdiction and improper venue. In January 2017, each of Teva and Sandoz filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of the Challenged Patents. In April 2017, Aurobindo and its affiliate filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of U.S. Patent No. 8,933,030. On July 13, 2017, Mylan filed a motion to dismiss for improper venue. In September 2017, Aurobindo and its affiliate filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of U.S. Patent Nos. 7,371,727, 7,704,947, 7,745,409, 8,080,526, 8,110,553, and 7,304,036. In November 2017, Teva filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of U.S. Patent No. 9,708,371. In December 2017, Mylan filed an answer to the lawsuit that we and Allergan filed in November 2017. In February 2018, Sandoz filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of U.S. Patent No. 9,703,371. In February 2018 and March 2018, we and Allergan filed lawsuits against Teva and Mylan, respectively, each in Delaware District Court. We asserted that the 72mcg Challenged Patents are valid and infringed by Teva and Mylan. These lawsuits have been consolidated with the lawsuit filed in November 2016. In May 2018, we, Allergan, Teva and Sandoz stipulated to dismiss without prejudice all claims, counterclaims and defenses with respect to U.S. Patent Nos. 9,708,371. In July 2018, we and Allergan filed a motion to dismiss for lack of subject matter jurisdiction all claims and counterclaims between Mylan and us with respect to U.S. Patent No. 9,708,371.

In April 2018, we and Allergan entered into a settlement agreement with Aurobindo and its affiliate. Pursuant to the terms of the settlement, we and Allergan will grant Aurobindo and its affiliate a license to market a generic version of LINZESS in the United States beginning on August 5, 2030 (subject to FDA approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. As a result of the settlement, all Hatch-Waxman litigation between the companies and Aurobindo regarding LINZESS patents has been dismissed.

Trial is scheduled in June 2019 for the action involving Teva, Sandoz, and Mylan.

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 cannot guarantee when, or if, we will attain profitability or positive cash flows.

We and our partner, Allergan plc (together with its affiliates), or Allergan, began selling LINZESS in the U.S. during December 2012. Revenues from our LINZESS collaboration constitute a significant portion of our total revenue, and we believe they will continue to do so for the foreseeable future. In addition, in June 2016, we entered into a license agreement for exclusive rights to commercialize products containing lesinurad in the U.S., which license agreement we refer to as the Lesinurad License Agreement, and we began selling ZURAMPIC and DUZALLO in October 2016 and October 2017, respectively. The commercial success of our products depends on a number of factors, including:

- the effectiveness of our products for their approved indications;
- the size of the treatable patient populations;
- the effectiveness of the sales, managed markets and marketing efforts for LINZESS by us and Allergan and for ZURAMPIC and DUZALLO by us;
- the adoption of our products by physicians, which depends on whether physicians view such products as safe and effective treatments for their approved patient populations and indications;
- our success in educating and activating potential 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, our products and our ability to demonstrate that our products are safer, more efficacious and/or more cost-effective than alternative therapies;
- the effectiveness of Allergan's distribution networks for LINZESS and the effectiveness of our distribution strategy and networks for ZURAMPIC and DUZALLO;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these or other areas, associated with our products; and
- the development or commercialization of competing products or therapies for the treatment of the approved indications for our products, or their associated symptoms.

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

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

The most commonly reported adverse reaction since linaclotide became commercially available, as well as in the clinical trials for linaclotide in IBS-C and CIC, has been diarrhea. In the linaclotide Phase III IBS-C and CIC trials, severe diarrhea was reported in 2% or less of the linaclotide-treated patients and its incidence was similar between the IBS-C and CIC populations. Linaclotide has been prescribed to millions of patients since its launch in the U.S. and other territories beginning in December 2012, and, as a result, it has been used in wider populations and in less rigorously controlled environments than in the clinical studies supporting its approval.

The most commonly reported adverse reactions in the clinical trials for lesinurad (in combination with a xanthine oxidase inhibitor, or XOI) for the treatment of hyperuricemia associated with uncontrolled gout were headache, influenza, increased blood creatinine and gastroesophageal reflux disease. ZURAMPIC and DUZALLO were launched in October 2016 and October 2017, respectively. As a result, such products are being used in wider populations and in less rigorously controlled environments than in the clinical studies supporting their approval. Additionally, because such products are approved for use in combination with an XOI for the treatment of hyperuricemia associated with uncontrolled gout, and DUZALLO is a fixed-dose combination treatment of lesinurad and allopurinol (an XOI), our patients may experience side effects and adverse reactions associated with the use of XOIs. Notwithstanding ZURAMPIC's U.S. Food and Drug Administration, or FDA, -approved label, if ZURAMPIC is taken without an XOI, patients may experience new or increased risk of adverse reactions, including the heightened risk of acute renal failure.

Further, as we and our partners (and, in the case of lesinurad, AstraZeneca's other licensees) conduct clinical trials, including in new or existing territories, indications, populations or formulations, as well as explore potential combination products, the number of patients treated with our products within and outside of such products' currently approved indications and patient populations has grown and continues to do so.

As patient experience increases and expands, we and others may identify previously unknown side effects, known side effects may be found to be more frequent or severe than in the past, and we and others may detect unexpected safety signals for our products or any products perceived to be similar to our products. The foregoing, or the perception of the foregoing, may have the following effects, among others:

- sales of our products may be impaired;
- regulatory approvals for our products may be denied, restricted or withdrawn;
- we or our partners may decide to, or be required to, change the products' label or send product warning letters or field alerts to physicians, pharmacists and hospitals;
- reformulation of the products, additional nonclinical or clinical studies, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we or our partners may be precluded from pursuing approval of linaclotide in new territories or from studying additional development opportunities to enhance our products' clinical profiles, including within new or existing indications, populations and formulations, as well as in potential combination products;
- our or our products' reputation in the marketplace may suffer; and
- government investigations or lawsuits, including class action suits, may be brought against us or our partners.

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

In addition, LINZESS, ZURAMPIC and DUZALLO each contain a boxed warning about their use. 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 to less than 18 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 Allergan 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.

The FDA-approved label for DUZALLO contains a boxed warning about the risk of acute renal failure with DUZALLO, and the FDA-approved label for ZURAMPIC contains a boxed warning about the risk of acute renal failure with ZURAMPIC, which is more common when ZURAMPIC is used without an XOI. ZURAMPIC and DUZALLO are both contraindicated in patients with severe renal impairment or end-stage renal diseases, kidney transplant recipients, patients on dialysis or patients with tumor lysis syndrome or Lesch-Nyhan syndrome. In addition, DUZALLO is contraindicated in patients with a known hypersensitivity to allopurinol. The FDA has required that a post-marketing clinical study be conducted to further evaluate the renal and cardiovascular safety of lesinurad, which is discussed below.

We rely entirely on contract manufacturers, our partners and other third parties to manufacture and distribute linaclotide and lesinurad. 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 active pharmaceutical ingredient, or API, and final drug product. We rely on our partners, with respect to linaclotide, and a third-party logistics provider and various distributors, with respect to products containing lesinurad, to store and distribute that drug product to third party purchasers. With respect to linaclotide, we and certain of our partners have commercial supply agreements with independent third parties to manufacture the linaclotide API used to support all of our partnered territories. Each of Allergan and Astellas is responsible for linaclotide drug product and finished goods manufacturing (including bottling and packaging) for its respective territories, and distributing the finished goods to wholesalers. Under our collaboration with AstraZeneca for linaclotide, we are accountable for drug product manufacturing for China, Hong Kong and Macau, with AstraZeneca accountable for finished goods manufacturing. Neither we nor AstraZeneca have experience manufacturing linaclotide on a commercial scale and we and AstraZeneca are working to achieve sufficient redundancy in this component of the linaclotide supply chain.

With respect to lesinurad, we have a commercial supply agreement with AstraZeneca to manufacture finished drug product during the pendency of the Lesinurad License Agreement. We rely exclusively on AstraZeneca as our supplier of finished drug product for ZURAMPIC and DUZALLO. If, for any reason, AstraZeneca is unable or unwilling to perform under our commercial supply agreement or if AstraZeneca performs poorly, our ability to timely deliver ZURAMPIC and DUZALLO to our customers would be significantly impaired or we might not be able to supply such products to our customers at all. Such failure to deliver finished drug product to our customers would negatively impact our reputation and sales of ZURAMPIC and DUZALLO would be adversely affected. If such event occurs, we may not be able to identify, validate and obtain necessary regulatory approvals for an alternative manufacturer, or do so on acceptable terms, during the pendency of the Lesinurad License Agreement. We also rely on a third-party logistics provider and various distributors to store and distribute lesinurad. Distribution requires significant coordination among our supply chain, sales and marketing, and finance organizations, as well as our external service providers and partners. Failure to coordinate financial and other systems could negatively impact our ability to accurately report product revenue and otherwise adversely impact our business and financial results. Our lesinurad distribution network and commercialization efforts may be significantly impacted if our logistics provider's warehouse is damaged or if there are disruptions in its, or one or more of our distributor's, business, or if we are unable to effectively manage the distribution process. Distribution practices will also need to comply with the applicable regulatory requirements. If our distributors do not comply with the applicable regulatory requirements, we could be exposed to potential enforcement actions.

Each of our 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 own quality assurance releases. Manufacturers of our products may be unable to comply with these GMP requirements and with other regulatory requirements. We have little control over our manufacturers' or 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, such as product specification and stability failures, procedural deviations, improper equipment installation or operation, utility failures, contamination and natural disasters. In addition, the raw materials necessary to make API for our products are acquired 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 or partners do not experience problems and commercial manufacturing is achieved, their maximum or available manufacturing capacities may be insufficient to meet commercial demand. Finding alternative manufacturers or adding additional manufacturers requires a significant amount of time and involves 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 or available capacities are insufficient to meet demand, we may not be able to successfully commercialize our products.

Maintaining our commercial infrastructure for lesinurad and the transition of lesinurad to AstraZeneca during the pendency of the Lesinurad License Agreement may be significant undertakings that could require substantial financial and managerial resources, and we may not be successful.

We are currently marketing and selling LINZESS in the U.S. with our partner Allergan, and ZURAMPIC is our first solely marketed product in the U.S. Unlike LINZESS, we currently are solely responsible for the commercialization of ZURAMPIC and DUZALLO and we do not have significant experience with all components of commercialization without a partner. Maintaining the necessary capabilities are competitive and time-consuming and the commercialization of ZURAMPIC and DUZALLO requires a significant expenditure of operating, financial and management resources, and we may incur more expenditures than anticipated during the pendency of the Lesinurad License Agreement. We cannot guarantee that we will be able to maintain these capabilities and any necessary agreements on acceptable terms, if at all, during this period. During the pendency of the Lesinurad License Agreement, if we are unable to maintain such capabilities, or are unable to do so in an efficient manner or on a timely basis, our business, operating results and financial condition would be adversely affected.

We also have no prior experience as a company developing or commercializing products in the field of uncontrolled gout. While we have significant experience, and have been successful, in marketing LINZESS to primary care physicians and other prescribers, our competitors in the field of uncontrolled gout have more experience marketing products in this indication and may more successfully market their products. During the pendency of the Lesinurad License Agreement, our competitors may also develop, manufacture and market products to treat hyperuricemia associated with uncontrolled gout that are more effective or less expensive than ours, or that have a more favorable safety profile.

We have made assumptions relating to the impact of ZURAMPIC and DUZALLO, or the Lesinurad Business, on our financial results during the pendency of the Lesinurad License Agreement relating to numerous matters, including the amount of goodwill and intangible assets related to the Lesinurad Business, the cost of development and commercialization of such products, and the associated costs and impact and the other financial and strategic risks related to the Lesinurad Business. Furthermore, during the pendency of the Lesinurad License Agreement, we may incur higher than expected operating and transaction costs, and we may encounter general economic and business conditions that adversely affect the Lesinurad Business. If one or more of these assumptions are incorrect, it could have an adverse effect on our business and operating results.

We may encounter further costs and delays related to transitioning the Lesinurad Business to AstraZeneca. We have never undertaken the process of transitioning a marketed product to a third party, and we may encounter challenges and costs that we do not currently anticipate. Our reputation with patients or physicians may be harmed as a result of transitioning the Lesinurad Business, and unforeseen complications with the FDA or other regulatory agencies could arise. For additional information relating to our expected costs and expenses of exiting the Lesinurad Business, see Note 14, *Subsequent Events*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

If any of our linaclotide partners undergoes a change in control or in management, this may adversely affect our collaborative relationship or the success of the commercialization of linaclotide in the U.S. or in the other countries where it is approved, or the ability to achieve regulatory approval, launch and commercialize linaclotide in other 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 linaclotide in the U.S. and the other countries where it is approved, 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 linaclotide 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 linaclotide partners undergoes a change of control and the acquirer either (i) is unable to perform such partner's obligations under its collaboration or license agreement with us or (ii) does not comply with the divestiture or certain other provisions of the applicable agreement, 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, gastrointestinal, or GI, therapy and who support the commercialization of LINZESS in the U.S. If Allergan 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 Allergan 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 Allergan, 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 Allergan to market and sell LINZESS in the U.S. in order for it to achieve its maximum commercial potential.

We are working closely with Allergan to execute 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 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 Allergan's sales representatives call, and the frequency with which the representatives meet with them.

In order to optimize the commercial potential of LINZESS, we and Allergan must execute upon this commercialization plan effectively and efficiently. In addition, we and Allergan 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 Allergan 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 Allergan 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 Allergan 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 in the U.S. which, if not favorable for our products, could hinder or prevent our products' commercial success.

Our and our partner's ability to commercialize our products successfully depend 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 our products and at what level, we expect that third-party payers will consider factors that include the efficacy, cost effectiveness and safety of our products, as well as the availability of other treatments including generic prescription drugs and over-the-counter alternatives. Further, in order to obtain and 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 Allergan (with respect to LINZESS) will be able to negotiate or continue to negotiate pricing terms with 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 our products, and others may do so in the future. Our business would be materially adversely affected if we and our partners are not able to receive approval for reimbursement of our products from third-party payers on a broad, timely or satisfactory basis; if reimbursement is subject to overly broad or restrictive prior authorization requirements; or if reimbursement is not maintained at satisfactory levels or becomes subject to prior authorization. In addition, our business could be adversely affected if private health 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 our products may be reimbursed.

We expect to experience pricing pressures in connection with the sale of our current and 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 managed care, the scrutiny of pharmaceutical pricing, 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 our products at satisfactory levels, or at all, which could materially harm our business and financial results.

We and our linaclotide partners are subject to uncertainty relating to pricing and reimbursement policies outside the U.S., as well as risks relating to the improper importation of linaclotide and sale of counterfeit versions of linaclotide. If such policies are not favorable, or if linaclotide is improperly imported or is counterfeited, our business and financial results could be adversely affected.

In some foreign countries, particularly Canada, the countries of Europe and Japan, 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. Reimbursement sources are different in each country, and each country may include a combination of distinct potential payers, including private insurance and governmental payers. Some countries 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. 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 and clinical 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 prescription product approved for the symptomatic treatment of moderate to severe IBS-C in adults in Europe and LINZESS as the only prescription treatment approved for the treatment of adults with IBS-C in Japan, there may be disagreement as to what the most comparable product is, or if there even is one. Further, several 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 linaclotide 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 and our partners' 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.

CONSTELLA was first launched in certain European countries for the symptomatic treatment of moderate to severe IBS-C in adults in the second quarter of 2013 and our partner Allergan is currently commercializing CONSTELLA in a number of European countries, including the United Kingdom, Italy and Spain. LINZESS was first launched in Japan for the treatment of IBS-C in adults in the first quarter of 2017 and our partner Astellas is currently commercializing LINZESS in Japan. The pricing and reimbursement strategy is a key component of our partners' commercialization plans for CONSTELLA in Europe and LINZESS in Japan. Our revenues may suffer if our partners are unable to successfully and timely conclude reimbursement, price approval or funding processes and market CONSTELLA in key member states of the E.U. or LINZESS in Japan, or if coverage and reimbursement for either CONSTELLA or LINZESS is limited or reduced. If our partners are 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, our partners may not be able to, or may decide not to, sell either CONSTELLA or LINZESS in such countries.

We and our partners also face the risk that linaclotide is imported or reimported into markets with relatively higher prices from markets with relatively lower prices, which would result in a decrease of sales and any payments we receive from the affected market. Additionally, third parties may illegally produce, distribute and/or sell counterfeit or otherwise unfit or adulterated versions of linaclotide. In either case, we and our partners may not be able to detect or, if detected, prevent or prohibit the sale of such products, which could result in dangerous health consequences for patients, loss of confidence in us, our partners and our products, and adverse regulatory or legal consequences. Any of the foregoing or other consequences could adversely impact our reputation, financial results and business.

Because we work with partners to develop, manufacture and commercialize our products, we are dependent upon third parties, and our relationships with those third parties, in our efforts to obtain regulatory approval for, and to commercialize, our products, as well as to comply with regulatory and other obligations with respect to such products.

Allergan played a significant role in the conduct of the clinical trials for linaclotide and in the subsequent collection and analysis of data, and Allergan holds the new drug application, or NDA, for LINZESS. In addition, we are commercializing LINZESS in the U.S. with Allergan. Allergan is also responsible for the development, regulatory approval and commercialization of linaclotide in countries worldwide other than Japan, China, Hong Kong and Macau. Allergan is commercializing LINZESS in Mexico and CONSTELLA in Canada, as well as commercializing

CONSTELLA in certain countries in Europe. Astellas, our partner in Japan, is responsible for completing the clinical programs and obtaining regulatory approval of linaclotide in its territory. Astellas is commercializing LINZESS in Japan. 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. Each of Astellas, AstraZeneca and Allergan is responsible for commercializing linaclotide in its respective territory, if approved. 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, and AstraZeneca is responsible for finished goods manufacturing for China, Hong Kong and Macau. 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 linaclotide partners, and vice versa. Our linaclotide 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. Further, 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 non-compete restrictions in place with each of our linaclotide partners, they may have competitive products or relationships with other commercial entities, some of which may compete with us. If any of our partners competes with us or assists our competitors, it could harm our competitive position.

With respect to lesinurad, as part of our acquisition of the Lesinurad Business, we rely on AstraZeneca to provide us with information about ZURAMPIC and DUZALLO that may be critical to the development and the commercial success of such products in the U.S. during the pendency of the Lesinurad License Agreement. For example, AstraZeneca is responsible for notifying us of certain material intellectual property related to lesinurad that is developed by it or its other licensees of lesinurad. If AstraZeneca does not notify us of such intellectual property or AstraZeneca's licensees fail to report such intellectual property to AstraZeneca, or, in each case, fail to provide such information on a timely basis, we may not be able to commercialize ZURAMPIC and DUZALLO as effectively or efficiently.

In addition, adverse event reporting requires significant coordination with our partners and third parties. We are the holder of the global safety database for linaclotide responsible for coordinating the safety surveillance and adverse event reporting efforts worldwide with respect to linaclotide, and an AstraZeneca partner is the holder of the global safety database for lesinurad responsible for coordinating the safety surveillance and adverse event reporting efforts worldwide with respect to lesinurad. If we or AstraZeneca's partner fails to perform such activities and maintain each safety database or if our partners (or their licensees) do not report adverse events related to our products, or fail to do so in a timely manner, we may not receive the information that we are required to report to the FDA regarding such products. Furthermore, we or our partners (or their licensees) may fail to adequately monitor, identify or investigate adverse events, or to report adverse events to the FDA or foreign regulatory authority accurately and within the prescribed timeframe. If we or our partners (or their licensees) are unsuccessful in any of the foregoing due to poor process, execution, systems, oversight, communication, adjudication or otherwise, then we may suffer any number of consequences, including the imposition of additional restrictions on the use of our products, removal of our products from the market, criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval of future products.

Even though LINZESS, ZURAMPIC and DUZALLO are approved by the FDA, such products face post-approval development and regulatory requirements, which 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. In December 2015, the FDA approved ZURAMPIC for use in combination with an XOI for the

treatment of hyperuricemia associated with uncontrolled gout, and in August 2017, the FDA approved DUZALLO for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum acid levels with a medically appropriate daily dose of allopurinol alone. Each of such products is subject to ongoing FDA requirements, including those governing the testing, manufacturing, labeling, packaging, storage, advertising, promotion, sale, distribution, 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 boxed warning advising physicians to avoid the use of LINZESS in pediatric patients 6 to less than 18 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 Allergan have established a nonclinical and clinical post-marketing plan with the FDA to understand the safety and efficacy of LINZESS in pediatric patients, are advancing clinical pediatric programs in IBS-C patients age seven to 17 and functional constipation patients age six to 17. Our ability to conduct clinical studies in younger pediatric patients will depend, in part, on the safety and efficacy data from our clinical programs in older pediatric patients. Our ability to ever expand the indication or label information for LINZESS to pediatrics will depend on, among other things, our successful completion of pediatric clinical programs. We and Allergan 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 two to four years.

ZURAMPIC and DUZALLO are contraindicated in patients with severe renal impairment or end-stage renal diseases, kidney transplant recipients, patients on dialysis or patients with tumor lysis syndrome or Lesch-Nyhan syndrome. In addition, DUZALLO is contraindicated in patients with a known hypersensivity to allopurinol. DUZALLO is approved for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum acid levels with a medically appropriate daily dose of allopurinol alone, and there is a boxed warning that acute renal failure has occurred with lesinurad, one of the components of DUZALLO. ZURAMPIC is approved for use in combination with an XOI for the treatment of hyperuricemia associated with uncontrolled gout, and there is a boxed warning about the risk of acute renal failure with ZURAMPIC, which is more common when ZURAMPIC is used without an XOI. The FDA has required a post-marketing clinical study to further evaluate the renal and cardiovascular safety of lesinurad, and has required that enrollment include patients with moderate renal impairment. We rely exclusively on AstraZeneca as our supplier of drug product for such study and other development activities pursuant to our clinical supply agreement. If, for any reason, AstraZeneca is unable or unwilling to perform under our clinical supply agreement or if AstraZeneca performs poorly, our ability to, among other things, continue the post-marketing clinical study for lesinurad during the pendency of the Lesinurad License Agreement could be delayed or we may not be able to continue it at all during such period. Additionally, as the holder of the approved NDA for each of ZURAMPIC and DUZALLO, we are obligated to monitor and report adverse events and any failure of such products to meet the specifications in the applicable NDA, to submit new or supplemental applications and to obtain FDA approval for certain changes to such products, including changes to product labeling and manufacturing processes.

These post-approval requirements impose burdens and costs on us. Failure to effectively, appropriately and timely conduct and complete the required studies relating to our products, monitor and report adverse events and meet our other post-approval commitments would lead to negative regulatory action at the FDA, which could include withdrawal of regulatory approval of our products for their currently approved indications and patient populations.

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 and other applicable 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 withdrawal of the product from the market or suspension of manufacturing. If we, our partners or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, a regulatory agency may take the following actions, among others:

- 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 or our partners;
- 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. and in a number of other countries, we or our partners may never receive approval to commercialize linaclotide in additional parts of the world.

In order to market any products outside of the countries where linaclotide is approved, 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. and the other countries where linaclotide is approved. Potential risks include that the regulatory authorities:

- 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 lesinurad 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 face competition and new products may emerge that provide different or better alternatives for treatment of the conditions that our products are approved to treat.

The pharmaceutical industry and the markets in which we operate are intensely competitive. We compete in the marketing and sale of our products, the development of new products and the acquisition of rights to new products with commercial potential. 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. Additionally, 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 our products obsolete or noncompetitive.

Our products compete with certain prescription therapies and over-the-counter products for the treatment of the indications for which they are approved, or their associated symptoms, and in many cases with products that have attained significant levels of market acceptance. The availability of prescription competitors and over-the-counter products for such conditions could limit the demand, and the price we are able to charge, for our products unless we are able to achieve market acceptance among the medical community and patients and differentiate our products on the basis of their cost and/or actual or perceived benefits. For example, Takeda Pharmaceuticals Limited's AMITIZA (lubiprostone) is approved by the FDA for sale in the U.S. for the treatment of IBS-C, CIC and opioid-induced constipation and Synergy Pharmaceuticals, Inc.'s, or Synergy, TRULANCE (plecanatide) is approved by the FDA for sale in the U.S. for the treatment of adults with IBS-C and CIC. Additionally, we believe other companies are developing products which could compete with our products, should they be approved by the FDA or foreign regulatory authorities. Currently, there are other compounds in late stage development and other potential competitors are in earlier stages of development for the treatment of the indications for which our products are approved. If our current or potential competitors are successful in completing drug development for their drug candidates and obtain approval from the FDA or foreign regulatory authorities, they could limit the demand for our products.

We will incur significant liability if it is determined that we are promoting any "off-label" uses of our products.

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 do not permit promotion of any approved product that we develop, license, commercialize, promote, 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 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 and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

The products that we promote are marketed in the U.S. and/or covered by federal healthcare programs, and, as a result, certain federal and state healthcare laws and regulations pertaining to product promotion and fraud and abuse are applicable to, and may affect, our business. These laws and regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from offering, 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, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to us for reasons including providing 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 prior to approval or for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the so-called “federal sunshine” law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians and other healthcare professionals and healthcare organizations to the federal government for re-disclosure to the public; and

- state law equivalents 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, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, 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.

Our global activities are subject to the U.S. Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to

otherwise influence a person working in an official capacity. We are also subject to similar anti-bribery laws in the other countries in which we do business.

In addition, we may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. For example, the processing of personal data in the European Economic Area, or the EEA, is subject to the 1995 Data Protection Directive, or the Directive, imposing strict obligations and restrictions on the ability to collect, analyze and transfer personal data. In May 2018, a new privacy regime, the General Data Protection Regulation, or the GDPR, will take effect, increasing our obligations with respect to clinical trials conducted in the EEA and increasing the scrutiny applied by clinical trial sites located in the EEA to transfers of personal data from such sites to countries that are considered by the European Commission to lack an adequate level of data protection, such as the United States. The compliance obligations imposed by the GDPR may increase our cost of doing business. In addition, the GDPR imposes substantial fines for breaches of data protection requirements, and it confers a private right of action on data subjects for breaches of data protection requirements.

If our operations are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, rules or regulations, we cannot be certain that our program will address all areas of potential exposure and the risks in this area cannot be entirely eliminated, particularly because the requirements and government interpretations of the requirements in this space are constantly evolving. Any action against us for violation of these laws, rules or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

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

The U.S. government and individual states have been aggressively pursuing healthcare reform designed to impact delivery of, and/or payment for, healthcare, which include initiatives intended to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as modified by the Health Care and Education Reconciliation Act, or the ACA, which, among other things, expanded healthcare coverage through Medicaid expansion and the implementation of the individual health insurance mandate; included changes to the coverage and reimbursement of drug products under government healthcare programs; imposed an annual fee on manufacturers of branded drugs; and expanded government enforcement authority. We face uncertainties because there have been, and may be additional, federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. Such efforts may lead to fewer Americans having more comprehensive health insurance compliant with the ACA, even in the absence of a legislative repeal. Adoption of new healthcare reform legislation at the federal or state level could affect demand for, or pricing of, our products or product candidates if approved for sale. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or action, or its impact on us, and healthcare reform could increase compliance costs and may adversely affect our future business and financial results.

In addition, other legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' or product candidates' commercial success. Tax reform legislation enacted in December 2017 includes provisions intended to affect healthcare insurance coverage and payment, such as the elimination of the individual mandate to have health insurance beginning in 2019. More broadly, the Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through 2025. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenues.

In addition to governmental efforts in the U.S., foreign jurisdictions as well as private health insurers and managed care plans are likely to continue challenging manufacturers' ability to obtain reimbursement, as well as the level of reimbursement, for pharmaceuticals and other healthcare-related products and services. These cost-control

initiatives could significantly decrease the available coverage and the price we might establish for our products, which would have an adverse effect on our financial results.

The Food and Drug Administration Amendments Act of 2007 also provides the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. We and Allergan have established a nonclinical and clinical post-marketing plan with the FDA to understand the safety and efficacy of LINZESS in pediatrics and we have established a clinical post-marketing plan with the FDA to further evaluate the renal and cardiovascular safety of lesinurad, each of which is discussed above. The FDA's exercise of this authority has resulted (and is expected to continue to result) in increased development-related costs following the commercial launch of our products, and could result in potential restrictions on the sale and/or distribution of our products, even in such products' approved indications and patient populations.

If we are unable to successfully partner with other companies to develop and commercialize our products and/or product candidates, our ability to grow would be impaired and our business would be adversely affected.

As part of our business strategy, we may partner with pharmaceutical, biotechnology or other companies to develop and commercialize our products or product candidates. Although we have entered into such arrangements with respect to the development and commercialization of linaclotide worldwide, there can be no assurance that we will be able to do so in the future with respect to other products or product candidates or that we will be able to gain the interest of potential partners; establish and maintain development, manufacturing, marketing, sales or distribution relationships on acceptable terms; that such relationships, if established, will be successful or on favorable terms; or that we will gain market acceptance for such products or product candidates. The process of proposing, negotiating and implementing a partnership arrangement is lengthy and complex. If we enter into any partnering arrangements with third parties, any revenues we receive will depend upon the efforts of such third parties. If we are unable to establish successful partnering arrangements, we may not gain access to the financial resources and industry experience necessary to develop, commercialize or successfully market our products or product candidates, may be forced to curtail, delay or stop a development program or one or more of our other development programs, delay commercialization, reduce the scope of our planned sales or marketing activities or undertake development or commercialization activities at our own expense, and therefore may be unable to generate revenue from our products or product candidates or do so to their full potential.

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

As part of our growth strategy, we intend to explore further linaclotide development opportunities. We and Allergan are exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. These development efforts may fail or may not increase the revenues that we generate from our products. Furthermore, they may result in adverse events, or perceived adverse events, in certain patient populations that are then attributed to the currently approved patient population, which may result in adverse regulatory action at the FDA or, with respect to linaclotide, in other countries or harm our products' reputation in the marketplace, each of which could materially harm our revenues from our products.

We are also pursuing various other programs in our pipeline. We may spend several years and make significant investments in developing any current or future internal product candidate, and failure may occur at any point. Our product candidates are in various stages of development and must satisfy rigorous standards of safety and efficacy before they can be approved for sale by the FDA. To satisfy these standards, we must allocate resources among our various development programs and we must engage in costly and lengthy discovery and development efforts, which are subject to unanticipated delays and other significant uncertainties. Despite our efforts, our product candidates may not offer therapeutic or other improvement over existing competitive drugs, be proven safe and effective in clinical trials, or meet applicable regulatory standards. It is possible that none of the product candidates we are developing will be approved for commercial sale, which would impair our ability to grow.

We have ongoing or planned nonclinical and clinical trials for linaclotide, lesinurad and a number of our internal product candidates, and the strength of our company's pipeline will depend in large part on the outcomes of

these studies. Many companies in the pharmaceutical industry have suffered significant setbacks in clinical trials even after achieving promising results in earlier nonclinical or clinical trials. The findings from our completed nonclinical studies may not be replicated in later clinical trials, and our clinical trials may not be predictive of the results we may obtain in later-stage clinical trials or of the likelihood of regulatory approval. Results from our clinical trials and findings from our nonclinical studies could lead to abrupt changes in our development activities, including the possible limitation or cessation of development activities associated with a particular product candidate or program. Furthermore, our analysis of data obtained from nonclinical and clinical activities is subject to confirmation and interpretation by the FDA and other applicable regulatory authorities, which could delay, limit or prevent regulatory approval. Satisfaction of FDA or other applicable regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays.

In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional products or product candidates on terms that we find acceptable, or at all.

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products, product candidates or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Furthermore, we may have little or no insight or control over the development and commercialization of any product that we have in-licensed outside the licensed territory. If other licensees do not effectively develop or commercialize any such product outside the licensed territory, our reputation or the reputation of any such product may be impacted. Also, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

The proposed separation of our business into two independent, publicly traded companies is subject to various risks and uncertainties and may not be completed on the terms or timeline currently contemplated, if at all, and will involve significant time, effort and expense, which could harm our business, results of operations and financial condition.

In May 2018, we announced the intent to separate our soluble guanylate cyclase, or sGC, business from our commercial and GI business, resulting in two independent, publicly traded companies, Ironwood and a new company, or

R&D Co. Following the separation, Ironwood is expected to focus on accelerating growth of its in-market products, including LINZESS, and advance development programs targeting treatments in GI diseases and abdominal pain. The separated R&D Co. is expected to focus on the sGC pipeline development programs for the treatment of serious and orphan diseases.

The separation is expected to be completed in the first half of 2019, subject to the satisfaction of certain conditions. Unexpected developments, including adverse market conditions or tax consequences or delays or difficulties effecting the proposed separation, could delay, prevent or otherwise adversely impact the anticipated benefits from the proposed separation. Consummation of the separation also will require final approval from our board of directors. We may not complete the separation on the terms or on the timeline that we announced, or may, for any or no reason and at any time until the proposed separation is complete, abandon the separation or modify or change its terms. Any of the foregoing may result in our not achieving the operational, financial, strategic and other benefits we anticipate, and in each case, our business, results of operations and financial condition could be adversely affected.

We will incur significant expenses in connection with the proposed separation, and such costs and expenses may be greater than we anticipate. In addition, completion of the separation will require a significant amount of management time and effort which may disrupt our business or otherwise divert management's attention from other aspects of our business, including strategic initiatives, discovery, development and commercialization efforts and relationships with our partners and other third parties. Any of the foregoing could adversely affect our business, results of operations and financial condition.

The proposed separation may not achieve some or all of the anticipated benefits.

Even if the separation is completed, the anticipated operational, financial, strategic and other benefits of the separation may not be achieved. The combined value of the common stock of the two publicly-traded companies may not be equal to or greater than what the value of our common stock would have been had the separation not occurred. The combined value of the common stock of the two companies could be lower than anticipated for a variety of reasons, including the failure of either company to operate and compete effectively as an independent company. The common stock price of each company may experience periods of extreme volatility. In addition, the two independent companies will be smaller and less diversified, with a narrower business focus, and may be more vulnerable to changing market conditions. The separation also presents a number of significant risks to our internal processes, including the failure to maintain an adequate control environment due to changes to our infrastructure technology systems and financial reporting processes.

Ironwood continues to assess the U.S. federal income tax consequences of potential structures to separate our business into two independent, publicly traded companies. If the separation is not generally tax-free for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

If not effected on a tax-free basis, the separation could result in both the use of Ironwood's net operating losses and significant tax liability to Ironwood. The separation could also give rise to a taxable dividend and, as such, may result in significant tax liability for Ironwood's stockholders. We intend to seek an opinion from an outside tax advisor regarding the U.S. federal and state income tax consequences of the separation. The opinion would be based on and rely on, among other things, certain facts and assumptions, as well as certain representations, statements, and undertakings of Ironwood and R&D Co., including those relating to the past and future operations and conduct of each company's respective business lines. If any of these facts, assumptions, representations, statements, or undertakings are, or become, inaccurate or incomplete, or if Ironwood or R&D Co. breach any of our respective covenants in the separation documents, any opinion of the outside tax advisor may be invalid, and the conclusions reached therein could be incorrect. The U.S. Internal Revenue Service, or the IRS, also could disagree with the conclusions in the opinion of the outside tax advisor. An opinion of an outside tax advisor is not binding on the IRS or any court, and the IRS could challenge the conclusions reached in the opinion.

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

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

- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of similar conditions; and
- maintaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

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

- failure to conduct the clinical trial in accordance with regulatory requirements or the study protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate enrollment or funding to continue the clinical trial.

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

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

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

We are highly dependent on the drug discovery, development, regulatory, commercial, financial and other expertise of our management, particularly Peter M. Hecht, Ph.D., our chief executive officer; Gina Consylman, our senior vice president, chief financial officer, and treasurer; Mark G. Currie, Ph.D., our senior vice president, chief scientific officer and president of research and development; Halley E. Gilbert, our senior vice president, chief legal

officer, and secretary; William Huyett, our chief operating officer; and Thomas A. McCourt, our senior vice president, marketing and sales and chief commercial officer. Transitions in our senior management team and other key employees, including any that occur in connection with the proposed separation of our business into two independent, publicly traded companies, may result in operational disruptions, and our business may be harmed as a result. In addition to the competition for personnel, the Boston area in particular is characterized by a high cost of living. We could have difficulty attracting experienced talent to our company and each of Ironwood and R&D Co. during and following the proposed separation and we may be required to expend significant financial resources in our recruitment efforts, which may or may not be successful.

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

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

In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of our patients, clinical trial participants and employees. We also rely to a large extent on information technology systems to operate our business, including to deliver our products. We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our large and complex information technology and infrastructure (and those of our partners, vendors and third-party providers) may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors and other third-party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. While we have invested in information technology and security and the protection of confidential information, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruptions or breach would substantially impair our ability to operate our business and would compromise our, and their, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business. While we maintain cyber liability insurance, this insurance may not be sufficient to cover the losses that may result from an interruption or breach of our (or our partners', vendors' and third-party providers') systems.

Our business could be negatively affected as a result of a proxy contest or certain other stockholder actions.

Responding to certain stockholder actions can be costly, disruptive and time-consuming, and could also impact our ability to attract, retain and motivate our employees. For example, a proxy contest for our annual meeting of stockholders relating to stockholder proposals or director nominees would require significant time and could divert the attention of our management, other employees and our board of directors. In addition, a proxy contest would require us to incur significant costs, including legal fees and proxy solicitation expenses.

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

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

curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage.

Risks Related to Intellectual Property

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

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

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Patent applications in the U.S. and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we or our licensors were the first to conceive inventions covered by our patents and pending patent applications or that we or our licensors were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property, or that such patents will not be challenged, narrowed, invalidated or circumvented.

We have several issued patents and pending applications in the U.S. related to LINZESS, including a LINZESS composition of matter and methods of use patent (U.S. Patent 7,304,036) expiring in 2026. Additional U.S. patents and pending applications related to LINZESS include multiple patents relating to our commercial, room temperature stable formulation of linaclotide and methods of using this formulation, the latest of which expire in the early 2030s, as well as other patents and pending patent applications covering processes for making LINZESS, formulations and dosing regimens thereof, and molecules related to LINZESS. Although none of these issued patents currently is subject to a patent reexamination or review, we cannot guarantee that they will not be subject to reexamination or review by the U.S. Patent and Trademark Office, or the USPTO, in the future. We believe in the strength of our linaclotide patent portfolio and that it gives us sufficient freedom to operate; however, if any of our present or future patents is invalidated, this could have an adverse effect on our business and financial results. In March 2013, an opposition to one of our granted patents covering linaclotide was filed in Europe. In April 2015, the patent was upheld in its entirety by the European Patent Office, affirming the strength of our intellectual property and our belief that the opposition was without merit. We believe in the strength of the patent that is the subject of this opposition, but we cannot be certain that it will not be invalidated until the opposition proceeding, including the associated appeals process, is complete. In September 2017, an opposition to one of our granted patents covering a component of CONSTELLA, as well as formulations comprising linaclotide and this component, was filed in Europe. In June 2018, we voluntarily requested that this patent be withdrawn from grant. While any oppositions are ongoing, we will incur additional expense and be required to focus additional efforts on the proceedings. Moreover, successful outcomes in the oppositions do not preclude later challenges to these or other of our patents in the courts. Even if these patents were ultimately found to be invalid, we have other linaclotide composition of matter-, use- and formulation-related patents that are granted and in force, and we believe in the strength of our patent protection in Europe.

We received an exclusive license from AstraZeneca for several issued patents and pending applications in the U.S. related to ZURAMPIC and DUZALLO, including a composition of matter patent for lesinurad covering both ZURAMPIC and DUZALLO (U.S. Patent 8,003,681), several patents directed to ZURAMPIC and DUZALLO pharmaceutical compositions and methods of use, and patents and applications relating to polymorphic forms of lesinurad and methods of manufacturing lesinurad. Although none of these issued patents currently is subject to a patent reexamination or review, we cannot guarantee that they will not be subject to reexamination or review by the USPTO during the pendency of the Lesinurad License Agreement. If any or all of the ZURAMPIC- or DUZALLO-related patents were invalidated, we would still have marketing exclusivity under the Hatch-Waxman Act from FDA approval of ZURAMPIC during the pendency of the Lesinurad License Agreement. We believe in the strength of AstraZeneca's U.S. lesinurad patent portfolio and that it gives us sufficient freedom to operate; however, if any of AstraZeneca's present or future lesinurad patents is invalidated, this could have an adverse effect on our business and financial results during the pendency of the Lesinurad License Agreement.

Furthermore, the America Invents Act, which was signed into law in 2011, has made several major changes in the U.S. patent statutes. These changes permit third parties to challenge our patents more easily and create uncertainty

with respect to the interpretation and practice of U.S. patent law. Moreover, the U.S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available and weakening the rights of patent owners in certain circumstances. Depending on the impact of these decisions and other actions by the U.S. Congress, the federal courts, the USPTO, and their foreign counterparts, the laws and regulations governing patents may change, or their interpretation or implementation may change, in unpredictable ways that could impact, potentially adversely, our ability to obtain new patents or to enforce and defend patents that we have already obtained or that we might obtain in the future. For example, such changes may increase the costs and complexity associated with obtaining, enforcing or defending our patents, including in abbreviated new drug application, or ANDA, litigation.

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

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

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

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

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

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

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling our product unless the third party licenses its rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We have received notices of Paragraph IV certifications related to linaclotide in conjunction with ANDAs filed by generic drug manufacturers, and may receive additional notices from others in the future. We have, and may continue to, become involved in legal proceedings to protect or enforce the patents relating to our products and our product candidates, which could be expensive and time consuming, and unfavorable outcomes in such proceedings could have a material adverse effect on our business.

Competitors may infringe the patents relating to our products and our product candidates or may assert that such patents are invalid. To counter ongoing or potential infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Litigation with generic manufacturers has become increasingly common in the biotechnology and pharmaceutical industries. In addition, in an infringement or invalidity proceeding, a court or patent administrative body may determine that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Generic drug manufacturers were first able to file ANDAs for generic versions of LINZESS in August 2016, but we may not become aware of these filings for several months after any such submission due to procedures specified under applicable FDA regulations. When filing an ANDA for one of our products, a generic drug manufacturer may choose to challenge one or more of the patents that cover such product. As such, we may need to protect our intellectual property rights by bringing legal proceedings against the generic drug manufacturer.

We and Allergan have received Paragraph IV certification notice letters, or Notice Letters, regarding ANDAs submitted to the FDA by generic drug manufacturers requesting approval to engage in commercial manufacture, use, sale and offer for sale of linaclotide capsules (72 mcg, 145 mcg and 290 mcg), proposed generic versions of our FDA-approved drug LINZESS. For additional information relating to such ANDAs, see Item 1, Legal Proceedings, elsewhere in this Quarterly Report on Form 10-Q. Frequently, innovators receive multiple ANDA filings. Consequently, we expect to receive additional notice letters regarding ANDAs submitted to the FDA, and may receive amendments to the Notice Letters.

After evaluation, we may file patent infringement lawsuits or take other action against the companies making ANDA filings. If a patent infringement suit has been filed within 45 days of receipt of a notice letter, the FDA is not permitted to approve any ANDA that is the subject of such lawsuit for 30 months from the date of the NDA holder's and patent owner's receipt of the ANDA filer's notice letter, or until a court decides that the relevant patents are invalid, unenforceable and/or not infringed. In the case of suits filed before expiration of the new chemical entity, or NCE, exclusivity period for a particular drug, the 30-month stay would be calculated from the end of the applicable NCE exclusivity period. In addition to shortening the 30-month stay based on a decision that the relevant patents are invalid, unenforceable and/or not infringed, a court can also shorten or lengthen the 30-month stay under certain limited circumstances. The NCE exclusivity period for LINZESS expired on August 30, 2017, and the 30-month stay for any ANDA that is the subject of the patent infringement lawsuits filed by us before such expiration date ends on February 29, 2020 (absent any of the foregoing adjustments). We have filed patent infringement lawsuits against the companies making such ANDA filings, and have entered into settlement agreements with two such companies. For additional information relating to such lawsuits and settlements, see Item 1, Legal Proceedings, elsewhere in this Quarterly Report on Form 10-Q.

Additionally, the validity of the patents relating to our products and our product candidates may be challenged by third parties pursuant to administrative procedures introduced by the America Invents Act, specifically *inter partes* review, or IPR, and/or post grant review, or PGR, before the USPTO. Generic drug manufacturers may challenge our patents through IPRs or PGRs instead of or in addition to ANDA legal proceedings.

Patent litigation (including any lawsuits that we file against generic drug manufacturers in connection with the receipt of a notice letter), IPRs and PGRs involve complex legal and factual questions and we may need to devote significant resources to such legal proceedings. We can provide no assurance concerning the duration or the outcome of any such patent-related lawsuits or administrative proceedings, including any settlements or other resolutions thereof which could, in addition to other risks, result in a shortening of exclusivity periods. An adverse result in any litigation or

defense proceedings could put one or more of the patents relating to our products and our product candidates at risk of being invalidated or interpreted narrowly, or could otherwise result in a loss of patent protection for the product or product candidate at issue, and could put our patent applications at risk of not issuing, which would materially harm our business. Upon any loss of patent protection for one of our products, or upon an "at-risk" launch (despite pending patent infringement litigation, before any court decision or while an appeal of a lower court decision is pending) by a manufacturer of a generic version of one of our patented products, our revenues for that product could be significantly reduced in a short period of time, which would materially and adversely affect our business.

Interference or derivation proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to the patents relating to our products and our product candidates and patent applications or those of our partners. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. In addition, we may not be able to prevent, alone or with our partners, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

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

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception and cannot guarantee when, if ever, we will become profitable or attain positive cash flows.

In recent years, we have focused primarily on developing, manufacturing and commercializing our products, as well as developing our other product candidates. We have financed our business to date primarily through the issuance of equity, our collaboration and license arrangements, our January 2013 issuance of our 11% PhaRMA Notes due 2024, or the PhaRMA Notes, related to the sales of LINZESS in the U.S. (which were redeemed, in full, in connection with the funding and issuance in January 2017 of our 8.375% Notes due 2026, or the 2026 Notes) and our June 2015 issuance of our 2.25% Convertible Senior Notes due June 15, 2022, or the 2022 Notes, and we have incurred losses in each year since our inception in 1998. We currently derive a significant portion of our revenue from our LINZESS collaboration with Allergan for the U.S. We believe that the revenues from the LINZESS collaboration will continue to constitute a significant portion of our total revenue for the foreseeable future. We incurred net losses of approximately $92.5 million and approximately $96.7 million in the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we had an accumulated deficit of approximately $1.4 billion. We cannot be certain that sales of our products, and the revenue from our other commercial activities will not fall short of our projections or be delayed. Further, we expect to continue to incur substantial expenses in connection with our efforts to commercialize linaclotide and to transition lesinurad to AstraZeneca, and research and develop our product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, as well as those related to our expectations for our products and our other activities, we are unable to predict the extent of any future losses or guarantee when, or if, our company will become profitable or cash flow positive. If we never achieve profitability or positive cash flows, or achieve either later than we anticipate, this will have an adverse effect on our stockholders' equity and working capital.

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

In January 2017, in connection with the redemption of our PhaRMA Notes, we issued $150.0 million aggregate principal amount of our 2026 Notes bearing an annual interest rate of 8.375%. In June 2015, we issued approximately $335.7 million aggregate principal amount of our 2022 Notes and we have previously raised additional funds through other capital raising activities, including the sale of shares of our Class A common stock in public offerings and the issuance of our PhaRMA Notes in January 2013 (which were redeemed, in full, in connection with the issuance of our 2026 Notes). However, marketing and selling primary care drugs, purchasing commercial quantities of pharmaceutical products, developing product candidates, conducting clinical trials and accessing externally developed products are expensive and uncertain. Circumstances, our strategic imperatives, or opportunities to create or acquire new programs, as

well as maturities, redemptions or repurchases of our outstanding debt securities, could require us to, or we may choose to, seek to raise additional funds. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the level of underlying demand for our products by prescribers and patients in the countries in which they are approved;
- the costs associated with commercializing our products in the U.S.;
- the costs of establishing, maintaining and/or expanding sales, marketing, distribution, and market access capabilities for our products;
- the regulatory approval of linaclotide outside of the U.S. and the other countries where it is approved and the timing of commercial launches in those countries, and the regulatory approval of linaclotide within new indications, populations and formulations, as well as the associated development and commercial milestones and royalties;
- the rate of progress, the cost of our clinical trials and the other costs associated with our linaclotide product development programs, including our post-approval nonclinical and clinical studies of linaclotide in pediatrics and our investment to enhance the clinical profile of LINZESS within IBS-C and CIC, as well as to study linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions;
- the rate of progress and the costs associated with development of lesinurad, including costs related to the post-marketing clinical trial for lesinurad required by the FDA;
- the costs and timing of in-licensing additional products or product candidates or acquiring other complementary companies or assets;
- the achievement and timing of milestone payments and royalties due or payable under our collaboration and license agreements;
- the status, terms and timing of any collaboration, licensing, co-commercialization or other arrangements;
- the timing of any regulatory approvals of our product candidates;
- whether the holders of our 2022 Notes hold the notes to maturity without conversion into our Class A common stock and whether we are required to repurchase our 2022 Notes prior to maturity upon a fundamental change, as defined in the indenture governing the 2022 Notes; and
- whether we seek to redeem or repurchase all or part of our outstanding debt through cash purchases and/or exchanges, in open market purchases, privately negotiated transactions, by tender offer or otherwise.

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

Our ability to pay principal of and interest on our outstanding debt securities will depend in part on the receipt of payments from Allergan under our collaboration agreement for North America.

In January 2017, we issued, in connection with the redemption of our PhaRMA Notes, $150.0 million aggregate principal amount of our 2026 Notes bearing an annual interest rate of 8.375% and in June 2015, we issued approximately $335.7 million aggregate principal amount of our 2022 Notes bearing an annual interest rate of 2.25%. Semi-annual payments on our 2022 Notes commenced on December 15, 2015. Quarterly interest payments on our 2026 Notes commenced on June 15, 2017 and, pursuant to the associated indenture, beginning in March 2019 we are obligated to make quarterly payments on our 2026 Notes equal to the greater of (i) 7.5% of net sales of linaclotide in the U.S. for the preceding quarter and (ii) the accrued and unpaid interest on the 2026 Notes. Principal on the 2026 Notes is to be repaid in an amount equal to the difference between (i) and (ii) above, when this is a positive number, until the principal has

been paid in full. We expect that for the next few years, at a minimum, the net quarterly payments from Allergan will be a significant source of cash flow from operations. If the cash flows derived from the net quarterly payments that we receive from Allergan under the collaboration agreement for North America are insufficient on any particular payment date to fund the interest payment on our outstanding indebtedness, at a minimum, we will be obligated to pay the amounts of such shortfall out of our general funds. The determination of whether Allergan will be obligated to make a net quarterly payment to us in respect of a particular quarterly period is a function of the revenue generated by LINZESS in the U.S. as well as the development, manufacturing and commercialization expenses incurred by each of us and Allergan under the collaboration agreement for North America. Accordingly, since we cannot guarantee when, or if, our company will become profitable or cash flow positive, we cannot provide assurances that (i) we will have the available funds to fund the interest payment on our outstanding indebtedness, at a minimum, in the event that there is a deficiency in the net quarterly payment received from Allergan, (ii) there will be a net quarterly payment from Allergan at all or (iii) we will not also be required to make a true-up payment to Allergan under the collaboration agreement for North America, in each case, in respect of a particular quarterly period.

Our indebtedness could adversely affect our financial condition or restrict our future operations.

As of June 30, 2018, we had total indebtedness of approximately $485.7 million and available cash, cash equivalents and available for sale securities of approximately $181.2 million. We chose to issue our 2026 Notes (in connection with the redemption, in full, of our PhaRMA Notes) and our 2022 Notes based on the additional strategic optionality that they create for us, and the limited restrictions that these debt securities place on our ability to run our business compared to other potential available financing transactions. However, our indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences on our business, including:

- limiting our ability to obtain additional financing to fund future working capital, capital expenditures or other general corporate purposes, including product development, commercialization efforts, research and development activities, strategic arrangements, acquisitions and refinancing of our outstanding debt;
- requiring a substantial portion of our cash flow to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flow available for working capital, capital expenditures, corporate transactions and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and competitive conditions;
- limiting our flexibility in planning for and reacting to changes in the industry in which we compete;
- placing us at a disadvantage compared to other, less leveraged competitors or competitors with comparable debt at more favorable interest rates; and
- increasing our cost of borrowing.

If we do not generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to pay our indebtedness, including payments of principal when due on our outstanding indebtedness or, in the case of our 2022 Notes, in connection with a transaction involving us that constitutes a fundamental change under the indenture governing the 2022 Notes, or to fund our liquidity needs, we may be forced to refinance all or a portion of our indebtedness on or before the maturity dates thereof, sell assets, reduce or delay currently planned activities or curtail operations, seek to raise additional capital or take other actions. We may not be able to execute any of these actions on commercially reasonable terms or at all. This, together with any of the factors described above, could materially and adversely affect our business, financial condition and results of operations.

In addition, while our 2022 Notes do not include covenants restricting the operation of our business except in certain limited circumstances, in the event of a default under the 2022 Notes, the noteholders or the trustee under the indenture governing the 2022 Notes may accelerate our payment obligations under the 2022 Notes, which could have a material adverse effect on our business, financial condition and results of operations. We are also required to offer to repurchase the 2022 Notes upon the occurrence of a fundamental change, which could include, among other things, any acquisition of our company (other than an acquisition in which at least 90% of the consideration is common stock listed on The NASDAQ Global or Global Select Market or The New York Stock Exchange), subject to the terms of the 2022

Notes indenture. The repurchase price must be paid in cash, and this obligation may have the effect of discouraging, delaying or preventing an acquisition of our company that would otherwise be beneficial to our security holders.

Further, although we are not as restricted under our 2026 Notes as we might have been under a more traditional secured credit facility provided by a bank, the indenture governing our 2026 Notes contains a number of restrictive covenants that impose restrictions on us and may limit our ability to engage in certain acts, including restrictions on our ability to:

- amend our collaboration agreement with Allergan for North America in a way that would have a material adverse effect on the noteholders' rights, or terminate this collaboration agreement with respect to the U.S.;
- transfer our rights to commercialize the product under our collaboration agreement with Allergan for North America; and
- incur certain liens.

Upon a breach of the covenants under our 2026 Notes indenture, or if certain other defaults thereunder occur, the holders of our 2026 Notes could elect to declare all amounts outstanding under our 2026 Notes to be immediately due and payable and we cannot be certain that we will have sufficient assets to repay them. If we are unable to repay those amounts, the holders of our 2026 Notes could proceed against the collateral granted to them to secure the debt securities and we could be forced into bankruptcy or liquidation. If we breach our covenants under our 2026 Notes indenture and seek a waiver, we may not be able to obtain a waiver from the required noteholders. If this occurs, we would be in default under our 2026 Notes indenture and the holders of our 2026 Notes could exercise their rights, as described above.

Each of our 2026 Notes and 2022 Notes also include cross-default features providing that a default under the indenture governing either the 2026 Notes or the 2022 Notes would likely result in a default under the indenture governing the other indebtedness. In the event of such default, the trustee or noteholders could elect to declare all amounts outstanding to be immediately due and payable under the applicable indenture, which could have a material adverse effect on our business, financial condition and results of operations.

Convertible note hedge and warrant transactions entered into in connection with our 2022 Notes may affect the value of our Class A common stock.

In connection with our 2022 Notes, we entered into Convertible Note Hedges and separate Note Hedge Warrant transactions with certain financial institutions. These transactions are expected generally to reduce the potential dilution upon any conversion of our 2022 Notes or offset any cash payments we are required to make in excess of the principal amount of converted 2022 Notes, as the case may be.

In connection with these transactions, the financial institutions purchased our Class A common stock in secondary market transactions and entered into various over-the-counter derivative transactions with respect to our Class A common stock. These entities or their affiliates are likely to modify their hedge positions from time to time prior to conversion or maturity of the 2022 Notes by purchasing and selling shares of our Class A common stock or other instruments they may wish to use in connection with such hedging. Any of these activities could adversely affect the value of our Class A common stock and, as a result, the number of shares and the value of the Class A common stock noteholders will receive upon conversion of the 2022 Notes. In addition, under certain circumstances the counterparties have the right to terminate the Convertible Note Hedges and settle the Note Hedge Warrants at fair value (as defined in the applicable confirmations), which may result in us not receiving all or any portion of the anticipated benefit of the Convertible Note Hedges. If the price of our Class A common stock increases such that the hedge transactions settle in our favor, we could also be exposed to credit risk related to the counterparties to the Convertible Note Hedges, which would limit or eliminate the benefit of such transactions to us.

Our quarterly and annual operating results may fluctuate significantly.

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

- the level of underlying demand for our products in the countries in which they are approved;

- wholesalers' buying patterns with respect to our products;
- the costs associated with commercializing our products in the U.S.;
- the achievement and timing of milestone payments and royalties due or payable under our collaboration and license agreements;
- our execution of any collaboration, partnership, licensing or other strategic arrangements, and the timing of payments we may make or receive under these arrangements;
- any excess or obsolete inventory, and associated write-downs;
- any changes in the fair value of contingent consideration and the associated impact on our statement of operations;
- any variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- regulatory developments affecting our products and product candidates; and
- any material lawsuit in which we may become involved.

In addition, any impairments of goodwill or intangible assets and any associated write-downs would have a negative effect on our operating results. Determining whether an impairment exists and the amount of the potential impairment is subject to significant uncertainty and involves the use of estimates and assumptions. For example, our ZURAMPIC and DUZALLO intangible assets are significant. In connection with the analysis of the data from the lesinurad franchise test markets and the notice of termination of the Lesinurad License Agreement, we expect to record a full intangible asset impairment of these intangible assets and a gain on fair value remeasurement of contingent consideration during the three months ending September 30, 2018. Additionally, we wrote down lesinurad inventory and purchase commitments during the three months ended June 30, 2018 as a result of revised lesinurad demand forecasts. For additional information relating to the impairment of such intangible assets and write-down of inventory and purchase commitments, see Note 14, *Subsequent Events*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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

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

We have incurred significant net losses since our inception and cannot guarantee when, if ever, we will become profitable. To the extent that we continue to generate federal and state taxable losses, unused net operating loss and tax credit carryforwards will carry forward to offset future taxable income, if any, until the date, if any, on which such unused carryforwards expire. Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal

to the product of the applicable long term tax exempt rate and the value of the company's stock immediately before the ownership change.

If we do not generate sufficient taxable income prior to the expiration, if any, of the applicable carryforwards or if the carryforwards are subject to the limitations described above, we may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal or state income tax liability. We have completed several financings since our inception which may have resulted in a change in control as defined by Section 382, or could result in a change in control in the future.

Risks Relating to Securities Markets and Investment in Our Stock

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

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

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

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

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

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

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

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

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

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

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

The concentration of voting control on certain corporate matters with our pre-IPO stockholders will limit the ability of the holders of our Class A common stock to influence such matters.

Because of our dual class common stock structure, the holders of our Class B common stock, who consist of our pre-IPO investors (and their affiliates), founders, directors, executives and certain of our employees, are able to control certain corporate matters listed below if any such matter is submitted to our stockholders for approval even though such stockholders own less than 50% of the outstanding shares of our common stock. As of June 30, 2018, there were 138,860,929 and 13,992,491 shares of our Class A common stock and Class B common stock issued and outstanding, respectively, and an aggregate of 20,920,816 and 1,134,823 outstanding stock options (vested and unvested) and 3,206,626 and no unvested restricted stock units for shares of our Class A common stock and Class B common stock, respectively. As of June 30, 2018, the holders of our Class A common stock own approximately 91% and the holders of our Class B common stock own approximately 9% of the outstanding shares of Class A common stock and Class B common stock, combined. However, because of our dual class common stock structure these holders of our Class A common stock have approximately 50% and holders of our Class B common stock have approximately 50% of the total votes on each of the matters identified in the list below. This concentrated control of our Class B common stockholders limits the ability of the Class A common stockholders to influence those corporate matters and, as a result, we may take actions that many of our stockholders do not view as beneficial, which could adversely affect the market price of our Class A common stock.

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

- adoption of a merger or consolidation agreement involving Ironwood;
- a sale of all or substantially all of Ironwood's assets;
- a dissolution or liquidation of Ironwood; and
- every matter, if and when any individual, entity or "group" (as that term is used in Regulation 13D of the Exchange Act) has, or has publicly disclosed (through a press release or a filing with the SEC) an intent to have, beneficial ownership of 30% or more of the number of outstanding shares of Class A common stock and Class B common stock, combined.

We expect that, in accordance with the terms of our certificate of incorporation, each outstanding share of Class B common stock will automatically convert into one share of Class A common stock on December 31, 2018.

If we identify a material weakness in our internal control over financial reporting, it could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our Class A common stock.

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

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

Further, we are dependent on our partners for information related to our results of operations. Our net profit or net loss generated from the sales of LINZESS in the U.S. is partially determined based on amounts provided by Allergan

and involves the use of estimates and judgments, which could be modified in the future. We are highly dependent on our linaclotide partners for timely and accurate information regarding any revenues realized from sales of linaclotide in their respective territories, and in the case of Allergan for the U.S. and AstraZeneca for China, Hong Kong and Macau, the costs incurred in developing and commercializing it in order to accurately report our results of operations. Our results of operations are also dependent on the timeliness and accuracy of information from any other licensing, collaboration or other partners we may have, as well as our and our partners' use of estimates and judgments. If we do not receive timely and accurate information or if estimated activity levels associated with the relevant collaboration or partnership at a given point in time are incorrect, whether the result of a material weakness or not, we could be required to record adjustments in future periods. Such adjustments, if significant, could have an adverse effect on our financial results, which could lead to a decline in our Class A common stock price.

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

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

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

- the commercial performance of our products in the countries in which they are approved, as well as the costs associated with such activities;
- any third-party coverage and reimbursement policies for our products;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments, litigation or public concern about the safety of our products or our potential products;
- announcements of the introduction of new products by us or our competitors;
- announcements concerning product development results, including clinical trial results, or intellectual property rights of us or others;
- actual and anticipated fluctuations in our quarterly and annual operating results;
- deviations in our operating results from any guidance we may provide or the estimates of securities analysts;
- sales of additional shares of our common stock or sales of securities convertible into common stock or the perception that these sales might occur;
- additions or departures of key personnel;
- developments concerning current or future collaboration, partnership, licensing or other strategic arrangements, or with respect to the proposed separation of our business into two independent, publicly traded companies; and
- discussion of us or our stock price in the financial or scientific press or in online investor communities.

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

Item 5. ***Other Information***

On August 3, 2018, in connection with its ongoing evaluation of our compensation practices and to better align to current market data, the Compensation and HR Committee of our Board of Directors approved certain amendments to the existing severance arrangements with our executive officers (each, an Officer and collectively, the Officers).

Under the amended severance arrangements, if an Officer's employment is terminated without Cause or by the Officer as a result of a Constructive Termination, each as defined in the severance arrangements (each, a Qualifying Termination), within six months before announcement of or entry into an agreement that would result in a change of control or 24 months following a change of control, such Officer will be entitled to receive severance payments under the severance arrangements, with the following amendments: (i) 150% of the Officer's current annual base salary (or, for Peter M. Hecht, our Chief Executive Officer, 200% of his current annual base salary), increased from 100% of the Officer's current annual base salary, (ii) 150% of the Officer's target annual cash incentive award for the current year (the Target Bonus) (or, for Dr. Hecht, 200% of his Target Bonus), increased from 100% of the Officer's Target Bonus, and (iii) subsidized benefits under the Consolidated Omnibus Budget Reconciliation Act (COBRA) for 18 months (or, for Dr. Hecht, 24 months), increased from 12 months. Additionally, the amended severance arrangements provide that Officers will have 24 months (or, for Dr. Hecht, 36 months) following such termination to exercise vested stock options.

Under the amended severance arrangements, if Dr. Hecht's employment is terminated in a Qualifying Termination outside of a change of control, he will be entitled to receive severance payments under the severance arrangements, with the following amendments: (i) 150% of his current annual base salary, increased from 100% of his current annual base salary, (ii) 150% of his Target Bonus, increased from 100% of his Target Bonus, and (iii) subsidized COBRA benefits for 18 months, increased from 12 months. If the employment of any Officer aside from Dr. Hecht is terminated in a Qualifying Termination outside of a change of control, such Officer will receive up to an additional six months of his or her current annual base salary and subsidized COBRA benefits so long as such Officer has not secured new employment following the end of the initial 12-month severance period. Additionally, the amended severance arrangements provide that time-based equity awards held by the Officer will vest as to those awards that would have vested by their terms during the 18-month period (or, for Dr. Hecht, the 24-month period) following such termination, with additional accelerated vesting for a portion of such awards that would have vested on the next regularly scheduled vesting date following the date that is 18 months (or, for Dr. Hecht, 24 months) following termination, and such Officer will have 24 months (or, for Dr. Hecht, 36 months) following such termination to exercise vested stock options.

All other benefits under, and terms and conditions of, the severance arrangements remained unchanged in all material respects. The foregoing description of the amended severance arrangements is a summary, is not complete, and is qualified in its entirety by the terms and conditions of the amended severance arrangements, forms of which will be filed as exhibits to our Quarterly Report on Form 10-Q for the quarter ending September 30, 2018.

Item 6. ***Exhibits***

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

EXHIBIT INDEX

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

* Filed herewith.

‡ Furnished herewith.

SIGNATURES

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

Ironwood Pharmaceuticals, Inc.

Date: August 6, 2018

By: /s/ PETER M. HECHT
Peter M. Hecht
Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 6, 2018

By: /s/ GINA CONSYLMAN
Gina Consylman
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION PURSUANT
TO RULES 13a-14(a) OR 15d-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Peter M. Hecht, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ironwood Pharmaceuticals, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2018

/s/ PETER M. HECHT
Peter M. Hecht
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT
TO RULES 13a-14(a) OR 15d-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Gina Consylman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ironwood Pharmaceuticals, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2018

/s/ GINA CONSYLMAN
Gina Consylman
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ironwood Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter M. Hecht, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ PETER M. HECHT
Peter M. Hecht
Chief Executive Officer
August 6, 2018

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ironwood Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gina Consylman, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ GINA CONSYLMAN
Gina Consylman
Chief Financial Officer
August 6, 2018

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.