

IRONWOOD PHARMACEUTICALS INC

Form 10-Q

May 04, 2018

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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 March 31, 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)

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Delaware
(State or other jurisdiction of
incorporation or organization)

04-3404176
(I.R.S. Employer
Identification Number)

301 Binney Street
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02142
(Zip Code)

(617) 621-7722

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes 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

Smaller reporting company

(Do not check if a 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.

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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 April 27, 2018, there were 137,944,013 shares of Class A common stock outstanding and 13,997,357 shares of Class B common stock outstanding.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors”, contains forward-looking statements. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words “may,” “continue,” “estimate,” “intend,” “plan,” “will,” “believe,” “project,” “expect,” “seek,” “anticipate” and similar expressions may identify forward-looking 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;

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- 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; 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.

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IRONWOOD PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 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)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 144,788	\$ 125,736
Available-for-sale securities	49,659	95,680
Accounts receivable, net	4,988	3,190
Related party accounts receivable, net	65,663	78,967
Inventory	1,705	735
Prepaid expenses and other current assets	8,924	7,288
Total current assets	275,727	311,596
Restricted cash	7,056	7,056
Property and equipment, net	16,844	17,274
Convertible note hedges	113,445	108,188
Intangible assets, net	156,429	159,905
Goodwill	785	785
Other assets	809	870
Total assets	\$ 571,095	\$ 605,674
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and related party accounts payable, net	\$ 11,609	\$ 15,958
Accrued research and development costs	4,673	7,313
Accrued expenses and other current liabilities	30,145	38,237
Current portion of capital lease obligations	3,359	4,077
Current portion of deferred rent	237	195
Current portion of 2026 Notes	11,958	—
Current portion of contingent consideration	355	247
Total current liabilities	62,336	66,027
Deferred rent, net of current portion	5,860	5,449
Contingent consideration, net of current portion	31,389	31,011
Note hedge warrants	96,129	92,188
Convertible senior notes	253,153	249,193
2026 Notes, net of current portion	135,220	146,898
Other liabilities	5,060	5,060
Commitments and contingencies		
Stockholders' (deficit) equity:		

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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 137,606,687 and 136,465,526 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	138	137
Class B common stock, \$0.001 par value, 100,000,000 shares authorized and 13,997,357 shares issued and outstanding at March 31, 2018 and 13,983,762 shares issued outstanding at December 31, 2017	14	14
Additional paid-in capital	1,333,791	1,318,536
Accumulated deficit	(1,351,904)	(1,308,760)
Accumulated other comprehensive loss	(91)	(79)
Total stockholders' (deficit) equity	(18,052)	9,848
Total liabilities and stockholders' (deficit) equity	\$ 571,095	\$ 605,674

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

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

(In thousands, except per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2018	2017
Revenues:		
Collaborative arrangements revenue	\$ 63,086	\$ 51,865
Product revenue, net	635	289
Sale of active pharmaceutical ingredient	5,434	12
Total revenues	69,155	52,166
Cost and expenses:		
Cost of revenues, excluding amortization of acquired intangible assets	2,607	531
Research and development	36,505	33,702
Selling, general and administrative	61,923	55,604
Amortization of acquired intangible assets	3,476	420
Loss on fair value remeasurement of contingent consideration	512	1,614
Total cost and expenses	105,023	91,871
Loss from operations	(35,868)	(39,705)
Other (expense) income:		
Interest expense	(9,273)	(8,983)
Interest and investment income	681	395
Gain (loss) on derivatives	1,316	(2,199)
Loss on extinguishment of debt	—	(2,009)
Other expense, net	(7,276)	(12,796)
Net loss	\$ (43,144)	\$ (52,501)
Net loss per share—basic and diluted	\$ (0.29)	\$ (0.36)
Weighted average number of common shares used in net loss per share—basic and diluted:	151,013	147,786

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

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)

(unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Net loss	\$ (43,144)	\$ (52,501)
Other comprehensive loss:		
Unrealized losses on available-for-sale securities	(12)	(34)
Total other comprehensive loss	(12)	(34)
Comprehensive loss	\$ (43,156)	\$ (52,535)

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

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Ironwood Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(In thousands)

(unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (43,144)	\$ (52,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,790	2,910
Amortization of acquired intangible assets	3,476	420
Gain on disposal of property and equipment	(34)	—
Share-based compensation expense	9,043	7,279
Change in fair value of note hedge warrants	3,941	20,187
Change in fair value of convertible note hedges	(5,257)	(17,988)
Write-down of excess non-cancellable ZURAMPIC sample purchase commitments	—	1,353
Gain on facility subleases	—	(1,579)
Accretion of discount/premium on investment securities	(118)	105
Non-cash interest expense	4,239	3,877
Non-cash change in fair value of contingent consideration	512	1,614
Loss on extinguishment of debt	—	2,009
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable	11,506	13,707
Prepaid expenses and other current assets	(1,647)	372
Inventory	(768)	71
Other assets	62	201
Accounts payable, related party accounts payable and accrued expenses	(12,300)	(5,238)
Accrued research and development costs	(2,640)	(1,831)
Deferred revenue	—	741
Deferred rent	453	(3,555)
Net cash used in operating activities	(30,886)	(27,846)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(2,491)	(44,777)
Sales and maturities of available-for-sale securities	48,620	133,830
Purchases of property and equipment	(1,509)	(1,037)
Proceeds from sale of property and equipment	33	43
Net cash provided by investing activities	44,653	88,059
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	—	(209)
Proceeds from exercise of stock options and employee stock purchase plan	6,203	8,171
Payments on capital leases	(827)	(796)
Principal payments on Pharma notes	—	(134,258)

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Payments on contingent purchase price consideration	(91)	(56)
Net cash provided by financing activities	5,285	19,102
Net increase in cash, cash equivalents and restricted cash	19,052	79,315
Cash, cash equivalents and restricted cash, beginning of period	132,792	62,251
Cash, cash equivalents and restricted cash, end of period	\$ 151,844	\$ 141,566
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	\$ 144,788	\$ 133,319
Restricted cash	7,056	8,247
Total Cash, cash equivalents, and restricted cash	\$ 151,844	\$ 141,566

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

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Ironwood Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business

Overview

Ironwood Pharmaceuticals, Inc. (the “Company”) is a commercial biotechnology company leveraging its proven development and commercial capabilities as it seeks to bring multiple medicines to patients. The Company is advancing innovative product opportunities in areas of large unmet need, 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.

The Company is advancing another GI development program, IW-3718, a gastric retentive formulation of a bile acid sequestrant for the potential treatment of uncontrolled 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 uncontrolled 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 uncontrolled GERD. In July 2017, the Company reported positive top-line data from a Phase IIb clinical trial evaluating IW-3718 that the Company believes supports the advancement of this program into Phase III development.

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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. The Company expects the data received in 2018 from these test markets to inform the Company’s future investment in the lesinurad franchise.

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 pralicyguat (IW-1973) and olinciguat (IW-1701). The Company is advancing pralicyguat, its lead clinical sGC stimulator, for the potential treatment of diabetic nephropathy and the potential treatment of heart failure with preserved ejection fraction (“HFpEF”). The Company’s second clinical sGC stimulator, olinciguat, is being developed for the potential treatment of achalasia and 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.

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.

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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 March 31, 2018, and the results of its operations for the three months ended March 31, 2018 and 2017, and its cash flows for the three months ended March 31, 2018 and 2017. The results of operations for the three months ended March 31, 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 three months ended March 31, 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

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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 months ended as of March 31, 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 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 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 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

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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

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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

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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.

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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

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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

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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 months ended March 31, 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. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application. Early adoption is permitted beginning after December 15, 2016, including interim reporting periods within those years. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing (“ASU 2016-10”), which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients (“ASU 2016-12”), related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date as ASU 2014-09. These standards allow for either a full retrospective or a modified retrospective transition approach. 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 three months ended March 31, 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, assessing

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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:

	Three Months Ended March 31, 2017		
	As previously reported	Adjustments	As adjusted
Net change in cash, cash equivalents, and restricted cash	79,315	—	79,315
Cash, cash equivalents, and restricted cash, beginning of period	54,004	8,247	62,251
Cash, cash equivalents, and restricted cash, end of period	\$ 133,319	\$ 8,247	\$ 141,566

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.

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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):

	Three Months Ended March 31,	
	2018	2017
Options to purchase common stock	22,973	22,274
Shares subject to repurchase	31	52
Restricted stock units	3,230	2,255
Note hedge warrants	20,250	20,250
2022 Notes	20,250	20,250
	66,734	65,081

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.

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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 March 31, 2018, the Company recognized accumulated amortization of approximately \$7.6 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 March 31, 2018, the Company recognized accumulated amortization of approximately \$3.1 million with respect to the developed technology – ZURAMPIC intangible asset.

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

	As of March 31, 2018
2018(1)	\$ 10,428
2019	13,905
2020	13,905
2021	13,905
2022 and thereafter	104,286