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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 June 30, 2020

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)
100 Summer Street, Suite 2300 Boston, Massachusetts	**02110**
(Address of Principal Executive Offices)	(Zip Code)

(617) 621-7722
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, $0.001 par value	IRWD	Nasdaq Global Select Market

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 ☐
	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 August 3, 2020, there were 159,978,137 shares of Class A 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," "could," "should," "target," "goal," "potential" 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 AbbVie Inc. in the U.S.;
- the execution of the launches and commercialization of CONSTELLA® in Europe and LINZESS in Japan and China, as well as our expectations regarding revenue generated from our partners;
- 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 active pharmaceutical ingredient, finished 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 and capped call transactions described herein;
- inventory levels and write downs, or asset impairments, and the drivers thereof, and inventory purchase commitments;
- 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;
- any benefits or costs of the separation of the Company's operations into two independent, publicly traded companies, including the tax treatment;
- the financial and operational impacts of the COVID-19 pandemic on our business and results of operations, including impacts on our day-to-day operations, collaborative arrangements revenue and marketing efforts, manufacturing and supply chain and clinical development of our pipeline; 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, 2020
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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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 253,252	$ 177,023
Accounts receivable, net	105,379	11,279
Related party accounts receivable, net	—	105,967
Inventory, net	—	648
Prepaid expenses and other current assets	14,394	10,685
Restricted cash	1,250	1,250
Total current assets	374,275	306,852
Restricted cash, net of current portion	971	971
Accounts receivable, net of current portion	22,995	32,597
Property and equipment, net	11,190	12,429
Operating lease right-of-use assets	17,156	17,743
Convertible note hedges	16,131	31,366
Other assets	820	790
Total assets	$ 443,538	$ 402,748
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 2,104	$ 3,978
Related party accounts payable, net	751	1,509
Accrued research and development costs	2,400	2,956
Accrued expenses and other current liabilities	17,955	30,465
Current portion of operating lease liabilities	2,610	1,146
Deferred revenue	875	875
Total current liabilities	26,695	40,929
Note hedge warrants	12,958	24,260
Convertible senior notes	418,924	407,994
Operating lease obligations, net of current portion	21,211	22,082
Other liabilities	602	734
Commitments and contingencies		
Stockholders' deficit:		
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 159,976,245 issued and outstanding at June 30, 2020 and 500,000,000 shares authorized and 157,535,962 shares issued and outstanding at December 31, 2019	160	158
Additional paid-in capital	1,506,671	1,478,823
Accumulated deficit	(1,543,683)	(1,572,232)
Total stockholders' deficit	(36,852)	(93,251)
Total liabilities and stockholders' deficit	$ 443,538	$ 402,748

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

Ironwood Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Collaborative arrangements revenue	$ 89,423	$ 77,322	$ 163,868	$ 143,474
Sale of active pharmaceutical ingredient	9	24,893	5,507	27,471
Total revenues	89,432	102,215	169,375	170,945
Cost and expenses:				
Cost of revenues	—	11,313	2,239	12,356
Research and development	22,076	28,758	50,103	60,956
Selling, general and administrative	34,643	43,246	71,093	92,341
Gain on lease modification	—	(3,169)	—	(3,169)
Restructuring expenses	—	490	—	3,818
Total cost and expenses	56,719	80,638	123,435	166,302
Income from operations	32,713	21,577	45,940	4,643
Other (expense) income:				
Interest expense	(7,318)	(9,430)	(14,538)	(19,022)
Interest and investment income	276	668	1,053	1,404
(Loss) gain on derivatives	(467)	(672)	(3,933)	3,272
Other income	—	140	27	140
Other expense, net	(7,509)	(9,294)	(17,391)	(14,206)
Net income (loss) from continuing operations	25,204	12,283	28,549	(9,563)
Net loss from discontinued operations	—	—	—	(37,438)
Net income (loss) and comprehensive income (loss)	$ 25,204	$ 12,283	$ 28,549	$ (47,001)
Net income (loss) per share from continuing operations—basic and diluted	$ 0.16	$ 0.08	$ 0.18	$ (0.06)
Net loss per share from discontinued operations—basic and diluted	$ —	$ —	$ —	$ (0.24)
Net income (loss) per share—basic and diluted	$ 0.16	$ 0.08	$ 0.18	$ (0.30)
Weighted average shares used in computing net income (loss) per share—basic:	159,407	155,849	158,890	155,405
Weighted average shares used in computing net income (loss) per share—diluted:	159,920	155,849	160,032	155,405

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

Ironwood Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Deficit
(In thousands, except share amounts)
(unaudited)

	Class A Common Stock		Additional paid-in capital	Accumulated deficit	Total Stockholders' deficit
	Shares	Amount			
Balance at December 31, 2019	157,535,962	$ 158	$1,478,823	$ (1,572,232)	$ (93,251)
Issuance of common stock related to share-based awards and employee stock purchase plan	1,832,164	1	11,984	—	11,985
Share-based compensation expense related to share-based awards and employee stock purchase plan	—	—	6,364	—	6,364
Net income	—	—	—	3,345	3,345
Balance at March 31, 2020	159,368,126	$ 159	$1,497,171	$ (1,568,887)	$ (71,557)
Issuance of common stock related to share-based awards and employee stock purchase plan	608,119	1	2,409	—	2,410
Share-based compensation expense related to share-based awards and employee stock purchase plan	—	—	7,091	—	7,091
Net income	—	—	—	25,204	25,204
Balance at June 30, 2020	159,976,245	$ 160	$1,506,671	$ (1,543,683)	$ (36,852)

	Class A Common Stock		Additional paid-in capital	Accumulated deficit	Total Stockholders' deficit
	Shares	Amount			
Balance at December 31, 2018	154,414,691	$ 154	$1,394,603	$ (1,591,128)	$ (196,371)
Issuance of common stock related to share-based awards and employee stock purchase plan	1,210,858	2	3,486	—	3,488
Share-based compensation expense related to share-based awards and employee stock purchase plan	—	—	14,988	—	14,988
Net loss	—	—	—	(59,284)	(59,284)
Balance at March 31, 2019	155,625,549	$ 156	$1,413,077	$ (1,650,412)	$ (237,179)
Issuance of common stock related to share-based awards and employee stock purchase plan, net of cancellations	621,588	—	1,801	—	1,801
Share-based compensation expense related to share-based awards and employee stock purchase plan	195,195	—	6,337	—	6,337
Dividend of sGC business	—	—	—	(2,609)	(2,609)
Net income	—	—	—	12,283	12,283
Balance at June 30, 2019	156,442,332	$ 156	$1,421,215	$ (1,640,738)	$ (219,367)

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,	
	2020	**2019**
Cash flows from operating activities:		
Net income (loss)	$ 28,549	$ (47,001)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,322	1,539
Loss on disposal of property and equipment	423	109
Share-based compensation expense	13,455	20,271
Gain on lease modification	—	(3,169)
Change in fair value of note hedge warrants	(11,302)	16,428
Change in fair value of convertible note hedges	15,235	(19,700)
Non-cash interest expense	10,930	9,300
Changes in assets and liabilities:		
Accounts receivable and related party accounts receivable, net	21,469	(21,529)
Prepaid expenses and other current assets	(3,638)	2,647
Inventory, net	648	(635)
Other assets	(30)	(6)
Accounts payable, related party accounts payable and accrued expenses	(13,861)	(25,205)
Accrued research and development costs	(556)	2,335
Operating lease right-of-use assets	587	6,315
Operating lease liabilities	593	(4,685)
Other liabilities	(133)	—
Net cash provided by (used in) continuing operating activities	63,691	(62,986)
Net cash provided by discontinued operating activities	—	11,364
Net cash provided by (used in) operating activities	63,691	(51,622)
Cash flows from investing activities:		
Purchases of property and equipment	(1,814)	(1,444)
Proceeds from sale of property and equipment	—	261
Net cash used in continuing investing activities	(1,814)	(1,183)
Net cash used in discontinued investing activities	—	(4,223)
Net cash used in investing activities	(1,814)	(5,406)
Cash flows from financing activities:		
Proceeds from exercise of stock options and employee stock purchase plan	14,352	5,204
Payments on 8.375% Notes due 2026	—	(21,469)
Net cash provided by (used in) continuing financing activities	14,352	(16,265)
Net cash used in discontinued financing activities	—	—
Net cash provided by (used in) financing activities	14,352	(16,265)
Net increase (decrease) in cash, cash equivalents and restricted cash	76,229	(73,293)
Cash, cash equivalents and restricted cash, beginning of period	179,244	180,848
Cash, cash equivalents and restricted cash, end of period	$ 255,473	$ 107,555
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 253,252	$ 98,908
Restricted cash	2,221	8,647
Total cash, cash equivalents, and restricted cash	$ 255,473	$ 107,555

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

Ironwood Pharmaceuticals, Inc. ("Ironwood" or the "Company") is a gastrointestinal ("GI") healthcare company dedicated to advancing the treatment of GI diseases and redefining the standard of care for millions of GI patients. The Company is focused on the development and commercialization of innovative GI product opportunities in areas of large unmet need, leveraging its demonstrated expertise and capabilities in GI diseases.

LINZESS® (linaclotide), the Company's commercial product, is the first product approved by the United States Food and Drug Administration (the "U.S. FDA") in a class of GI medicines called guanylate cyclase type C agonists, and is indicated for adult men and women suffering from irritable bowel syndrome with constipation ("IBS-C") or chronic idiopathic constipation ("CIC"). LINZESS is available 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 and China. 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 has strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world. The Company and its partner, AbbVie Inc. (together with its affiliates, "AbbVie") (successor to Allergan plc (together with its affiliates) ("Allergan")), began commercializing LINZESS in the U.S. in December 2012.

In May 2020, AbbVie announced the completion of its acquisition of Allergan. The Company's collaboration, now with AbbVie, for the development and commercialization of linaclotide in North America, and the Company's license, now to AbbVie, to develop and commercialize linaclotide in all countries worldwide other than China (including Hong Kong and Macau) and Japan, remain in effect. Under the Company's collaboration with AbbVie for North America, total net sales of LINZESS in the U.S., as recorded by AbbVie, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between the Company and AbbVie. AbbVie also has an exclusive license from the Company to develop and commercialize linaclotide in all countries other than China (including Hong Kong and Macau), Japan and the countries and territories of North America (the "AbbVie License Territory"). On a country-by-country and product-by-product basis in the AbbVie License Territory, AbbVie pays the Company a royalty as a percentage of net sales of products containing linaclotide as an active ingredient. In addition, AbbVie 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 2018, Astellas began commercializing LINZESS for the treatment of adults with chronic constipation in Japan. In August 2019, the Company amended and restated its license agreement with Astellas. Beginning in 2020, the Company will no longer be responsible for the supply of linaclotide active pharmaceutical ingredient ("API") to Astellas (Note 4).

In October 2012, the Company and AstraZeneca AB (together with its affiliates) ("AstraZeneca") entered into a collaboration agreement to co-develop and co-commercialize linaclotide in China (including Hong Kong and Macau) (the "AstraZeneca License Territory"). In September 2019, the Company amended and restated its existing collaboration agreement with AstraZeneca. As of September 16, 2019, AstraZeneca obtained the exclusive right to develop, manufacture, and commercialize products containing linaclotide in the AstraZeneca License Territory (Note 4). In November 2019, AstraZeneca began commercializing LINZESS for the treatment of adults with IBS-C in China.

The Company and AbbVie are exploring 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 June 2019, the Company announced positive topline data from its Phase IIIb trial demonstrating the efficacy and safety of LINZESS 290 mcg on the overall abdominal symptoms of bloating, pain and discomfort, in adult patients with IBS-C.

The Company also is developing IW-3718, a gastric retentive formulation of a bile acid sequestrant, for the potential treatment of refractory gastroesophageal reflux disease ("refractory GERD"). In June 2018, the Company initiated two Phase III clinical trials evaluating the safety and efficacy of IW-3718 in patients with refractory GERD.

The Company and AbbVie were developing MD-7246, a delayed release formulation of linaclotide. In May 2020, the Company and AbbVie announced top-line data from a Phase II trial evaluating MD-7246 in adult patients with abdominal pain associated with irritable bowel syndrome with diarrhea. The Phase II trial did not meet its primary or key secondary endpoints. Based on these findings, the Company and AbbVie are discontinuing the development of MD-7246.

Additionally, the Company periodically enters into co-promotion agreements to bolster its salesforce productivity. In August 2019, the Company entered into a disease education and promotional agreement with Alnylam Pharmaceuticals, Inc. ("Alnylam") for Alnylam's GIVLAARI™ (givosiran), an RNAi therapeutic targeting aminolevulinic acid synthase 1, for the treatment of acute hepatic porphyria ("AHP"). GIVLAARI was approved by the U.S. FDA in December 2019. Under the agreement, the Company performs disease awareness activities related to AHP and sales detailing activities of GIVLAARI.

The agreements described above, as well as other of the Company's agreements, are more fully described in Note 4, *Collaboration, License, Co-Promotion and Other Commercial Agreements*, to these condensed consolidated financial statements.

On April 1, 2019, Ironwood completed the separation (the "Separation") of its soluble guanylate cyclase ("sGC") business, and certain other assets and liabilities, into Cyclerion Therapeutics, Inc. ("Cyclerion"). The Separation was effected by means of a distribution of all of the outstanding shares of common stock, with no par value, of Cyclerion through a dividend of all outstanding shares of Cyclerion's common stock, to Ironwood's stockholders of record as of the close of business on March 19, 2019 (Note 2).

In August 2019, the Company issued $200.0 million in aggregate principal amount of 0.75% Convertible Senior Notes due 2024 (the "2024 Convertible Notes") and $200.0 million in aggregate principal amount of 1.50% Convertible Senior Notes due 2026 (the "2026 Convertible Notes"). The Company received net proceeds of approximately $391.0 million from the sale of the 2024 Convertible Notes and the 2026 Convertible Notes, after deducting fees and expenses of approximately $9.0 million (Note 8). The proceeds from the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes were used in August 2019 to pay the cost of associated capped call transactions (the "Capped Calls") and to repurchase $215.0 million aggregate principal amount of the existing 2.25% Convertible Senior Notes due 2022 (the "2022 Convertible Notes") and in September 2019 to redeem all of the outstanding principal balance of the 8.375% Notes due 2026.

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, 2019, which was filed with the Securities and Exchange Commission on February 13, 2020 (the "2019 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, 2020, and the results of its operations for the three and six months ended June 30, 2020 and 2019, its statements of stockholders' deficit for the three and six months ended June 30, 2020 and 2019, and its cash flows for the six months ended June 30, 2020 and 2019. The results of operations for the three and six months ended June 30, 2020 and 2019 are not necessarily indicative of the results that may be expected for the full year or any other subsequent interim period.

The Company has presented its sGC business as discontinued operations in its condensed consolidated financial statements for all periods presented (Note 2). For periods following the Separation, the Company continues to report financial results under one business segment.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Ironwood and its wholly-owned subsidiaries as of June 30, 2020, Ironwood Pharmaceuticals Securities Corporation and Ironwood Pharmaceuticals GmbH. Cyclerion was a wholly-owned subsidiary until it became an independent, publicly-traded company on April 1, 2019. All intercompany transactions and balances are eliminated in consolidation.

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles requires the Company's management to make estimates and judgments that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the amounts of revenues and expenses during the reported periods. On an ongoing basis, the Company's management evaluates its estimates, judgments and methodologies. Significant estimates and assumptions in the condensed consolidated financial statements include those related to revenue recognition; accounts receivable; inventory valuation and related reserves; useful lives of long-lived assets; impairment of long-lived assets, including goodwill; valuation procedures for right-of-use assets and operating lease liabilities; valuation procedures for the issuance and repurchase of convertible notes; losses related to discontinued operations; fair value of derivatives; balance sheet classification of convertible notes; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; 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 2019 Annual Report on Form 10-K. During the six months ended June 30, 2020, the Company did not adopt any additional significant accounting policies, except as outlined below.

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, 2020 that had a material effect on its condensed consolidated financial statements.

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments* ("ASU 2019-04"), ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* ("ASU 2019-05"), ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Date*, ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, ASU No. 2020-02, *Financial Instruments—Credit Losses (Topic 326) and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842)* to provide additional guidance on the adoption of ASU 2016-13. ASU 2019-04 added Topic 326, *Financial Instruments—Credit Losses*, and made several amendments to the codification, including modifying the accounting for available-for-sale debt securities. ASU 2019-05 provides targeted transition relief by providing an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. ASU 2016-13 and related amendments are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption was permitted. The Company adopted these ASUs during the three months ended March 31, 2020. The adoption of these ASUs did not have a material impact on the Company's financial position and 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 was permitted. The Company adopted ASU 2017-04 during the three months ended March 31, 2020. The adoption of ASU 2017-04 did not have a material impact on the Company's financial position and results of operations.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirement for Fair Value Measurement* ("ASU 2018-13") which amends the disclosure requirements for fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-13 during the three months ended March 31, 2020. The adoption of ASU 2018-13 did not have a material impact on the Company's financial position, results of operations and financial statement disclosures.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract (a consensus of the FASB Emerging Issues Task Force)* ("ASU 2018-15") which provides guidance on the accounting for costs of implementation activities performed in a cloud computing arrangement that is a service contract. ASU 2015-18 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance to determine which implementation costs to capitalize as assets or expense as incurred. The internal-use software guidance requires that certain costs incurred during the application development stage be capitalized and other costs incurred during the preliminary project and post-implementation stages be expensed as they are incurred. A customer's accounting for the hosting component of the arrangement is not affected by this guidance. The amendments in ASU 2018-15 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-15 using the prospective transition method during the three months ended March 31, 2020. The adoption of ASU 2018-15 did not have a material impact on the Company's financial position and results of operations.

In October 2018, the FASB issued ASU No. 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities* ("ASU 2018-17"). The update is intended to improve general purpose financial reporting by considering indirect interests held through related parties in common control arrangements on a proportional basis for determining whether fees paid to decision makers and service providers are variable interests. The amendments in ASU 2018-17 will be effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted ASU 2018-17 during the three months ended March 31, 2020. The adoption of ASU 2018-17 did not have a material impact on the Company's financial position and results of operations.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 may have on the Company's financial position and results of operations.

No other accounting standards known by the Company to be applicable to it that have been issued by the FASB or other standard-setting bodies and that do not require adoption until a future date are expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

2. Cyclerion Separation

On April 1, 2019, Ironwood completed the Separation of Cyclerion. The Separation was effected by means of a distribution of all of the outstanding shares of common stock, with no par value, of Cyclerion through a dividend of Cyclerion's common stock, to Ironwood's stockholders of record as of the close of business on March 19, 2019. Prior to the Separation on April 1, 2019, Cyclerion was a wholly owned subsidiary of the Company. On March 30, 2019, the Company entered into certain agreements with Cyclerion relating to the Separation, including a separation agreement, a tax matters agreement, and an employee matters agreement.

Agreements with Cyclerion

The separation agreement with Cyclerion, dated as of March 30, 2019, sets forth, among other things, the Company's agreements with Cyclerion regarding the principal actions to be taken in connection with the Separation, including the dividend, which was effective as of April 1, 2019. The separation agreement identifies assets transferred, liabilities assumed by and contracts assigned to each of Cyclerion and Ironwood as part of the Separation, and provides for when and how these transfers, assumptions and assignments occur. The purpose of the separation agreement was to provide Cyclerion and Ironwood with assets to operate their respective businesses and retain or assume liabilities related to those assets.

The transfer of assets and liabilities to Cyclerion was effected through a contribution in accordance with the separation agreement as summarized below (in thousands):

	As of April 1, 2019
Assets:	
Prepaid expenses and other current assets	$ 1,169
Property and equipment, net	10,241
Other assets	21
	$ 11,431
Liabilities:	
Accrued research and development costs	$ 5,673
Accrued expenses and other current liabilities	3,149
	$ 8,822
Net Assets Transferred to Cyclerion	$ 2,609

In addition, the Company received approximately $1.3 million during the year ended December 31, 2019 associated with tenant improvement reimbursement provisions related to the Cyclerion lease in accordance with the separation agreement.

The tax matters agreement, dated as of March 30, 2019, governs each party's rights, responsibilities and obligations with respect to taxes, including taxes, if any, incurred as a result of any failure of the Separation to qualify as tax-free. In general, if the parties incur tax liabilities in the event that the Separation is not tax-free, each party is expected to be responsible for any taxes imposed on Ironwood or Cyclerion that arise from the failure of the Separation to qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, under Sections 355 and 368(a)(1)(D) and certain other relevant provisions of the Internal Revenue Code of 1986, as amended, to the extent that the failure to so qualify is attributable to an acquisition of stock or assets of, or certain actions, omissions or failures to act of, such party. If both Ironwood and Cyclerion are responsible for such failure, liability will be shared according to relative fault. U.S. tax otherwise resulting from the failure of the Separation to qualify as a transaction that is tax-free generally will be the responsibility of Ironwood. Each party otherwise agreed to indemnify the other party from and against any liability for taxes allocated to such party under the tax matters agreement and any taxes resulting from breach of any such party's covenants under the tax matters agreement, the separation agreement, or any ancillary agreement entered into in connection with the Separation. Cyclerion agreed to certain covenants that contain restrictions intended to preserve the tax-free status of the distribution and certain related transactions.

The employee matters agreement, dated as of March 30, 2019, allocates assets, liabilities and responsibilities relating to the employment, compensation, and employee benefits of Ironwood and Cyclerion employees, and other related matters in connection with the Separation, including the treatment of outstanding Ironwood incentive equity awards. Pursuant to the employee matters agreement, the outstanding Ironwood equity awards held by Cyclerion and Ironwood employees were adjusted in connection with the Separation, with the intent to maintain, immediately following the Separation, the economic value of the awards.

Additionally, the Company entered into two transition services agreements and a development agreement with Cyclerion.

Pursuant to the transition service agreements, the Company was obligated to provide and was entitled to receive certain transition services related to corporate functions, such as finance, procurement, facilities and development. Services provided by the Company to Cyclerion were to continue for an initial term of one to two years from the date of

the Separation (as applicable), unless earlier terminated or extended according to the terms of the transition services agreement. Services provided by Cyclerion to the Company continued for a term of one year from the date of the Separation. Services received and performed under each transition services agreement were paid at a mutually agreed upon rate. Amounts received for services provided to Cyclerion were recorded as other income and amounts paid for services provided by Cyclerion were recorded as selling, general and administrative expense and research and development expense, as applicable. The transition services agreements terminated on March 31, 2020. During the three months ended March 31, 2020, the Company recorded an insignificant amount of income as other income for services provided to Cyclerion. During each of the three and six months ended June 30, 2019, the Company recorded an insignificant amount of other income for services provided to Cyclerion. During the three months ended March 31, 2020, the Company recorded an insignificant amount of expense in selling, general and administrative expense for services provided by Cyclerion. During each of the three and six months ended June 30, 2019, the Company recorded an insignificant amount of expense in both selling, general and administrative expense and research and development expense for services provided by Cyclerion.

Pursuant to the development agreement, Cyclerion is obligated to provide the Company with certain research and development services with respect to certain of Ironwood's products and product candidates, including MD-7246 and IW-3718. Such research and development activities are governed by a joint steering committee comprised of representatives from both Cyclerion and Ironwood. Services received are paid at a mutually agreed upon rate. The Company recorded approximately $0.8 million and approximately $1.8 million in research and development expenses under the development agreement during the three and six months ended June 30, 2020, respectively. The Company recorded approximately $1.7 million in research and development expenses under the development agreement during each of the three and six months ended June 30, 2019.

Discontinued Operations

Upon Separation, the Company determined its sGC business qualified for discontinued operations accounting treatment in accordance with Accounting Standards Codification ("ASC") 205-20, *Discontinued Operations*. There were no sGC expenses related to Cyclerion for the six months ended June 30, 2020. The following is a summary of sGC expenses related to Cyclerion for the six months ended June 30, 2019 (in thousands):

	Six months ended June 30, 2019
Costs and expenses:	
Research and development	21,792
Selling, general and administrative	15,646
Net loss from discontinued operations	37,438

There were no assets or liabilities related to discontinued operations as of June 30, 2020 or December 31, 2019, as all balances were transferred to Cyclerion upon Separation.

3. Net Income (Loss) Per Share

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

In June 2015, in connection with the issuance of the 2022 Convertible Notes (Note 8), the Company entered into convertible note hedge transactions ("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 Convertible Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted 2022 Convertible 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 Convertible Notes. 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 sold note hedge warrants ("Note Hedge Warrants"), to the Convertible Note Hedge counterparties to acquire shares of the Company's Class A

Common Stock, subject to customary anti-dilution adjustments (Note 8). 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. The Note Hedge Warrants are not considered for purposes of calculating the number of diluted weighted averages shares outstanding, as their effect would be anti-dilutive.

In August 2019, in connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, the Company entered into the Capped Calls. The Capped Calls are generally expected to reduce the potential dilution to the Company's Class A common stockholders upon a conversion of the 2024 Convertible Notes or the 2026 Convertible Notes and/or offset any cash payments that the Company is required to make in excess of the principal amount of converted 2024 Convertible Notes or 2026 Convertible 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 Capped Calls, is greater than the conversion price of the 2024 Convertible Notes or the 2026 Convertible Notes. The Capped Calls are not considered for purposes of calculating the number of diluted weighted average shares outstanding, as their effect would be anti-dilutive.

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

	Six Months Ended June 30,	
	2020	2019
Options to purchase Class A Common Stock	14,828	19,324
Shares subject to repurchase	174	182
Time-vesting restricted stock units	5,012	2,799
Performance-based restricted stock units	586	—
Note Hedge Warrants	8,318	23,135
2022 Convertible Notes	8,318	23,135
2024 Convertible Notes	14,934	—
2026 Convertible Notes	14,934	—
	67,104	68,575

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

For the three and six months ended June 30, 2020, the Company had linaclotide collaboration agreements with AbbVie for North America and AstraZeneca for China (including Hong Kong and Macau), as well as linaclotide license agreements with Astellas for Japan and with AbbVie for the AbbVie License Territory. The Company also had an agreement with Alnylam to perform disease awareness activities for AHP and sales detailing activities for GIVLAARI. The following table provides amounts included in the Company's condensed consolidated statements of operations as

collaborative arrangements revenue and sale of API primarily attributable to transactions from these arrangements (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
Collaborative Arrangements Revenue	**2020**	**2019**	**2020**	**2019**
Linaclotide Collaboration and License Agreements				
AbbVie (North America)	$ 86,926	$ 75,498	$ 158,618	$ 140,283
AbbVie (Europe and other)	440	262	1,083	682
AstraZeneca (China, including Hong Kong and Macau)	187	—	519	—
Astellas (Japan)	504	—	983	—
Co-Promotion and Other Agreements:				
AbbVie (VIBERZI)[1]	—	1,239	—	1,239
Alnylam (GIVLAARI)	1,061	—	2,006	—
Other	305	323	659	1,270
Total collaborative arrangements revenue	$ 89,423	$ 77,322	$ 163,868	$ 143,474
Sale of API				
Linaclotide Agreements:				
Astellas (Japan)	$ —	$ 24,893	$ —	$ 27,468
AstraZeneca (China, including Hong Kong and Macau)	9	—	5,507	—
Other	—	—	—	3
Total sale of API	$ 9	$ 24,893	$ 5,507	$ 27,471

(1) The Company's agreement with AbbVie to perform sales detailing activities for VIBERZI® (eluxadoline) terminated as of December 31, 2019.

Accounts receivable, net, included approximately $128.4 million related to collaborative arrangements revenue and sale of API, collectively, as of June 30, 2020, including approximately $88.3 million, net of accounts payable of approximately $3.6 million from the Company's partner AbbVie. Accounts receivable, net, included approximately $43.9 million related to collaborative arrangements revenue and sale of API, collectively, as of December 31, 2019.

The Company previously reflected amounts due from Allergan prior to its acquisition by AbbVie as related party accounts receivable. Related party accounts receivable, net, included approximately $110.1 million related to collaborative arrangements revenue, net of approximately $4.1 million related to related party accounts payable to Allergan prior to the transaction with AbbVie, at December 31, 2019. Following acquisition of Allergan by AbbVie, the Company determined that AbbVie is not a related party to the Company (Note 10).

At both June 30, 2020 and December 31, 2019, deferred revenue was approximately $0.9 million related to the disease education and promotional agreement with Alnylam.

The Company routinely assesses the creditworthiness of its license and collaboration partners. The Company has not experienced any material losses related to receivables from its license or collaboration partners.

Linaclotide Agreements

Collaboration Agreement for North America with AbbVie

In September 2007, the Company entered into a collaboration agreement with AbbVie 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 received a non-refundable, upfront licensing fee and shares equally with AbbVie 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. AbbVie 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, 2020, $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. 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.

During the three and six months ended June 30, 2020, the Company incurred approximately $6.2 million and approximately $12.9 million, respectively, in total research and development expenses under the linaclotide collaboration for North America. During the three and six months ended June 30, 2019, the Company incurred approximately $9.6 million and approximately $19.6 million, respectively, in total research and development expenses under the linaclotide collaboration for North America. As a result of the research and development cost-sharing provisions of the linaclotide collaboration for North America, the Company incurred approximately $0.5 million and approximately $1.2 million in research and development costs during the three and six months ended June 30, 2020, respectively, and offset approximately $2.4 million and approximately $5.6 million in incremental research and development costs during the three and six months ended June 30, 2019, respectively, to reflect the obligations of each party under the collaboration to bear half of the development costs incurred.

The Company and AbbVie 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 AbbVie and may include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions.

The Company evaluated its collaboration arrangement for North America with AbbVie under ASC Topic 606, *Revenue from Contracts with Customers* ("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 AbbVie. 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 AbbVie during the commercialization period will be recognized as earned in accordance with the right-to-invoice practical expedient, as the Company's right to consideration corresponds directly with the value of the services transferred during the commercialization period.

Under the Company's collaboration agreement with AbbVie for North America, LINZESS net sales are calculated and recorded by AbbVie and include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions, as noted above. These amounts include the use of estimates and judgments, which could be adjusted based on actual results in the future. 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 less commercial expenses and presents the settlement payments to and from AbbVie as collaboration expense or collaborative arrangements revenue, as applicable. This treatment is in accordance with the Company's revenue recognition policy, given that the Company is not the primary obligor and does not have the inventory risks in the collaboration agreement with AbbVie for North America. The Company relies on AbbVie to provide accurate and complete information related to net sales of LINZESS in accordance with U.S. generally accepted accounting principles in order to calculate its settlement payments to and from AbbVie and record collaboration expense or collaborative arrangements revenue, as applicable.

The Company recognized collaborative arrangements revenue from the AbbVie collaboration agreement for North America during the three and six months ended June 30, 2020 and 2019 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaborative arrangements revenue related to sales of LINZESS in the U.S.	$ 86,503	$ 74,973	$ 157,645	$ 139,267
Royalty revenue	423	525	973	1,016
Total collaborative arrangements revenue	$ 86,926	$ 75,498	$ 158,618	$ 140,283

The collaborative arrangements revenue recognized in the three and six months ended June 30, 2020 and 2019 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 selling, general and administrative costs related to the sale of LINZESS in the U.S. in accordance with the cost-sharing arrangement with AbbVie for the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Selling, general and administrative costs incurred by the Company[1]	$ (3,936)	$ (10,359)	$ (12,610)	$ (20,636)

(1) Excludes an insignificant amount and approximately $0.4 million for the three and six months ended June 30, 2020, respectively, and excludes approximately $0.8 million and approximately $1.3 million for the three and six months ended June 30, 2019, respectively, related to patent prosecution and patent litigation costs recognized in connection with the collaboration agreement with AbbVie for North America.

In May 2014, CONSTELLA became commercially available in Canada and, in June 2014, LINZESS became commercially available in Mexico. The Company records royalties on sales of CONSTELLA in Canada and LINZESS in Mexico in the period earned. The Company recognized approximately $0.4 million and approximately $1.0 million of combined royalty revenues from Canada and Mexico during the three and six months ended June 30, 2020, respectively. The Company recognized approximately $0.5 million and approximately $1.0 million of combined royalty revenues from Canada and Mexico during the three and six months ended June 30, 2019, respectively.

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

In April 2009, the Company entered into a license agreement with Almirall, S.A. ("Almirall") to develop and commercialize linaclotide in Europe (including the Commonwealth of Independent States and Turkey) for the treatment of IBS-C, CIC and other GI conditions (the "European License Agreement"). 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. In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to AbbVie.

Additionally, in October 2015, the Company and AbbVie 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) AbbVie 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 AbbVie for North America.

In January 2017, the Company and AbbVie entered into an amendment to the European License Agreement (the "2017 Amendment"). The 2017 Amendment extended the license to develop and commercialize linaclotide in all countries other than China (including Hong Kong and Macau), Japan, and the countries and territories of North America.

On a country-by-country and product-by-product basis in such additional territory, AbbVie 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. The 2017 Amendment did not modify any of the milestones or royalty terms related to Europe.

In evaluating the terms of the European License Agreement and the 2017 Amendment under ASC 606, the Company determined that there are no remaining performance obligations. 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 and the 2017 Amendment relate predominantly to the license granted to AbbVie. 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 under the sales-based royalty exception. The commercial launch milestones are recognized as revenue when it is probable that a significant reversal of revenue would not occur and the associated constraint has been lifted.

The Company recognized approximately $0.4 million and approximately $1.1 million of royalty revenue from the 2017 Amendment during the three and six months ended June 30, 2020, respectively. The Company recognized approximately $0.3 million and approximately $0.7 million of royalty revenue from the 2017 Amendment during the three and six months ended June 30, 2019, 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 (the "2009 License Agreement with Astellas"). 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 was 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 2009 License Agreement with Astellas, the Company received royalties which escalated based on sales volume, beginning in the low-twenties percent, less the transfer price paid for the API included in the product sold and other contractual deductions.

Under the 2009 License Agreement with Astellas, the Company received an up-front licensing fee of $30.0 million and three development milestone payments that totaled $45.0 million, which were recognized as revenue prior to the adoption of ASC 606 on January 1, 2018.

The Company evaluated the terms of the 2009 License Agreement with Astellas and determined that there were no remaining performance obligations as of the adoption of ASC 606. Additionally, under the terms of the Astellas Commercial Supply Agreement, the Company determined it had an ongoing performance obligation to supply API.

During the three and six months ended June 30, 2019, the Company recognized approximately $24.9 million and approximately $27.5 million, respectively, from the sale of API to Astellas under the 2009 License Agreement with Astellas and the Astellas Commercial Supply Agreement. The royalties on sales of LINZESS in Japan did not exceed the transfer price of API sold and other contractual deductions during each of the periods presented.

In August 2019, the Company and Astellas amended and restated the 2009 License Agreement with Astellas (the "Amended Astellas License Agreement"). This amendment was a modification to the 2009 License Agreement with Astellas and was accounted for as a new and separate contract. Under the terms of the Amended Astellas License Agreement, the Company will no longer be responsible for the supply of linaclotide API to Astellas, and Astellas will be responsible for its own supply of linaclotide API in Japan beginning in 2020.

In connection with the execution of the Amended Astellas License Agreement, Astellas paid the Company a non-refundable upfront payment of $10.0 million in August 2019. Further, beginning in 2020, Astellas, in lieu of the

royalty payment terms set forth in the 2009 License Agreement with Astellas, is required to pay royalties to the Company at rates beginning in the mid-single digit percent and escalating to low-double-digit percent, based on aggregate annual net sales in Japan of products containing linaclotide API. These royalty payments will be subject to reduction following the expiration of certain licensed patents and the occurrence of generic competition in Japan. The Company continued to supply linaclotide API for Japan during 2019 at a contractually defined rate. Additionally, Astellas reimbursed the Company for the Company's performance of adverse event reporting services at a fixed monthly rate until such services were terminated in February 2020.

The Company identified the following performance obligations under the Amended Astellas License Agreement:

- delivery of the expanded license of intellectual property, including the applicable manufacturing know-how;
- obligation to supply linaclotide API for 2019; and
- adverse event reporting services.

The Company allocated the $10.0 million upfront payment to the delivery of the expanded license of intellectual property and recognized it as collaborative arrangements revenue at contract inception. The Company allocated the approximately $20.4 million in remaining purchase orders for API to the obligation to supply linaclotide API to Astellas for 2019. Consideration for the supply of linaclotide API is recognized over the performance period as linaclotide API is shipped to Astellas using an output method. Consideration allocated to the adverse event reporting services is recognized as such services are provided over the performance period based on the amount to which the Company has a right to invoice using an output method.

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.

The Company recognized approximately $0.5 million and approximately $1.0 million in collaborative arrangements revenue during the three and six months ended June 30, 2020, respectively, under the Amended Astellas License Agreement, of which approximately $0.5 million and approximately $0.9 million related to royalties, respectively.

Collaboration Agreement for China (including Hong Kong and Macau) with AstraZeneca

In October 2012, the Company entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in the AstraZeneca License Territory (the "AstraZeneca Collaboration Agreement"). The collaboration provided AstraZeneca with an exclusive nontransferable license to exploit the underlying technology in the AstraZeneca License Territory. The parties shared 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. In September 2019, the Company and AstraZeneca entered into an amendment and restatement of the AstraZeneca Collaboration Agreement (the "Amended AstraZeneca Agreement") under which AstraZeneca obtained the exclusive right to develop, manufacture and commercialize products containing linaclotide in the AstraZeneca License Territory (the "AstraZeneca License").

Prior to the execution of the Amended AstraZeneca Agreement, the Company identified the following performance obligations under the AstraZeneca Collaboration Agreement:

- research, development and regulatory services pursuant to the development plan ("R&D Services");
- Joint Development Committee ("JDC") services;
- obligation to supply clinical trial material; and
- Joint Commercialization Committee services.

Under the original AstraZeneca Collaboration Agreement, the Company shared development costs with AstraZeneca, with AstraZeneca incurring 55% of the net losses from the development and commercialization of

linaclotide in the AstraZeneca License Territory. 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 AstraZeneca License Territory were recorded as a reduction in expense. Development costs incurred by the Company that pertained to the joint development plan and subsequent amendments to the joint development plan, as approved by the JDC, were recorded as research and development expense as incurred. Payments to AstraZeneca were recorded as incremental research and development expense.

During the three and six months ended June 30, 2019, the Company incurred no costs and offset an insignificant amount of costs related to R&D Services and JDC services, respectively, under the AstraZeneca Collaboration Agreement. During the three and six months ended June 30, 2019, the Company recognized no revenue and an insignificant amount of revenue, respectively, related to the sale of linaclotide drug product and API under the AstraZeneca Collaboration Agreement. Additionally, the Company incurred approximately $0.3 million and approximately $0.5 million in costs related to pre-launch commercial services and supply chain services during the three and six months ended June 30, 2019, respectively.

Under the Amended AstraZeneca Agreement, the Company will receive non-contingent payments totaling $35.0 million in three installments through 2024. In addition, AstraZeneca may be required to make milestone payments totaling up to $90.0 million contingent on the achievement of certain sales targets and will be required to pay tiered royalties to the Company at rates beginning in the mid-single-digit percent and increasing up to twenty percent based on the aggregate annual net sales of products containing linaclotide in the AstraZeneca License Territory. In connection with the Amended AstraZeneca Agreement, the Company and AstraZeneca entered into a transition services agreement ("AstraZeneca TSA") and an amended commercial supply agreement ("AstraZeneca CSA"). Under the terms of the AstraZeneca TSA, the Company will provide certain regulatory and administrative services for a term of approximately two years from the date of execution, unless earlier terminated or extended according to the terms of the transition services agreement. Services performed are paid at a mutually agreed upon rate. Amounts for AstraZeneca TSA services are recorded as collaborative arrangements revenue. Under the terms of the AstraZeneca CSA, the Company supplied linaclotide API, finished drug product and finished goods for the Licensed Territory through March 31, 2020 at predetermined rates.

The Company evaluated the Amended AstraZeneca Agreement in accordance with ASC 606 and determined that it would be accounted for 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 Amended AstraZeneca Agreement were identified:

- delivery of the expanded AstraZeneca License;
- AstraZeneca TSA services; and
- supply of linaclotide API, finished drug product and finished goods under the AstraZeneca CSA.

The Company determined that the non-contingent payments should be allocated to the delivery of the AstraZeneca License. The non-contingent payments totaling $35.0 million will be paid in installments through 2024. The Company determined that the performance obligation related to the transfer of the AstraZeneca License was satisfied as of the execution date of the Amended AstraZeneca Agreement. As a portion of the payments relating to the transfer of the AstraZeneca License are due significantly after the performance obligation was satisfied, the Company adjusted its transaction price for the significant financing component of approximately $2.6 million. Accordingly, the Company recognized approximately $32.4 million relating to the delivery of the AstraZeneca License as collaborative arrangements revenue at contract inception and will recognize the approximately $2.6 million relating to the significant financing component as interest income through 2024 using the effective interest method. Consideration allocated to the AstraZeneca TSA services will be recognized as collaborative arrangements revenue as such services are provided over the performance period using an output method based on the amount to which the Company has a right to invoice. Consideration for the supply of linaclotide API, finished drug product and finished goods under the AstraZeneca CSA was recognized over the performance period using an output method as linaclotide API, finished drug product and finished goods are shipped to AstraZeneca.

During the three and six months ended June 30, 2020, the Company recognized approximately $0.2 million and approximately $0.4 million, respectively, in collaborative arrangements revenue under the Amended AstraZeneca Agreement related to the AstraZeneca TSA services. During the three and six months ended June 30, 2020, the Company recognized an insignificant amount and approximately $0.2 million, respectively, in collaborative arrangements revenue under the Amended AstraZeneca Agreement related to royalties. During the three and six months ended June 30, 2020,

the Company recognized an insignificant amount and approximately $5.5 million, respectively, of sale of API on its condensed consolidated statement of operations relating to the supply of linaclotide finished drug product and finished goods, under the AstraZeneca CSA. The Company recognized approximately $0.2 million and approximately $0.4 million, respectively, in interest income related to the significant financing component of the Amended AstraZeneca Agreement during the three and six months ended June 30, 2020.

Co-Promotion Agreements

Disease Education and Promotional Agreement with Alnylam

In August 2019, the Company and Alnylam entered into a disease education and promotional agreement for Alnylam's GIVLAARI (the "Alnylam Agreement"). GIVLAARI was approved by the U.S. FDA in December 2019 for the treatment of adult patients with AHP. Under the terms of the agreement, the Company's sales force is performing disease awareness activities and sales detailing activities for GIVLAARI to gastroenterologists and health care practitioners to whom they detail LINZESS in the first position.

The Company is entitled to receive service fees, payable by Alnylam quarterly, totaling up to $9.5 million over the term of the agreement, which is approximately three years from execution. The Company also is eligible to receive a royalty based on a percentage of net sales of GIVLAARI that are directly attributable to the Company's promotional efforts. The Company identified the following performance obligation under the Alnylam Agreement:

- performance of disease education activities for AHP and performance of sales details for GIVLAARI (together "Givosiran Education and Promotion Activities").

The Company allocated the service fees to the performance of Givosiran Education and Promotion Activities and recognizes collaborative arrangements revenue over the term of the agreement as the services are performed using an output method based on the amount to which the Company has a right to invoice. Royalties will be recognized as collaborative arrangements revenue using an output method for Givosiran Education and Promotion Activities based on the amount to which the Company has a right to invoice when the associated constraints have been lifted.

During the three and six months ended June 30, 2020, the Company recognized approximately $1.1 million and approximately $2.0 million, respectively in collaborative arrangements revenue, of which approximately $0.9 million and approximately $1.8 million, respectively, related to the service fees and approximately $0.2 million and approximately $0.2 million, respectively, related to royalties. At both June 30, 2020 and December 31, 2019, the Company had a deferred revenue balance of approximately $0.9 million related to advance billings of service fees.

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 up to $18.0 million for regulatory milestones, none of which had been paid as of June 30, 2020. Pursuant to the terms of another license agreement, the Company recognized no collaborative arrangements revenue during the three months ended June 30, 2019 and recognized approximately $0.5 million in collaborative arrangements revenue during the six months ended June 30, 2019, related to a nonrefundable upfront payment. The Company is eligible to receive up to $63.5 million in development and sales-based milestones, as well as royalties as a percentage of net sales of a product, under the terms of this agreement. 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, 2020 and 2019.

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, 2020 and December 31, 2019 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 may include 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 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, 2020	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	$ 238,230	$ 238,230	$ —	$ —
Restricted cash:				
Money market funds	2,221	2,221	—	—
Convertible Note Hedges	16,131	—	—	16,131
Total assets measured at fair value	$ 256,582	$ 240,451	$ —	$ 16,131
Liabilities:				
Note Hedge Warrants	$ 12,958	$ —	$ —	$ 12,958
Total liabilities measured at fair value	$ 12,958	$ —	$ —	$ 12,958

		Fair Value Measurements at Reporting Date Using		
	December 31, 2019	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	$ 139,190	$ 139,190	$ —	$ —
Repurchase agreements	37,800	37,800	—	—
Restricted cash:				
Money market funds	2,221	2,221	—	—
Convertible Note Hedges	31,366	—	—	31,366
Total assets measured at fair value	$ 210,577	$ 179,211	$ —	$ 31,366
Liabilities:				
Note Hedge Warrants	$ 24,260	$ —	$ —	$ 24,260
Total liabilities measured at fair value	$ 24,260	$ —	$ —	$ 24,260

There were no transfers between fair value measurement levels during each of the three and six months ended June 30, 2020 or 2019.

Cash equivalents, accounts receivable, related party accounts receivable, prepaid expenses and other current assets, accounts payable, related party accounts payable, accrued research and development costs, accrued expenses and other current liabilities, deferred revenue and current portion of operating lease obligations at June 30, 2020 and December 31, 2019 are carried at amounts that approximate fair value due to their short-term maturities.

Convertible Note Hedges and Note Hedge Warrants with Respect to 2022 Convertible Notes

The Company's Convertible Note Hedges and the Note Hedge Warrants are recorded as derivative assets and liabilities, respectively, and are classified as Level 3 measurements 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, 2020 included the price per share of the Company's Class A Common Stock, expected terms of the derivative instruments, strike prices of the derivative instruments, risk-free interest rates, and expected volatility of the Company's Class A Common Stock. 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, 2020 and December 31, 2019:

	Six Months Ended June 30, 2020		Year Ended December 31, 2019	
	Convertible Note Hedges	Note Hedge Warrants	Convertible Note Hedges	Note Hedge Warrants
Risk-free interest rate [1]	0.2 %	0.2 %	1.6 %	1.6 %
Expected term	2.0	2.5	2.5	3.0
Stock price [2]	$ 10.32	$ 10.32	$ 13.31	$ 13.31
Strike price [3]	$ 14.51	$ 18.82	$ 14.51	$ 18.82
Common stock volatility [4]	54.4 %	52.7 %	49.1 %	46.5 %
Dividend yield [5]	— %	— %	— %	— %

(1) Based on U.S. Treasury yield curve, with terms commensurate with the expected 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 days of the quarters ended June 30, 2020 and December 31, 2019, respectively.
(3) As per the respective agreements for the Convertible Note Hedges and Note Hedge Warrants.
(4) Expected volatility based on historical volatility of the Company's Class A Common Stock.
(5) 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.

The Convertible Note Hedges and the Note Hedge Warrants are recorded at fair value at each reporting date and changes in fair value are recorded in other (expense) income, 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 Hedges and Note Hedge Warrants from December 31, 2019 through June 30, 2020 (in thousands):

	Convertible Note Hedges	Note Hedge Warrants
Balance at December 31, 2019	$ 31,366	$ (24,260)
Change in fair value, recorded as a component of (loss) gain on derivatives	(15,235)	11,302
Balance at June 30, 2020	$ 16,131	$ (12,958)

Convertible Senior Notes

In June 2015, the Company issued approximately $335.7 million aggregate principal amount of its 2022 Convertible Notes. In August 2019, the Company issued $200.0 million aggregate principal amount of its 2024 Convertible Notes and $200.0 million aggregate principal amount of its 2026 Convertible Notes and used a portion of the proceeds from such issuances to repurchase $215.0 million aggregate principal amount of its 2022 Convertible Notes. The Company separately accounted for the liability and equity components of each of the 2022 Convertible Notes, 2024 Convertible Notes, and 2026 Convertible Notes by allocating the proceeds between the liability component and equity component (Note 8). The fair value of the respective convertible senior 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 respective convertible senior notes observed in market trading, which are Level 2 inputs.

The estimated fair value of the 2022 Convertible Notes was approximately $126.4 million and approximately $141.3 million as of June 30, 2020 and December 31, 2019, respectively. The estimated fair value of the 2024 Convertible Notes was approximately $206.0 million and approximately $235.7 million as of June 30, 2020 and December 31, 2019, respectively. The estimated fair value of the 2026 Convertible Notes was approximately $206.3 million and approximately $240.1 million as of June 30, 2020 and December 31, 2019, respectively.

Capped Calls with Respect to 2024 Convertible Notes and 2026 Convertible Notes

In connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, the Company entered into the Capped Calls with certain financial institutions. The Capped Calls cover 29,867,480 shares of Class A Common Stock (subject to anti-dilution and certain other adjustments), which is the same number of shares of Class A Common Stock that initially underlie the 2024 Convertible Notes and the 2026 Convertible Notes. The Capped Calls have an initial strike price of approximately $13.39 per share, which corresponds to the initial conversion price of the 2024 Convertible Notes and the 2026 Convertible Notes, and have a cap price of approximately $17.05 per share (Note 8). The strike price and cap price are subject to anti-dilution adjustments generally similar to those applicable to the 2024 Convertible Notes and the 2026 Convertible Notes. These instruments meet the conditions outlined in ASC Topic 815, *Derivatives and Hedging* ("ASC 815") to be classified in stockholders' deficit and are not subsequently remeasured as long as the conditions for equity classification continue to be met.

6. Accrued Expenses and Other Current Liabilities

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

	June 30, 2020	December 31, 2019
Accrued incentive compensation	$ 5,522	$ 11,760
Accrued vacation	3,484	2,540
Salaries	2,662	2,973
Professional fees	2,313	1,421
Other employee benefits	1,072	1,260
Accrued interest	301	301
Other	2,601	10,210
	$ 17,955	$ 30,465

As of June 30, 2020, other accrued expenses of approximately $2.6 million included approximately $1.0 million related to sales and marketing projects and approximately $0.8 million related to information technology service contracts.

As of December 31, 2019, other accrued expenses of approximately $10.2 million included approximately $4.1 million related to API batches yet to be invoiced, approximately $0.9 million related to activities associated with the Company's move to the 100 Summer Street headquarters, approximately $0.6 million related to unbilled inventory, and approximately $0.2 million related to equipment for clinical studies.

7. Leases

Effective January 1, 2019, the Company adopted ASC 842, *Leases*, using the optional transition method. The Company's lease portfolio for the three and six months ended June 30, 2020 includes: leases for its current headquarters location, a data center colocation lease, vehicle leases for its salesforce representatives, and leases for computer and office equipment.

Lease cost is recognized on a straight-line basis over the lease term. The components of lease cost for the three and six months ended June 30, 2020 and 2019 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease cost during period[1]	$ 633	$ 3,155	$ 1,266	$ 7,680
Variable lease payments	360	654	732	654
Short-term lease cost	—	379	—	768
Total lease cost	$ 993	$ 4,188	$ 1,998	$ 9,102

(1) Operating lease cost is presented net of approximately $0.3 million of sublease income for each of the three and six months ended June 30, 2019. Sublease income relates to a sublease agreement between Ironwood and Cyclerion executed upon the Separation. The sublease agreement terminated in May 2019.

Supplemental cash flow information related to leases for the periods reported is as follows:

	Six Months Ended June 30,	
	2020	2019
Right-of-use assets obtained in exchange for new operating lease upon adoption of ASC 842 (in thousands)	$ —	$ 88,299
Adjustment to right-of-use assets as a result of the lease modification at the Separation date (in thousands)	—	(40,427)
Adjustment to right-of-use assets as a result of the termination of the Binney Street Lease (in thousands)	—	(34,440)
Right-of-use assets obtained in exchange for new operating lease liabilities[1] (in thousands)	—	18,452
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	86	6,619
Weighted-average remaining lease term of operating leases (in years)	9.7	7.9
Weighted-average discount rate of operating leases	5.8 %	5.3 %

(1) Relates to right-of-use assets and operating lease liabilities for the Summer Street Lease (as defined below).

Future minimum lease payments under non-cancelable operating leases as of June 30, 2020 are as follows (in thousands):

	Operating Lease Payments
2020[1]	$ 1,060
2021	3,128
2022	3,129
2023	3,065
2024	3,126
2025 and thereafter	18,044
Total future minimum lease payments	31,552
Less: present value adjustment	(7,731)
Operating lease liabilities at June 30, 2020	23,821
Less: current portion of operating lease liabilities	(2,610)
Operating lease liabilities, net of current portion	$ 21,211

(1) For the six months ending December 31, 2020.

Summer Street Lease (current headquarters)

On June 11, 2019, the Company entered into a non-cancelable operating lease (the "Summer Street Lease") for approximately 39,000 square feet of office space on the 23rd floor of 100 Summer Street, Boston, Massachusetts (the "Summer Street Property"). The Summer Street Property began serving as the Company's headquarters in October 2019, replacing its prior headquarters at 301 Binney Street in Cambridge, Massachusetts. The Summer Street Lease terminates on June 11, 2030 and includes an option to extend the term of the lease for an additional five years at a market base rental rate, a 2% annual rent escalation, free rent periods, and a tenant improvement allowance. The rent expense for the Summer Street Property, inclusive of the escalating rent payments and lease incentives, is recognized on a straight-line basis over the lease term. Additionally, the Summer Street Lease requires a letter of credit to secure the Company's obligations under the lease agreement of approximately $1.0 million, which is collateralized by a money market account recorded as non-current restricted cash on the Company's condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019.

At lease inception, the Company recorded a right-of-use asset and a lease liability using an incremental borrowing rate of approximately 5.8%. At June 30, 2020, the balances of the right-of-use asset and operating lease liability were approximately $17.2 million and approximately $23.5 million, respectively. At December 31, 2019, the balances of the right-of-use asset and operating lease liability were approximately $17.7 million and approximately $22.8 million, respectively.

Lease cost related to the Summer Street Lease recorded during the three and six months ended June 30, 2020 was approximately $0.7 million and approximately $1.3 million, respectively. Lease cost related to the Summer Street Lease recorded during each of the three and six months ended June 30, 2019 was approximately $0.2 million.

Binney Street Lease (prior headquarters)

The Company rented office space at 301 Binney Street, Cambridge, Massachusetts ("Binney Street Property") under a non-cancelable operating lease, entered into in January 2007, as amended ("Binney Street Lease") through October 2019. The Binney Street Property previously served as the Company's headquarters and was replaced by the Summer Street Property in October 2019, as discussed above.

On April 1, 2019, the Company modified its lease with BMR-Rogers Street LLC ("Binney Street Landlord"), to reduce its leased premises to approximately 108,000 rentable square feet of office space on the first and third floors. The surrendered portion of approximately 114,000 rentable square feet on the first and second floor of the building was then occupied by Cyclerion under a direct lease between Cyclerion and the Binney Street Landlord. As a result of the modification, the Company adjusted the value of its right-of-use asset and operating lease liability using an incremental borrowing rate of approximately 5.1%, and recognized a gain of approximately $3.2 million, which was recorded as a reduction to operating expenses on its condensed consolidated statement of operations. The Company elected to

determine the proportionate reduction in the right-of-use asset based on the reduction to the lease liability and will apply that methodology consistently to all comparable future modifications that decrease the scope of the lease.

On June 11, 2019, the Company entered into a lease termination agreement (the "Lease Termination") with the Binney Street Landlord to terminate the Company's lease for approximately 108,000 square feet of office space. The Lease Termination was effective during the fourth quarter of 2019 in exchange for an approximately $9.0 million payment to the Binney Street Landlord. The Company determined that the Lease Termination would be accounted for as a lease modification that reduces the term of the existing lease. As a result of this modification, the Company adjusted the value of its right-of-use asset and operating lease liability using an incremental borrowing rate of approximately 4.0%.

Lease cost related to the Binney Street Lease recorded during the three and six months ended June 30, 2019 was approximately $3.6 million and approximately $8.0 million, respectively, net of sublease income of approximately $0.3 million in each period.

Data center colocation lease

The Company rents space for its data center at a colocation in Boston, Massachusetts under a non-cancelable operating lease (the "Data Center Lease"). The Data Center Lease includes a 4% annual rent escalation. The rent expense, inclusive of the escalating rent payments, is recognized on a straight-line basis over the lease term through August 2022. The Company recorded a right-of-use asset of approximately $0.6 million and a lease liability of approximately $0.6 million associated with the Data Center Lease upon adoption of ASC 842. The incremental borrowing rate for the outstanding Data Center Lease obligation upon adoption of ASC 842 was approximately 6.0%. During the three months ended March 31, 2019, the Company migrated its data management process to a cloud-based services system, rendering its current data center technology and assets obsolete. As a result, the Company considered the right-of-use asset associated with the Data Center Lease to be fully impaired. The Company recorded a charge of approximately $0.5 million to selling, general, and administrative expenses on its condensed consolidated statement of operations as a result of the impairment during the three months ended March 31, 2019.

At June 30, 2020 and December 31, 2019, the lease liability associated with the Data Center Lease was approximately $0.4 million and approximately $0.4 million, respectively.

Costs related to the Data Center Lease were insignificant for each of the three and six months ended June 30, 2020 and 2019, respectively.

Vehicle fleet leases

During April 2018, the Company entered into a master services agreement containing 12-month leases (the "2018 Vehicle Leases") for vehicles within its fleet for its field-based sales force and medical science liaisons. These leases are classified as short-term in accordance with the practical expedient in ASC 842. The 2018 Vehicle Leases expire at varying times beginning in June 2019, with a monthly renewal provision. In accordance with the terms of the 2018 Vehicle Leases, the Company maintains a letter of credit securing its obligation under the lease agreements of $1.3 million, which is collateralized by a money market account recorded as current restricted cash on the Company's condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019.

Lease cost related to the 2018 Vehicle Leases was approximately $0.4 million and approximately $0.7 million for the three and six months ended June 30, 2020, respectively. Lease cost related to the 2018 Vehicle Leases was approximately $0.4 million and approximately $0.8 million for the three and six months ended June 30, 2019, respectively.

8. Notes Payable

2.25% Convertible Senior Notes due 2022

In June 2015, the Company issued approximately $335.7 million aggregate principal amount of the 2022 Convertible Notes. The Company received net proceeds of approximately $324.0 million from the sale of the 2022 Convertible 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 Convertible 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 Convertible Notes are governed by an indenture (the "2022 Indenture") between the Company and U.S. Bank National Association, as trustee (the "Trustee"). The 2022 Convertible 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 Convertible Notes will mature on June 15, 2022, unless earlier converted or repurchased. The Company may settle conversions of the 2022 Convertible 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 2022 Indenture). The initial conversion rate for the 2022 Convertible Notes was 60.3209 shares of Class A Common Stock (subject to adjustment as provided for in the 2022 Indenture) per $1,000 principal amount of the 2022 Convertible Notes, which was equal to an initial conversion price of approximately $16.58 per share and 20,249,665 shares.

In connection with the Separation in April 2019, the conversion rate under the 2022 Indenture was adjusted to equal 68.9172 shares of Ironwood Class A Common Stock per $1,000 principal amount of the 2022 Convertible Notes, which is equal to an adjusted conversion price of approximately $14.51 per share and 23,135,435 shares.

Holders of the 2022 Convertible Notes may convert their 2022 Convertible 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 Convertible 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 2022 Indenture) per $1,000 principal amount of the 2022 Convertible 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 Convertible Notes on each such trading day; or

- upon the occurrence of specified corporate events described in the 2022 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 Convertible 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 2022 Indenture, occurs and a holder elects to convert its 2022 Convertible 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 2022 Indenture. The Company may not redeem the 2022 Convertible Notes prior to the maturity date and no "sinking fund" is provided for by the 2022 Convertible Notes, which means that the Company is not required to periodically redeem or retire the 2022 Convertible Notes. Upon the occurrence of certain fundamental changes involving the Company, holders of the 2022 Convertible Notes may require the Company to repurchase for cash all or part of their 2022 Convertible Notes at a repurchase price equal to 100% of the principal amount of the 2022 Convertible Notes to be repurchased, plus accrued and unpaid interest.

The 2022 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 2022 Indenture provides for customary events of default. In the case of an event of default with respect to the 2022 Convertible Notes arising from specified events of bankruptcy or insolvency, all outstanding 2022 Convertible Notes will become due and payable immediately without further action or notice. If any other event of default with respect to the 2022 Convertible Notes under the 2022 Indenture occurs or is continuing, the Trustee or holders of at least 25% in aggregate principal amount of the then outstanding 2022 Convertible Notes may declare the principal amount of the 2022 Convertible Notes to be immediately due and payable.

Notwithstanding the foregoing, the 2022 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 2022 Indenture consists exclusively of the right to receive additional interest on the 2022 Convertible 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 Convertible 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 Convertible 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 Convertible Notes was recognized as a debt discount and represents the difference between the gross proceeds from the issuance of the 2022 Convertible Notes and the fair value of the liability component of the 2022 Convertible 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 expected life of the 2022 Convertible Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

In connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes in August 2019, the Company repurchased $215.0 million aggregate principal amount of the 2022 Convertible Notes. The 2022 Convertible Notes were repurchased at a premium totaling approximately $227.3 million. The Company recognized a loss on extinguishment of debt of approximately $23.4 million during the year ended December 31, 2019 related to the premium and proportional write-off of the 2022 Convertible Notes unamortized debt issuance costs and unamortized debt discount. Additionally, the repurchase resulted in a reduction to additional paid-in capital of approximately $27.0 million during the year ended December 31, 2019 related to the equity component of the 2022 Convertible Notes.

0.75% Convertible Senior Notes due 2024 and 1.50% Convertible Senior Notes due 2026

In August 2019, the Company issued $200.0 million aggregate principal amount of the 2024 Convertible Notes and $200.0 million aggregate principal amount of the 2026 Convertible Notes. The Company received net proceeds of approximately $391.0 million from the sale of the 2024 Convertible Notes and 2026 Convertible Notes, after deducting fees and expenses of approximately $9.0 million. The Company used approximately $25.2 million of the net proceeds from the sale of the 2024 Convertible Notes and 2026 Convertible Notes to pay the cost of the Capped Calls, as described below. For purposes of this section, "Notes" refer to the 2024 Convertible Notes and the 2026 Convertible Notes, collectively.

The 2024 Convertible Notes and 2026 Convertible Notes were issued by the Company on August 12, 2019, pursuant to separate Indentures, each dated as of such date (each an "Indenture" and together the "Indentures"), between the Company and the Trustee. The 2024 Convertible Notes bear cash interest at the annual rate of 0.75% and the 2026 Convertible Notes bear cash interest at the annual rate of 1.50%, each payable on June 15 and December 15 of each year, which began on December 15, 2019. The 2024 Convertible Notes will mature on June 15, 2024 and the 2026 Convertible Notes will mature on June 15, 2026, unless earlier converted or repurchased. The Company will settle conversions of the 2024 Convertible Notes and 2026 Convertible 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 applicable Indenture). The initial conversion rate for each of the 2024 Convertible Notes and the 2026 Convertible Notes is 74.6687 shares of Class A Common Stock (subject to adjustment as provided for in the applicable Indenture) per $1,000 principal amount of the 2024 Convertible Notes and 2026 Convertible Notes, which is equal to an initial conversion price of approximately $13.39 per share, representing a conversion premium of approximately 37.5% above the last reported sale price of Class A Common Stock of $9.74 per share on August 7, 2019.

Holders of the 2024 Convertible Notes and 2026 Convertible Notes may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding December 15, 2023, with respect to

the 2024 Convertible Notes, and December 15, 2025, with respect to the 2026 Convertible Notes, in multiples of $1,000 principal amount, only under the following circumstances:

- during any calendar quarter commencing after the calendar quarter ending on December 31, 2019 (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 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 each Indenture) per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of Class A Common Stock and the conversion rate for the Notes on each such trading day; or

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

On or after December 15, 2023, with respect to the 2024 Convertible Notes, and December 15, 2025, with respect to the 2026 Convertible Notes, until the close of business on the second scheduled trading day immediately preceding the applicable maturity date, the holders of the Notes may convert their Notes, in multiples of $1,000 principal amount, regardless of the foregoing conditions.

If the Company experiences a make-whole fundamental change, as described in the Indentures, prior to the maturity date of the respective Notes, holders of such Notes will, subject to specified conditions, have the right, at their option, to require the Company to repurchase for cash all or a portion of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but not including, the fundamental change repurchase date. In addition, following certain corporate events that occur prior to the applicable maturity date of the Notes, the Company will increase the conversion rate for a holder who elects to convert its Notes in connection with such corporate event.

The Indentures do 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 Indentures provide for customary events of default. In the case of an event of default with respect to a series of Notes arising from specified events of bankruptcy or insolvency, all outstanding Notes of such series will become due and payable immediately without further action or notice. If any other event of default with respect to a series of Notes under the relevant Indenture occurs or is continuing, the Trustee or holders of at least 25% in aggregate principal amount of the then outstanding Notes of such series may declare the principal amount of such Notes to be immediately due and payable. Notwithstanding the foregoing, the Indentures provide 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 Indentures consists exclusively of the right to receive additional interest on the 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 2024 Convertible Notes and the 2026 Convertible Notes by allocating the proceeds between the liability components and the embedded conversion options, or equity components, due to the Company's ability to settle the 2024 Convertible Notes and the 2026 Convertible 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 respective liability components were 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 respective equity components of the 2024 Convertible Notes and the 2026 Convertible Notes were recognized as a debt discount and represent the difference between the gross proceeds from the issuance of the 2024 Convertible Notes and 2026 Convertible Notes and the fair value of the liability of the 2024 Convertible Notes and 2026 Convertible 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 approximately five and seven years, or the expected life of the 2024 Convertible Notes and the 2026 Convertible Notes, respectively. The respective equity components are not remeasured as long as they continue to meet the conditions for equity classification.

The Company's outstanding balances for the convertible senior notes as of June 30, 2020 and December 31, 2019 consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Liability component:		
Principal:		
2022 Convertible Notes	$ 120,699	$ 120,699
2024 Convertible Notes	200,000	200,000
2026 Convertible Notes	200,000	200,000
Less: unamortized debt discount	(94,475)	(104,700)
Less: unamortized debt issuance costs	(7,300)	(8,005)
Net carrying amount	$ 418,924	$ 407,994
Equity component:		
2022 Convertible Notes	19,807	19,807
2024 Convertible Notes	41,152	41,152
2026 Convertible Notes	51,350	51,350
Total equity component	$ 112,309	$ 112,309

In connection with the issuance of the 2022 Convertible 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 upon issuance. 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 condensed consolidated balance sheet and are amortized to interest expense using the effective interest method over the expected life of the 2022 Convertible Notes. In connection with the partial repurchase of the 2022 Convertible Notes, the Company recorded a loss on extinguishment of debt of approximately $23.4 million, of which approximately $2.8 million related to the initial debt issuance costs, during the year ended December 31, 2019.

The Company determined the expected life of the 2022 Convertible Notes was equal to their seven-year term. From the date of the partial repurchase of the 2022 Convertible Notes in August 2019 through June 30, 2020, the effective interest rate on the liability component of the 2022 Convertible Notes was 9.6%.

In connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, the Company incurred approximately $9.0 million of debt issuance costs, which primarily consisted of initial purchaser's 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 $2.1 million were recorded as a reduction to additional paid-in capital. The portion of these costs allocated to the liability components totaling approximately $6.9 million were recorded as a reduction in the carrying value of the debt on the condensed consolidated balance sheet and are amortized to interest expense using the effective interest method over the expected life of the 2024 Convertible Notes and the 2026 Convertible Notes.

The Company determined the expected life of the 2024 Convertible Notes and the 2026 Convertible Notes was equal to their approximately five and seven-year terms, respectively. The effective interest rates on the liability

components of the 2024 Convertible Notes and the 2026 Convertible Notes for the period from the date of issuance through June 30, 2020 was 6.2% and 6.5%, respectively.

The following table sets forth total interest expense recognized related to convertible senior notes during the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Contractual interest expense	$ 1,802	$ 1,889	$ 3,609	$ 3,777
Amortization of debt issuance costs	360	283	705	555
Amortization of debt discount	5,156	4,164	10,224	8,239
Total interest expense	$ 7,318	$ 6,336	$ 14,538	$ 12,571

Future minimum payments under the convertible senior notes as of June 30, 2020 are as follows (in thousands):

2020[1]	$ 3,608
2021	7,216
2022	126,556
2023	4,500
2024	203,750
2025	3,000
2026 and Thereafter	201,500
Total future minimum payments under the convertible senior notes	550,130
Less: amounts representing interest	(29,431)
Less: unamortized debt discount	(94,475)
Less: unamortized debt issuance costs	(7,300)
Convertible senior notes balance	$ 418,924

(1) For the six months ending December 31, 2020.

Convertible Note Hedge and Note Hedge Warrant Transactions with Respect to 2022 Convertible Notes

To minimize the impact of potential dilution to the Company's Class A common stockholders upon conversion of the 2022 Convertible 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 Convertible Notes. The Convertible Note Hedges had an initial exercise price of $16.58 per share, subject to adjustment upon the occurrence of certain corporate events or transactions, and are exercisable if the 2022 Convertible Notes are converted. In connection with the adjustment to the conversion rate of the 2022 Convertible Notes related to the Separation in April 2019, the exercise price of the Convertible Note Hedges was adjusted to $14.51 per share and the number of shares underlying the Convertible Note Hedges was increased to 23,135,435 shares. If upon conversion of the 2022 Convertible 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 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 was initially $21.50 per share, subject to adjustment, and such warrants are exercisable over the 150 trading day period beginning on September 15, 2022. In connection with the Separation in April 2019, the exercise price was adjusted to $18.82 per share and the number of shares underlying the Note Hedge Warrants was increased to 23,135,435 shares. 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 Convertible Notes. Holders of the Convertible Note Hedges and the Note Hedge Warrants do not have any rights with respect to the 2022 Convertible Notes. The Company paid approximately $91.9 million for the Convertible Note Hedges and recorded this amount as a long-term asset on its 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.

In August 2019, concurrently with the repurchase of $215.0 million aggregate principal amount of the 2022 Convertible Notes, the Company terminated the respective portion of the Convertible Note Hedges and Note Hedge Warrants. The Company received approximately $3.2 million of termination payments from the counterparties of the Convertible Note Hedges and Note Hedge Warrants during the year ended December 31, 2019.

The Convertible Note Hedges and Note Hedge Warrants are accounted for as derivative assets and liabilities, respectively, in accordance with ASC 815.

Capped Calls with Respect to 2024 Convertible Notes and 2026 Convertible Notes

To minimize the impact of potential dilution to the Company's Class A common stockholders upon conversion of the 2024 Convertible Notes and the 2026 Convertible Notes, the Company entered into separate Capped Calls in connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes. The Company paid the counterparties approximately $25.2 million to enter into the Capped Calls.

The Capped Calls have an initial strike price of approximately $13.39 per share, which corresponds to the initial conversion price of the 2024 Convertible Notes and the 2026 Convertible Notes and is subject to anti-dilution adjustments generally similar to those applicable to the 2024 Convertible Notes and the 2026 Convertible Notes. The Capped Calls have a cap price of approximately $17.05 per share, representing an approximately 75% premium over the last reported sale price of the Class A Common Stock as of August 7, 2019, which cap price is subject to certain adjustments under the terms of the Capped Calls. The Capped Calls cover 29,867,480 shares of Class A Common Stock (subject to anti-dilution and certain other adjustments), which is the same number of shares of Class A Common Stock that initially underlie the 2024 Convertible Notes and the 2026 Convertible Notes.

The Capped Calls are expected generally to reduce the potential dilution to the Class A Common Stock upon conversion of the 2024 Convertible Notes and the 2026 Convertible Notes in the event that the market price per share of Class A Common Stock, as measured under the terms of the Capped Calls, is greater than the strike price of the Capped Calls as adjusted pursuant to the anti-dilution adjustments. If, however, the market price per share of Class A Common Stock as measured under the terms of the Capped Calls, exceeds the cap price of the Capped Calls, there would nevertheless be dilution upon conversion of the 2024 Convertible Notes and the 2026 Convertible Notes to the extent that such market price exceeds the cap price of the Capped Calls.

The Capped Calls are separate transactions entered into by and between the Company and the Capped Calls counterparties and are not part of the terms of the 2024 Convertible Notes or the 2026 Convertible Notes. Holders of the 2024 Convertible Notes and the 2026 Convertible Notes do not have any rights with respect to the Capped Calls. The Company recorded a reduction to additional paid-in capital of approximately $25.0 million during the year ended December 31, 2019 related to the premium payments for the Capped Calls. Additionally, the Company recorded an approximately $0.2 million reduction to equity related to transaction costs incurred in connection with the Capped Calls during the year ended December 31, 2019. These instruments meet the conditions outlined in ASC 815 to be classified in stockholders' deficit and are not subsequently remeasured as long as the conditions for equity classification continue to be met.

9. Employee Stock Benefit Plans

The Company has several share-based compensation plans under which stock options, restricted stock awards, restricted stock units and other share-based awards are available for grant to employees, officers, directors and consultants of the Company.

The following table summarizes share-based compensation expense (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 1,405	$ 1,179	$ 2,801	$ 4,098
Selling, general and administrative	5,686	5,021	10,654	15,519
Restructuring expenses	—	137	—	654
	$ 7,091	$ 6,337	$ 13,455	$ 20,271

In February 2019, following further analysis of the Company's strategy and core business needs, and in an effort to further strengthen the operational efficiency of the organization, the Company commenced a reduction in workforce by approximately 35 employees, primarily based in the home office. Certain share-based payment awards were modified in connection with the reduction in workforce. As a result of the modifications, the Company recorded an insignificant amount of share-based compensation expense and approximately $0.7 million to restructuring expenses for the three and six months ended June 30, 2019, respectively.

In April 2019, in connection with the Separation, all outstanding share-based payment awards were modified in accordance with the equity conversion-related provisions of the employee matters agreement with Cyclerion. No share-based compensation expense was recognized in connection with the modifications. Additionally, modifications with respect to the Company's Employee Stock Purchase Plan ("ESPP") were made due to the change in share price as a result of the Separation. As a result of the modification to the ESPP, the Company recorded share-based compensation expense of approximately $0.3 million during each of the three and six months ended June 30, 2019.

In connection with certain other modifications of share-based payment awards for the six months ended June 30, 2020, the Company recognized an insignificant amount in share-based compensation expense. In connection with certain other modifications of share-based payment awards during the three and six months ended June 30, 2019, the Company recognized no expense and approximately $2.4 million in share-based compensation expense.

10. Related Party Transactions

In May 2020, AbbVie announced the completion of its acquisition of Allergan. The Company's collaboration, now with AbbVie, for the development and commercialization of linaclotide in North America, and the Company's license, now to AbbVie, to develop and commercialize linaclotide in all countries worldwide other than China (including Hong Kong and Macau) and Japan, remain in effect. Under the collaboration agreement, the Company and AbbVie equally support the development and commercialization of linaclotide (Note 4).

The Company previously reflected amounts due to and due from Allergan prior to its acquisition by AbbVie as related party accounts payable and related party accounts receivable, respectively. Following the acquisition of Allergan by AbbVie, the Company determined that AbbVie is not a related party to the Company. As such, only historical amounts paid to and received from Allergan (prior to its acquisition by AbbVie) are considered related party accounts payable and related party accounts receivable, respectively. Balances of related party accounts payable and related party accounts receivable, respectively, were reported net of any balances due to or from the related party. As of December 31, 2019, the Company had approximately $106.0 million in related party accounts receivable, net of related party accounts payable, associated with Allergan, (prior to its acquisition by AbbVie).

In connection with the Separation, the Company executed certain contracts with Cyclerion whose President and Chief Scientific Officer became a member of the Company's Board of Directors in April 2019 (Note 2). As of June 30, 2020, the Company had approximately $0.8 million of accounts payable due to Cyclerion. As of December 31, 2019, the Company had an insignificant amount of accounts receivable and approximately $1.5 million of accounts payable due from and to Cyclerion, respectively. The transition services agreements with Cyclerion terminated on March 31, 2020.

11. Workforce Reduction

On February 7, 2019, following analysis of the Company's strategy and core business needs, and in an effort to further strengthen the operational efficiency of the organization, the Company commenced a reduction in workforce by approximately 35 employees, primarily based in the home office. During the three and six months ended June 30, 2019,

the Company recorded approximately $0.5 million and approximately $3.8 million, respectively, of costs including employee severance, benefits, and related costs that are reflected in the condensed consolidated statement of operations as restructuring expenses.

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 gastrointestinal, or GI, healthcare company dedicated to advancing the treatment of GI diseases and redefining the standard of care for millions of GI patients. We are focused on the development and commercialization of innovative GI product opportunities in areas of large unmet need, leveraging our demonstrated expertise and capabilities in GI diseases.

LINZESS® (linaclotide), our commercial product, is the first product approved by the United States Food and Drug Administration, or U.S. FDA in a class of GI medicines called guanylate cyclase type C agonists, and is indicated for adult men and women suffering from irritable bowel syndrome with constipation, or IBS-C, or chronic idiopathic constipation, or CIC. LINZESS is available 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 and China. 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.

In May 2020, AbbVie Inc. (together with its affiliates), or AbbVie, (successor to Allergan plc (together with its affiliates), or Allergan) announced the completion of its acquisition of Allergan. Our collaboration, now with AbbVie, for the development and commercialization of linaclotide in North America, and our license, now to AbbVie, to develop and commercialize linaclotide in all countries worldwide other than China (including Hong Kong and Macau) and Japan, remain in effect.

We have strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world, including with AbbVie in the U.S., AstraZeneca AB (together with its affiliates), or AstraZeneca, in China (including Hong Kong and Macau) and Astellas Pharma Inc., or Astellas, in Japan.

We are also developing IW-3718, a gastric retentive formulation of a bile acid sequestrant for the potential treatment of refractory gastroesophageal reflux disease, or refractory GERD. In June 2018, we initiated two Phase III clinical trials evaluating the safety and efficacy of IW-3718 in patients with refractory GERD. In line with new U.S. FDA guidance on statistical considerations for trials impacted by COVID-19, we stopped enrollment of study subjects into one of our two Phase III clinical trials for IW-3718 to conduct an early efficacy assessment. We are continuing to enroll patients in the other Phase III clinical trial for IW-3718.

We and AbbVie were developing MD-7246, a delayed release formulation of linaclotide, as an oral, intestinal, non-opioid, pain-relieving agent for patients with abdominal pain associated with certain GI diseases. In May 2020, we and AbbVie announced top-line data from a Phase II trial evaluating MD-7246 in adult patients with abdominal pain associated with irritable bowel syndrome with diarrhea, or IBS-D. The Phase II trial did not meet its primary or key secondary endpoints. Based on these findings, we and AbbVie are discontinuing the development of MD-7246.

We are also leveraging our leading capabilities in GI to bring additional treatment options to GI patients. This includes our U.S. disease education and promotional agreement with Alnylam Pharmaceuticals, Inc., or Alnylam, for

Alnylam's GIVLAARI™ (givosiran), an RNAi therapeutic targeting aminolevulinic acid synthase 1, for the treatment of acute hepatic porphyria.

In January 2020, we and AbbVie entered into settlement agreements with Sandoz Inc. and Teva Pharmaceuticals, USA resolving patent litigation brought in response to the last outstanding abbreviated new drug applications seeking approval to market generic versions of LINZESS prior to the expiration of our and AbbVie's applicable patents.

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, as well as to the research and development of our other product candidates. Prior to the year ended December 31, 2019 when we recorded net income for the year of approximately $21.5 million, we incurred net losses in each year since our inception in 1998. For the three and six months ended June 30, 2020, we recorded net income of approximately $25.2 million and approximately $28.5 million, respectively. As of June 30, 2020, we had an accumulated deficit of approximately $1.5 billion. We are unable to predict the extent of any future losses or guarantee that our company will be able to maintain positive cash flows.

On April 1, 2019, we completed the separation, or the Separation, of our soluble guanylate cyclase, or sGC, business, and certain other assets and liabilities, into a separate, independent publicly traded company, Cyclerion Therapeutics, Inc., or Cyclerion. The Separation was effected by means of a distribution of all of the outstanding shares of common stock, with no par value, of Cyclerion, through a dividend of Cyclerion's common stock to our stockholders of record as of the close of business on March 19, 2019. The Separation is more fully described in Note 2, *Cyclerion Separation*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

In August 2019, we issued $200.0 million in 0.75% Convertible Senior Notes due 2024, or the 2024 Convertible Notes, and $200.0 million in 1.50% Convertible Senior Notes due 2026, or the 2026 Convertible Notes. We received net proceeds of approximately $391.0 million from the sale of the 2024 Convertible Notes and the 2026 Convertible Notes, after deducting fees and expenses of approximately $9.0 million.

The proceeds from the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes were used in August 2019 to pay approximately $25.2 million related to the associated capped call transactions, or the Capped Calls, and to repurchase $215.0 million aggregate principal amount of the existing 2.25% Convertible Senior Notes due 2022, or the 2022 Convertible Notes. The proceeds from the issuance of the 2024 Convertible Notes and 2026 Convertible Notes were also used to redeem the outstanding principal balance of the 8.375% Notes due 2026, or the 2026 Notes, in September 2019. We retired the 2026 Notes, which had an outstanding aggregate principal balance of approximately $116.5 million, for a redemption price of approximately $123.0 million. During the year ended December 31, 2019, we recognized a loss on extinguishment of debt of approximately $31.0 million related to the redemption of the 2026 Notes and the partial repurchase of the 2022 Convertible Notes. In connection with the partial repurchase of the 2022 Convertible Notes, we also terminated the respective portion of our existing convertible note hedges transactions, or the Convertible Note Hedges, and the respective portion of our existing warrants, or the Note Hedge Warrants, which we had entered into in June 2015 in connection with our issuance of the 2022 Convertible Notes. These transactions are more fully described in Note 8, *Notes Payable*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

In December 2019, a novel strain of coronavirus, or COVID-19, emerged in Wuhan, Hubei Province, China. On March 11, 2020, the World Health Organization declared a global pandemic and recommended containment and mitigation measures worldwide. On March 13, 2020, U.S. President Donald Trump announced a national emergency relating to the pandemic. There continues to be significant uncertainty surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations. During the three and six months ended June 30, 2020, the COVID-19 pandemic resulted in changes to our business and operations which impacted our financial condition and results of operations, as more fully described below in *Trends and Uncertainties*. The COVID-19 pandemic may have a material adverse impact on our business and our financial condition in the future.

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. 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 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) education or 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. 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. Through September 16, 2019, the date of the amended and restated AstraZeneca Collaboration Agreement, or the Amended AstraZeneca Agreement, we received our share of the net profits or bore our share of the net losses from the development and sale of linaclotide in 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 AbbVie 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 AbbVie 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.

Cost of Revenues. Cost of revenues primarily includes costs associated with linaclotide API and finished drug product related to collaborative arrangements revenue and sale of API. Cost related to the sales of linaclotide API and finished drug product are recognized upon shipment of linaclotide API and finished 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 finished drug product for certain of our partners outside of the U.S.

Research and Development Expense. Research and development expense consists of expenses incurred in connection with the research into and development of 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 AbbVie for the U.S. and, prior to the execution of the Amended AstraZeneca Agreement in September 2019, AstraZeneca for China (including Hong Kong and Macau), we were reimbursed for certain research and development activities and we netted these reimbursements against our research and development expenses as incurred. Amounts owed to AbbVie on an ongoing basis, or AstraZeneca prior to the execution of the Amended AstraZeneca Agreement, under our respective collaboration agreements were recorded as incremental research and development expense.

The core of our research and development strategy is to leverage our demonstrated expertise and capabilities in GI diseases to bring multiple medicines to patients. We are developing innovative product opportunities in areas of large unmet need, including IBS-C and CIC, and refractory GERD.

Linaclotide. Our commercial product, linaclotide, is available to adult men and women suffering from IBS-C or CIC in certain countries around the world. LINZESS is commercially available in the U.S. for the treatment of IBS-C or CIC in adults. Linaclotide also is approved and commercially available in China, Japan and in a number of E.U. and other countries.

We and AbbVie continue 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 January 2017, the U.S. FDA approved a 72 mcg dose of LINZESS for adults with CIC, which became available in the U.S. in March 2017. In June 2019, we announced positive topline data from our Phase IIIb trial demonstrating the efficacy and safety of linaclotide 290 mcg on the overall abdominal symptoms of bloating, pain and discomfort in adult patients with IBS-C. We submitted a Supplemental New Drug Application to the U.S. FDA in November 2019 to seek a more comprehensive description of the effects of LINZESS on its approved label.

We and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients. Clinical pediatric programs in IBS-C and functional constipation are currently ongoing.

IW-3718. We are developing IW-3718, a gastric retentive formulation of a bile acid sequestrant, for the potential treatment of refractory 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 refractory 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 refractory GERD. In June 2018, we initiated two Phase III clinical trials evaluating the safety and efficacy of IW-3718 in patients with refractory GERD.

The COVID-19 pandemic has impacted enrollment of new patients into the Phase III clinical trials with IW-3718. Most of the clinical trial sites were not screening new patients during the second quarter due to the suspension of in-person procedures required to enroll patients and lower patient participation compared to pre-COVID levels. In line with new U.S. FDA guidance on statistical considerations for trials impacted by COVID-19, we stopped enrollment of study subjects into one of our two Phase III clinical trials for IW-3718 to conduct an early efficacy assessment. Many clinical sites have now resumed screening new patients in our ongoing clinical trial for IW-3718; however, enrollment continues to be slower than prior to the COVID-19 pandemic. The impact of COVID-19 on our clinical trials with IW-3718 is more fully described below in *Trends and Uncertainties.*

MD-7246. We and AbbVie were developing MD-7246, a delayed release formulation of linaclotide. MD-7246 was designed to have the pain-relieving effect of linaclotide with minimal impact on bowel function. In May 2020, we and AbbVie announced top-line data from a Phase II trial evaluating MD-7246 in adult patients with abdominal pain associated with IBS-D. The Phase II trial did not meet its primary or key secondary endpoints. Based on these findings, we and AbbVie are discontinuing the development of MD-7246.

Early research and development. After the Separation, our early research and development efforts have been focused on supporting our development stage GI programs, including exploring strategic options for further development of certain of our internal programs, as well as evaluating potential external development stage GI programs.

The following table sets forth our research and development expenses related to our product pipeline for the three and six months ended June 30, 2020 and 2019. 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,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Linaclotide[1]	$ 6,362	$ 8,284	$ 14,149	$ 18,147
Lesinurad[2]	—	155	—	371
IW-3718	13,629	18,562	32,522	35,464
Early research and development	2,085	1,757	3,432	6,974
Total research and development expenses	$ 22,076	$ 28,758	$ 50,103	$ 60,956

(1) Includes linaclotide in all indications, populations and formulations.
(2) Includes lesinurad in all indications, populations and formulations.

Since 2004, the date we began tracking costs by program, we have incurred approximately $515.8 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 AbbVie for the U.S. and AstraZeneca for China (including Hong Kong and Macau), prior to the execution of the Amended AstraZeneca Agreement in August 2019, 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 U.S. FDA approval of LINZESS, we were required to conduct certain nonclinical and clinical studies including those aimed at further understanding the safety profile of linaclotide. We and AbbVie completed such additional studies and determined that: (a) orally administered linaclotide was not detected in breast milk, (b) there is little or no evidence of any potential for antibodies to be developed to linaclotide, and (c) there were no signs or symptoms of an immunogenic response to linaclotide. The results observed do not alter the known safety profile for linaclotide based on the clinical studies and post-marketing experience to-date. In addition, we and AbbVie established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the efficacy and safety of LINZESS in pediatric patients. Clinical pediatric programs in IBS-C and functional constipation are currently ongoing.

We and AbbVie 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. 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.

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 U.S. 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 early research and development, including 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; and
- 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 to invest in our development programs for the foreseeable future. We will continue to invest in linaclotide, including the investigation of ways to enhance the clinical profile within its currently approved indications, and the exploration of its potential utility in other indications, populations and formulations. We will also continue to invest in our other GI-focused product candidates as we advance them through clinical trials, in addition to funding 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 legal costs of pursuing patent protection of our intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting, tax, consulting, legal and other 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.

Prior to the execution of the Amended AstraZeneca Agreement in September 2019, we were reimbursed for certain selling, general and administrative expenses and we netted these reimbursements against our selling, general and administrative expenses as incurred. AstraZeneca is responsible for all costs and expenses incurred to develop, manufacture and commercialize products containing linaclotide in territories pursuant to the Amended AstraZeneca Agreement.

We include AbbVie'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 AbbVie as collaboration expense or collaborative arrangements revenue, respectively.

Restructuring Expenses. We record costs and liabilities associated with exit and disposal activities in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations*, or ASC 420. Such costs are based on estimates of fair value in the period the liabilities are incurred in accordance with ASC 420. We evaluate and adjust these liabilities 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 convertible senior notes. Non-cash interest expense consists of amortization of the debt discount and debt issuance costs associated with the convertible senior notes. We amortize these costs using the effective interest rate method over the expected life of the respective note agreements as interest expense in our condensed consolidated statements of operations.

Interest and investment income consists of interest earned on our cash and cash equivalents as well as significant financing components identified under ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606.

(Loss) gain 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. The Convertible Note Hedges and Note Hedge Warrants are more fully described in Note 8, *Notes Payable*, to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Discontinued Operations. We have recast all 2019 historical expenses directly associated with our sGC business as discontinued operations in accordance with ASC Subtopic 250-20, *Discontinued Operations*. For additional information refer to Note 2, *Cyclerion Separation*, 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; accounts receivable; inventory valuation and related reserves; useful lives of long-lived assets; impairment of long-lived assets, including goodwill; valuation procedures for right-of-use assets and operating lease liabilities; valuation procedures for the issuance and repurchase of convertible notes; losses related to discontinued operations; fair value of derivatives; balance sheet classification of convertible notes; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; 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.

During the three and six months ended June 30, 2020, 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, 2019, which was filed with the Securities and Exchange Commission on February 13, 2020, or the 2019 Annual Report on Form 10-K.

Results of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Revenues:				
Collaborative arrangements revenue	$ 89,423	$ 77,322	$ 163,868	$ 143,474
Sale of active pharmaceutical ingredient	9	24,893	5,507	27,471
Total revenues	89,432	102,215	169,375	170,945
Cost and expenses:				
Cost of revenues	—	11,313	2,239	12,356
Research and development	22,076	28,758	50,103	60,956
Selling, general and administrative	34,643	43,246	71,093	92,341
Gain on lease modification	—	(3,169)	—	(3,169)
Restructuring expenses	—	490	—	3,818
Total cost and expenses	56,719	80,638	123,435	166,302
Income from operations	32,713	21,577	45,940	4,643
Other (expense) income:				
Interest expense	(7,318)	(9,430)	(14,538)	(19,022)
Interest and investment income	276	668	1,053	1,404
(Loss) gain on derivatives	(467)	(672)	(3,933)	3,272
Other income	—	140	27	140
Other expense, net	(7,509)	(9,294)	(17,391)	(14,206)
Net income (loss) from continuing operations	25,204	12,283	28,549	(9,563)
Net loss from discontinued operations	—	—	—	(37,438)
Net income (loss)	$ 25,204	$ 12,283	$ 28,549	$ (47,001)

Three and six months ended June 30, 2020 compared to three and six months ended June 30, 2019

Revenues

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)				(dollars in thousands)			
Revenues:								
Collaborative arrangements revenue	$ 89,423	$ 77,322	$ 12,101	16 %	$ 163,868	$ 143,474	$ 20,394	14 %
Sale of active pharmaceutical ingredient	9	24,893	(24,884)	(100)%	5,507	27,471	(21,964)	(80)%
Total revenues	$ 89,432	102,215	(12,783)	(13)%	169,375	170,945	(1,570)	(1)%

Collaborative Arrangements Revenue. The increase in revenue from collaborative arrangements of approximately $12.1 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily related to an approximately $11.5 million increase in our share of the net profits from the sale of LINZESS in the U.S. driven by increased prescription demand and lower collaboration-related selling expenses due to the COVID-19 pandemic and an approximately $0.8 million increase in royalty revenue. These increases were partially offset by an approximately $0.4 million decrease in co-promotion revenue.

The increase in revenue from collaborative arrangements of approximately $20.4 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily related to an approximately $18.4 million increase in our share of the net profits from the sale of LINZESS in the U.S. driven by increased prescription demand and lower collaboration-related selling expenses due to the COVID-19 pandemic; an approximately $1.6 million increase in royalty revenue; and an approximately $0.5 million increase in co-promotion revenue. These increases were partially offset by a $0.5 million decrease in upfront payments received in connection with a license agreement executed in the first half of 2019.

Sale of Active Pharmaceutical Ingredient. The decrease in sale of API of approximately $24.9 million for the three months ended June 30, 2020, compared to the three months ended June 30, 2019, was primarily due to an approximately $24.9 million decrease in sales of API to Astellas in Japan.

The decrease in sale of API of approximately $22.0 million for the six months ended June 30, 2020, compared to the six months ended June 30, 2019, respectively, was primarily due to an approximately $27.5 million decrease in sales of API to Astellas in Japan, offset by an approximately $5.5 million increase in sales of API, drug product, and finished goods to AstraZeneca in China.

Cost and Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)				(dollars in thousands)			
Cost and expenses:								
Cost of revenues	$ —	$ 11,313	$ (11,313)	(100)%	$ 2,239	$ 12,356	$ (10,117)	(82)%
Research and development	22,076	28,758	(6,682)	(23)%	50,103	60,956	(10,853)	(18)%
Selling, general and administrative	34,643	43,246	(8,603)	(20)%	71,093	92,341	(21,248)	(23)%
Gain on lease modification	—	(3,169)	3,169	(100)%	—	(3,169)	3,169	(100)%
Restructuring expenses	—	490	(490)	(100)%	—	3,818	(3,818)	(100)%
Total cost and expenses	$ 56,719	$ 80,638	$ (23,919)	(30)%	$ 123,435	$ 166,302	$ (42,867)	(26)%

Cost of Revenue. The decrease of approximately $11.3 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was related to a decrease in cost of revenues as a result of a decrease in linaclotide API sales to Astellas in Japan. The decrease of approximately $10.1 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily related to an approximately $12.3 million decrease in cost of revenues as a result of a decrease in linaclotide API sales to Astellas in Japan, offset by an approximately $2.2 million increase in cost of revenues related to sales of API, drug product, and finished goods to AstraZeneca in China.

Research and Development Expense. The decrease in research and development expense of approximately $6.7 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily related to a decrease of approximately $6.0 million in external development costs related to IW-3718; a decrease of approximately $0.9 million in operating expenses, including facilities and IT-related costs; and a decrease of approximately $0.7 million in research costs related to our early research and development efforts. These decreases were partially offset by an increase of approximately $1.2 million in compensation, benefits and other employee-related expenses.

The decrease in research and development expense of approximately $10.9 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily related to a decrease of approximately $4.9 million in external development costs related to IW-3718; a decrease of $2.5 million in facilities and operating costs due to change in headquarters location; a decrease of approximately $2.3 million in compensation, benefits and other employee-related expenses; a decrease of approximately $1.1 million in research costs related to our early research and development efforts; and a decrease of approximately $0.8 million in IT-related costs. These decreases were partially offset by an increase of approximately $1.1 million related to linaclotide development.

Selling, General and Administrative Expense. Selling, general and administrative expenses decreased approximately $8.6 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. The approximately $8.6 million decrease in selling, general and administrative expense included an approximately $5.6 million decrease in costs associated with the Separation which was completed on April 1, 2019, and an approximately $3.0 million decrease in non-Separation costs. The approximately $5.6 million decrease in Separation costs includes an approximately $2.1 million decrease in compensation, benefits, and employee-related expenses; an approximately $1.4 million decrease in facilities costs primarily due to our change in headquarters location; an approximately $1.2 million decrease in consulting and investment banking costs; and an approximately $0.9 million decrease in legal costs. The approximately $3.0 million decrease in non-Separation costs includes an approximately $1.9 million decrease in legal costs; an approximately $1.8 million decrease in sales and marketing programs; and an approximately $1.6 million decrease in facilities costs. These decreases in non-Separation costs were partially offset by an approximately $1.7 million increase in compensation, benefits and employee-related expenses and an approximately $0.9 million increase in consulting costs.

Selling, general and administrative expenses decreased approximately $21.2 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The decrease of approximately $21.2 million was primarily due to decreases in non-Separation costs of approximately $11.2 million and an approximately $10.0 million decrease in costs associated with the Separation. The approximately $11.2 million decrease in non-Separation costs includes an approximately $3.2 million decrease in other compensation, benefits and employee-related expenses; an approximately $2.8 million decrease in facilities and other operating costs primarily due to our change in headquarters location; an approximately $2.8 million decrease in legal costs; and approximately $1.7 million decrease in post-marketing requirements for lesinurad as a result of our termination of the license agreement with AstraZeneca for the development, manufacture, and commercialization of products in the U.S. containing lesinurad as a an active ingredient; and an approximately $1.2 million decrease in sales and marketing programs. The approximately $10.0 million decrease in costs associated with the Separation includes an approximately $6.0 million decrease in compensation, benefits, and employee-related expenses; an approximately $1.9 million decrease in facilities costs; an approximately $1.2 million decrease in consulting and investment banking costs; and an approximately $0.9 million decrease in legal costs.

Gain on Lease Modification. The gain on lease modification of approximately $3.2 million for each of the three and six months ended June 30, 2019 was due to the modification of the Binney Street Lease in 2019 in connection with the Separation.

Restructuring Expenses. The decrease in restructuring expenses of approximately $0.5 million and approximately $3.8 million, respectively, for the three and six months ended June 30, 2020 compared to the three and six months ended June 30, 2019 was due to costs associated with the workforce reduction that occurred in February 2019.

Other (Expense) Income, Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2020	2019	$	%	2020	2019	$	%
	(dollars in thousands)				(dollars in thousands)			
Other (expense) income:								
Interest expense	$ (7,318)	$ (9,430)	$ 2,112	(22)%	$ (14,538)	$ (19,022)	$ 4,484	(24)%
Interest and investment income	276	668	(392)	(59)%	1,053	1,404	(351)	(25)%
(Loss) gain on derivatives	(467)	(672)	205	(31)%	(3,933)	3,272	(7,205)	(220)%
Other income	—	140	(140)	(100)%	27	140	(113)	(81)%
Total other expense, net	$ (7,509)	$ (9,294)	$ 1,785	(19)%	$ (17,391)	$ (14,206)	$ (3,185)	22 %

Interest Expense. Interest expense decreased by approximately $2.1 million during the three months ended June 30, 2020 compared to the three months ended June 30, 2019, due to a decrease of approximately $3.9 million in interest expense related to the 2022 Convertible Notes and a decrease of approximately $3.1 million in interest expense associated with the 2026 Notes that were fully redeemed in September 2019, partially offset by an increase of approximately $2.5 million in interest expense associated with the 2024 Convertible Notes and an increase of approximately $2.4 million in interest expense associated with the 2026 Convertible Notes.

For the six months ended June 30, 2020 compared to the six months ended June 30, 2019 interest expense decreased by approximately $4.5 million due to a decrease of approximately $7.7 million in interest expense related to the 2022 Convertible Notes and a decrease of approximately $6.5 million in interest expense associated with the 2026 Notes that were fully redeemed in September 2019, partially offset by an increase of approximately $4.9 million in interest expense associated with the 2024 Convertible Notes and an increase of approximately $4.8 million in interest expense associated with the 2026 Convertible Notes.

Interest and Investment Income. Interest and investment income decreased by approximately $0.4 million in the three months ended June 30, 2020 compared to the three months ended June 30, 2019, resulting primarily from a decrease in investment income of approximately $0.6 million due to lower investment interest rates, partially offset by an increase in interest income of $0.2 million related to the significant financing component of long-term receivables.

For the six months ended June 30, 2020 compared to the six months ended June 30, 2019, interest and investment income decreased by approximately $0.4 million resulting primarily from a decrease in investment income of

approximately $0.8 million due to lower investment interest rates, partially offset by an increase in interest income of approximately $0.4 million due to the significant financing component of long-term receivables.

(Loss) Gain on Derivatives. For the three months ended June 30, 2020, we recorded a loss on derivatives of approximately $0.5 million resulting from an approximately $0.3 million increase in the fair value of the Convertible Note Hedges and an approximately $0.8 million increase in the fair value of the Note Hedge Warrants. For the three months ended June 30, 2019, we recorded a loss on derivatives of approximately $0.7 million resulting from an approximately $10.1 million increase in the fair value of the Convertible Note Hedges and an approximately $10.8 million increase in the fair value of the Note Hedge Warrants.

For the six months ended June 30, 2020, we recorded a loss on derivatives of approximately $3.9 million resulting from an approximately $15.2 million decrease in the fair value of the Convertible Note Hedges and an approximately $11.3 million decrease in the fair value of the Note Hedge Warrants. For the six months ended June 30, 2019, we recorded a gain on derivatives of approximately $3.3 million resulting from an approximately $19.7 million increase in the fair value of the Convertible Note Hedges and an approximately $16.4 million increase in the fair value of the Note Hedge Warrants.

Other Income. Other income decreased by an insignificant amount during each of the three and six months ended June 30, 2020 compared to the three and six months ended June 30, 2019 due to income related to a transition service agreement with Cyclerion.

Net Loss from Discontinued Operations

There was no net loss from discontinued operations for each of the three and six months ended June 30, 2020. There was no net loss from discontinued operations for the three months ended June 30, 2019, and net loss from discontinued operations was approximately $37.4 million for the six months ended June 30, 2019. For additional information on discontinued operations, see Note 2, *Cyclerion Separation*, to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Liquidity and Capital Resources

As of June 30, 2020, we had approximately $253.3 million of unrestricted cash and cash equivalents. Our cash equivalents include amounts held in money market funds. 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 AA- rated, with a remaining final maturity when purchased of less than twenty-four months, so as to achieve liquidity and capital preservation objectives.

During the six months ended June 30, 2020, our balances of cash and cash equivalents increased by approximately $76.2 million. Net cash provided by operating activities totaled approximately $63.7 million as a result of decreases in the cash required to operate our business, including payments related to, among other things, research and development, and selling, general and administrative expenses. Additionally, cash provided by financing activities totaled approximately $14.4 million in proceeds from the exercise of stock options. These cash inflows were partially offset by approximately $1.8 million in capital expenditures.

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.

The COVID-19 pandemic is disrupting the U.S. healthcare system, as well as global capital markets. There continues to be significant uncertainty surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations. The COVID-19 pandemic could have a material adverse impact on our financial condition and results of operations in the future, including by impacting our ability to obtain financing. The impact of COVID-19 on our business and financial condition is more fully described below in *Trends and Uncertainties*.

Sources of Liquidity

Until the year ended December 31, 2019, we had incurred losses since our inception in 1998 and, as of June 30, 2020, we had an accumulated deficit of approximately $1.5 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, 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 up-front 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 Convertible Notes in June 2015, and approximately $391.0 million of net proceeds from the private placement of our 2024 Convertible Notes and 2026 Convertible Notes in August 2019.

Funding Requirements

We began commercializing LINZESS in the U.S. with our collaboration partner, AbbVie, in December 2012, and we currently derive a significant portion of our revenue from this collaboration. In addition, we are deploying significant resources to advance product opportunities in IBS-C and CIC and refractory GERD, as well as to fulfill U.S. FDA requirements for linaclotide. We have also historically derived revenue from the sale of linaclotide API to Astellas for Japan; beginning in 2020, however, we will no longer be responsible for the supply of linaclotide API to Astellas. Our goal is to generate and maintain positive cash flows, driven by increased revenue generated through sales of LINZESS and other commercial activities and financial discipline.

Under our collaboration with AbbVie for North America, total net sales of LINZESS in the U.S., as recorded by AbbVie, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between us and AbbVie. Additionally, we receive royalties from AbbVie 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 AbbVie 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 generate positive cash flows, 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. and other markets, develop and commercialize other products, and invest in our pipeline and potentially other external opportunities. We believe that our cash on hand as of June 30, 2020 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, obtain regulatory approval for, and commercialize linaclotide in the U.S. and other markets, as well as our expectations regarding revenue from Astellas for Japan and AstraZeneca for China (including Hong Kong and Macau) and our goal to generate and maintain positive cash flows, 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 and CONSTELLA and from any other sources;
- the rate of progress and cost of our commercialization activities, including the expense we incur in marketing and selling LINZESS in the U.S. and from any other sources;
- 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.

Trends and Uncertainties

Impact of the COVID-19 Pandemic

In December 2019, COVID-19 emerged in Wuhan, Hubei Province, China. On March 11, 2020, the World Health Organization declared a global pandemic and recommended containment and mitigation measures worldwide. On March 13, 2020, U.S. President Donald Trump announced a national emergency relating to the pandemic. Government authorities in the U.S. have recommended or imposed various containment and mitigation measures on large portions of the population, and similar measures have also been taken in many other countries around the world. Both the outbreak of COVID-19 and the containment and mitigation efforts have had a serious adverse impact on the U.S. economy and the economies of other countries around the world, the severity and duration of which remain uncertain.

The COVID-19 pandemic, including containment and mitigation measures has impacted, and is expected to continue to impact, our business and operations in a number of ways, including:

- Day to Day Operations
  As of the date of this Quarterly Report on Form 10-Q, many of our customer-facing employees have resumed in-person work practices; however, they are limited in the number of in-person details they are able to conduct due to containment and mitigation measures related to the COVID-19 pandemic. We monitor the impact of the COVID-19 pandemic in the territories where our customer-facing employees have resumed in-person work practices, and in some cases, we have paused the in-person work practices as a result of the impact of the COVID-19 pandemic in those territories. Customer-facing employees who are not providing in-person services continue to support their customers virtually through telephone and web-based technologies. The majority of our headquarters employees continue to work remotely. We have developed plans to resume in-person work practices for all employees as we determine it to be safe to do so and pending relevant health authority guidance.

- Collaboration Agreement for North America with AbbVie
  We and our partner, AbbVie, are focused on maintaining the availability of LINZESS for adult men and women suffering from IBS-C or CIC. We include our and AbbVie's collaboration-related selling, general, and administrative expenses, including expenses from in-person details, in the calculation of net profits from the sale of LINZESS in the U.S. and present net payments to us as collaborative

arrangements revenue. Costs we and AbbVie have incurred associated with the remote selling activities performed by our and AbbVie's customer-facing employees have been excluded from the collaboration-related selling, general, and administrative expenses. As such, we have experienced fluctuations in our settlement payments based on the ratio of selling, general and administrative expenses incurred by each party during the three and six months ended June 30, 2020, and may continue to experience such fluctuations in the future. The COVID-19 pandemic may negatively impact future net sales of LINZESS in the U.S., including as a result of reduced and/or restricted in-person promotion or potential changes in patient access to healthcare (including due to unemployment or modifications in insurance coverage) and payor reimbursement levels.

- Manufacturing and Supply Chain
  We and AbbVie continue to monitor the supply and availability of LINZESS for adult men and women suffering from IBS-C or CIC in the U.S. As of the date of this Form 10-Q, the COVID-19 pandemic has not caused significant disruptions to manufacturing operations or supply of LINZESS in the U.S. or of clinical trial material for our ongoing trials.

- Clinical Development of GI Pipeline
  The COVID-19 pandemic has impacted, and is expected to continue impacting, the development of our pipeline; specifically, the COVID-19 pandemic has impacted enrollment of new patients into our Phase III clinical trials with IW-3718 for the treatment of refractory GERD. Most of the clinical trial sites were not screening new patients during the second quarter due to the suspension of in-person procedures required to enroll patients and lower patient participation compared to pre-COVID levels. In line with new U.S. FDA guidance on statistical considerations for trials impacted by COVID-19, we have stopped enrollment of study subjects into one of our two Phase III clinical trials for IW-3718 to conduct an early efficacy assessment. Many clinical sites have now resumed screening new patients in our ongoing clinical trial for IW-3718; however, enrollment continues to be slower than prior to the COVID-19 pandemic. Certain research and development expenses related to IW-3718 clinical trials have been and are expected to continue to be delayed during the year ended December 31, 2020; however, aggregate clinical trial expenses over the duration of these trials is expected to increase.

The COVID-19 pandemic resulted in changes to our business and operations which impacted our financial condition and results of operations for the three and six months ended June 30, 2020 as described above. During the three and six months ended June 30, 2020, we incurred a total of approximately $0.3 million and approximately $0.6 million, respectively, of incremental facilities, administrative, and selling costs related to the COVID-19 pandemic, including a donation of approximately $0.3 million to the Life Science Cares' COVID-19 Response Fund. There continue to be significant uncertainties surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations and we expect to incur additional expenses in 2020 related to the impact of the COVID-19 pandemic on our operations. We continue to evaluate the impact of the COVID-19 pandemic on our operating results and financial condition. The COVID-19 pandemic may have a material adverse impact on our business and financial condition in the future.

Contractual Commitments and Obligations

The disclosure of our contractual obligations and commitments was reported in our 2019 Annual Report on Form 10-K. There have not been any material changes from the contractual commitments and obligations previously disclosed in our 2019 Annual Report on Form 10-K.

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*, to our 2019 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, 2020 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 and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents 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 and cash equivalents 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 convertible senior 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 Convertible Notes

Our 2.25% Convertible Senior Notes due 2022, or 2022 Convertible 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 Convertible 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 Convertible 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 Convertible Notes are convertible into Class A Common Stock at an adjusted conversion rate of 68.9172 shares of Class A Common Stock (subject to adjustment as provided for in the 2022 Convertible Notes that are governed by an indenture, or the 2022 Indenture) per $1,000 principal amount of the 2022 Convertible Notes, which is equal to a conversion price of approximately $14.51 per share. The 2022 Convertible Notes will mature on June 15, 2022 unless earlier converted or repurchased. We will settle conversions of the 2022 Convertible Notes through payment or delivery, as the case may be, of cash, shares of our Class A Common Stock or a combination of cash and shares of Class A Common Stock, at our option (subject to, and in accordance with, the settlement provisions of the 2022 Indenture). The 2022 Convertible 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, 2020, the fair value of the 2022 Convertible Notes was estimated by us to be approximately $126.4 million. The 2022 Convertible Notes are more fully described in Note 5, *Fair Value of Financial Instruments*, and Note 8, *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 Note Hedge Warrant Transactions with Respect to 2022 Convertible Notes

To minimize the impact of potential dilution to our common stock upon conversion of the 2022 Convertible Notes, we entered into Convertible Note Hedges to acquire, subject to customary adjustments, 23,135,435 shares of our Class A Common Stock at a strike price of $14.51 per share, as adjusted. 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, 23,135,435 shares of our Class A Common Stock at a strike price of $18.82 per share, as adjusted. In August 2019, in connection with the repurchase of a portion of a portion of the 2022 Convertible Notes, we partially terminated the respective portion of the Convertible Note Hedges and Note Hedge Warrants. We remeasure the remaining Convertible Note Hedges and Note Hedge Warrants to fair value at each reporting date using the Black-Scholes option-pricing model, with changes in fair value recorded as (loss) gain on derivatives in our condensed consolidated statements of operations. The Convertible Note Hedges and Note Hedge Warrants are more fully described in Note 8, *Notes Payable,* in the accompanying notes to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

2024 Convertible Notes and 2026 Convertible Notes

Our 0.75% Convertible Senior Notes due 2024, or 2024 Convertible Notes, and our 1.50% Convertible Senior Notes due 2026, or 2026 Convertible 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 2024 Convertible Notes and 2026 Convertible 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 2024 Convertible Notes and 2026 Convertible 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 initial conversion rate for each of the 2024 Convertible Notes and 2026 Convertible Notes is 74.6687 shares of Class A Common Stock (subject to adjustment as provided for in the applicable Indenture) per $1,000 principal amount of the 2024 Convertible Notes and 2026 Convertible Notes, which is equal to an initial conversion price of approximately $13.39 per share. The 2024 Convertible Notes will mature on June 15, 2024 and the 2026 Convertible Notes will mature on June 15, 2026, unless earlier converted or repurchased. We will settle conversions of the 2024 Convertible Notes and 2026 Convertible Notes through payment or delivery, as the case may be, of cash, shares of our Class A Common Stock or a combination of cash and shares of Class A Common Stock, at our option (subject to, and in accordance with, the settlement provisions of the applicable Indenture). The 2024 Convertible Notes bear cash interest at the annual rate of 0.75% and the 2026 Convertible Notes bear cash interest at the annual rate of 1.50%, each payable on June 15 and December 15 of each year, which began on December 15, 2019. As of June 30, 2020, the fair value of the 2024 Convertible Notes and 2026 Convertible Notes was estimated by us to be approximately $206.0 million and approximately $206.3 million, respectively. The 2024 Convertible Notes and 2026 Convertible Notes are more fully described in Note 5, *Fair Value of Financial Instruments*, and Note 8, *Notes Payable,* in the accompanying notes to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Capped Calls with Respect to 2024 Convertible Notes and 2026 Convertible Notes

In August 2019, in connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, we entered into the capped call transactions, or the Capped Calls, with certain financial institutions. Subject to customary anti-dilution and certain other adjustments, the Capped Calls cover the same number of shares of Class A Common Stock that initially underlie the 2024 Convertible Notes and the 2026 Convertible Notes. These instruments meet the conditions outlined in ASC Topic 815, *Derivatives and Hedging*, or ASC 815, to be classified in stockholders' deficit on our condensed consolidated balance sheet and are not subsequently remeasured as long as the conditions for equity classification continue to be met. The Capped Calls are more fully described in Note 8, *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 monetary assets or liabilities expected to be settled in foreign currency 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, 2020 and 2019 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 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 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 the COVID-19 Pandemic

Public health emergencies, epidemics, or pandemics, such as the COVID-19 pandemic, impact our business.

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. On March 11, 2020, the World Health Organization declared a global pandemic and recommended containment and mitigation measures worldwide. On March 13, 2020, U.S. President Donald Trump announced a national emergency relating to the pandemic. Government authorities in the U.S. have recommended or imposed various containment and mitigation measures on large portions of the population, and similar measures have also been taken in many other countries around the world. Both the outbreak of COVID-19 and the containment and mitigation efforts have a serious adverse impact on the U.S. economy and the economies of other countries around the world, the severity and duration of which are uncertain. Government stabilization efforts will only partially mitigate the consequences.

The COVID-19 pandemic has impacted, and is expected to continue to impact, our business and operations in a number of ways and there are significant uncertainties surrounding the extent and duration of such impacts. Factors that will influence the impact on our business and operations include the duration and extent of the outbreak, the duration and extent of imposed or recommended containment and mitigation measures, and the general economic consequences of the

pandemic. Addressing the impacts of the COVID-19 pandemic has, and likely will for an extended period, required significant time and has diverted the attention of our management, other employees and our board of directors.

As of the date of this Quarterly Report on Form 10-Q, many of our customer-facing employees have resumed in-person work practices; however, they are limited in the number of in-person details they are able to conduct due to containment and mitigation measures related to the COVID-19 pandemic. We monitor the impact of the COVID-19 pandemic in the territories where our customer-facing employees have resumed in-person work practices, and in some cases, we have paused or delayed in-person work practices as a result of the impact of the COVID-19 pandemic in those territories. Customer-facing employees who are not providing in-person services continue to support their customers virtually through telephone and web-based technologies. The majority of our headquarters employees continue to work remotely. Although we have developed plans to resume in-person work practices for all employees, the extent and duration of our ongoing remote working arrangements remains uncertain. We may delay these plans or otherwise stop or limit in-person work in the future pending relevant health authority guidance and additional safety or other considerations. If our employees are unable to work from home effectively, or if the COVID-19 pandemic otherwise impacts employees' ability to work, for example due to containment and mitigation measures related to the COVID-19 pandemic, illness, lack of resources or inadequate technology, or restrictions, closures or other limits on school and other childcare options, our business will be materially harmed. Specifically, new or continuing limits on the ability of our customer-facing employees to meet with physicians and patients to visit healthcare providers and pharmacists (including due to continued or future remote working arrangements, containment and mitigation measures that limit access to customers or other restrictions related to the COVID-19 pandemic) may have an extended negative impact on LINZESS® (linaclotide) sales.

The increase in virtual customer support and limitations on customer access, both by our and our competitors' customer-facing employees, that was prompted by the COVID-19 pandemic, may fundamentally change our commercial model or the market strategy in the industry. Should we be unable to evolve with any changes in the commercial landscape, we may be unable to maintain or grow our revenues from the commercialization of LINZESS or successfully commercialize future products. In addition, changes in insurance coverage or reimbursement levels by governmental authorities, private health insurers and other third-party payors, or changes in the type of such coverage held by patients (including changes from commercial insurance to Medicaid) or the loss of coverage by some patients, due to the impacts of the COVID-19 pandemic (including the related increase in unemployment in the U.S.) may negatively impact our revenue from LINZESS. Moreover, continuing impacts to healthcare access or administration (including, for example, limitations on medications or procedures deemed "non-essential" and reduced interaction between patients and physicians) due to the COVID-19 pandemic may impact demand for LINZESS and materially harm our business and commercialization efforts.

Revenue from LINZESS sales or the progression of our trials will be affected should the COVID-19 pandemic cause significant disruptions to manufacturing operations or supply of LINZESS to the U.S. or active pharmaceutical ingredient, or API, finished drug product or finished goods for linaclotide or our product candidates, for example due to impacts of the COVID-19 pandemic on personnel involved in the manufacturing and supply chain, international travel and shipping restrictions, inability of vendors to provide services, closed manufacturing sites, or any other disruptions in the international supply chain.

The COVID-19 pandemic has impacted and is expected to continue to impact enrollment in our clinical trials, and specifically our Phase III clinical trials of IW-3718 for the treatment of refractory gastroesophageal reflex disease, or refractory GERD. Most of the IW-3718 Phase III clinical trial sites were not screening new patients during the second quarter of 2020 due to the suspension of in-person procedures required to enroll patients and lower patient participation compared to pre-COVID levels. In line with new U.S. Food and Drug Administration, or U.S. FDA, guidance on statistical considerations for trials impacted by COVID-19, we have stopped enrollment of study subjects into one of our two Phase III clinical trials for IW-3718 to conduct an early efficacy assessment. Many clinical sites have now resumed screening new patients in our ongoing clinical trial for IW-3718; however, enrollment continues to be slower than prior to the COVID-19 pandemic. Moreover, patients who are already enrolled in the trials also may discontinue participation due to the various impacts of the COVID-19 pandemic, including impacts on the healthcare system and daily life. Enrollment impacts to our Phase III clinical trials with IW-3718 delayed the date by which we previously expected to receive top-line data for these trials; we may experience further delays (including potential delays in the early efficacy assessment or receipt of top-line data from our IW-3718 program), which delays may continue for an extended period of time, or other impacts to the trials, and we expect to incur increased aggregate expenses relating to the trials, each due to the COVID-19 pandemic. In addition, the progression of our pipeline could be impacted should any of our key vendors,

including clinical research organizations, or CROs, and other clinical vendors, be unable to provide timely or sufficient services due to the impact of the COVID-19 pandemic.

The spread of COVID-19 continues to disrupt the U.S. healthcare and healthcare regulatory system. Capital markets in the U.S. and around the world have also been negatively impacted, which may harm our business, including our ability to obtain future financing. The COVID-19 pandemic, including containment and mitigation measures, has impacted our business and operations, and could have a material adverse impact on our financial condition and results of operations in the future, including for an extended period of time.

Risks Related to Our Business and Industry

We are highly dependent on the commercial success of LINZESS® (linaclotide) in the United States, or the U.S., for the foreseeable future; we cannot guarantee that we will generate sufficient revenues from LINZESS to cover our expenses.

We and our partner, AbbVie Inc. (together with its affiliates), or AbbVie, (successor to Allergan plc (together with its affiliates), or Allergan), began selling LINZESS in the U.S. in 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. The commercial success of LINZESS depends on a number of factors, including:

- the effectiveness of LINZESS as a treatment for adult patients with irritable bowel syndrome with constipation, or IBS-C, or chronic idiopathic constipation, or CIC;
- the size of the treatable patient population;
- the effectiveness of the sales, managed markets and marketing efforts by us and AbbVie;
- the adoption of LINZESS by physicians, which depends on whether physicians view it as safe and effective treatment for adult patients with IBS-C and CIC;
- our success in educating and activating adult IBS-C and CIC patients to enable them to more effectively communicate their symptoms and treatment history to their physicians;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, LINZESS and our ability to demonstrate that LINZESS is safer, more efficacious and/or more cost-effective than alternative therapies;
- the effectiveness of our partners' distribution networks;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these or other areas, associated with linaclotide; and
- the development or commercialization of competing products or therapies for the treatment of IBS-C or CIC, or their associated symptoms.

Our revenues from the commercialization of LINZESS are subject to these and other factors, and therefore may be unpredictable from quarter-to-quarter. Revenues from LINZESS or other sources in any quarter may be insufficient to cover our expenses.

Our products may cause undesirable side effects or have other properties that could limit their commercial potential.

Linaclotide has been prescribed to millions of patients since its launch in the U.S. and other territories beginning in December 2012. 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.

The number and type of patients treated with linaclotide could continue to grow if physicians prescribe linaclotide to more patients and as we and our partners conduct clinical trials, including in new indications, populations or formulations, as well as explore potential combination products, in existing and new territories. 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 and/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 delayed, 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, the U.S. FDA-approved label for LINZESS contains a boxed warning about its use in pediatric patients. LINZESS is contraindicated in pediatric patients up to six years of age based on nonclinical data from studies in neonatal mice approximately equivalent to human pediatric patients less than two years of age. There is also a warning advising physicians to avoid the use of LINZESS in pediatric patients six to less than 18 years of age. This warning is based on data in young juvenile mice and, at the time of approval, the lack of clinical safety and efficacy data in pediatric patients across age groups. We and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients, which is discussed below. These and other restrictions could limit the commercial potential of LINZESS.

We rely entirely on contract manufacturers, our partners and other third parties to manufacture linaclotide and our other product candidates and distribute linaclotide. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties, or are otherwise unable to manufacture and distribute sufficient quantities to meet demand, our development and 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 API, finished drug product and finished goods for linaclotide and our other product candidates. Beginning in 2020, each of our partners for linaclotide will be responsible for API, finished drug product and finished goods manufacturing (including bottling and packaging) for its respective territories and distributing the finished goods to wholesalers. Should we, or any of our partners or any third-party manufacturers we or our partners engage, experience setbacks or challenges in our manufacturing efforts, including setbacks related to the COVID-19 pandemic described further above, our development and commercialization efforts may be materially harmed. We or our partners have commercial supply agreements with independent third parties to manufacture linaclotide API.

Each of our partners and the third-party manufacturers we or our partners engage must comply with current good manufacturing practices, or GMP, and other stringent regulatory requirements enforced by the U.S. 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 and our partners' 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 compliance with these regulations and standards by our partners and the third-party manufacturers we or our partners engage.

Our partners and the third-party manufacturers we or our partners engage 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, natural disasters and public health epidemics, including the COVID-19 pandemic. In addition, the raw materials necessary to make API for our products and product candidates are acquired from a limited number of sources. Any delay or disruption in the availability of 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 partners or the third-party manufacturers we or our partners engage 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 partners or the third-party manufacturers we or our partners engage 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 maximum or available manufacturing capacities are insufficient to meet demand, our and our partners' development or commercialization efforts may be materially harmed.

If any of our linaclotide partners undergoes a change of 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 partners on many aspects of the development, manufacturing and/or 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 develop and 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. In May 2020, AbbVie announced the completion of its acquisition of Allergan. Our collaboration, now with AbbVie, for the development and commercialization of linaclotide in North America, and our license, now to AbbVie, to develop and commercialize linaclotide in all countries worldwide other than China (including Hong Kong and Macau) and Japan, remain in effect. In connection with this transaction, we are in the process of reestablishing many relationships and confirming alignment, including on our development and commercialization strategy for linaclotide. Any failure to do so could adversely affect the development and commercialization of linaclotide. If any of our linaclotide partners undergoes a change of control or in management, we would similarly need to reestablish many relationships and confirm alignment, including on our development and commercialization strategy for linaclotide. Further, in connection with any change of control or change 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 that represents the functional areas necessary to support the commercialization of LINZESS in the U.S. If AbbVie 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, as well as develop others, to replace the capabilities that AbbVie 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 AbbVie, Astellas Pharma, Inc., or Astellas, or AstraZeneca AB (together with its affiliates), 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 development and commercialization of linaclotide could be negatively impacted.

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

We are working closely with AbbVie 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 AbbVie'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 AbbVie must execute upon this commercialization plan effectively and efficiently. In addition, we and AbbVie 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 AbbVie 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 AbbVie must provide our sales forces with the highest quality support, guidance and oversight for them to continue to effectively promote LINZESS to gastroenterologists and primary care physicians. In light of the recently completed merger of AbbVie and Allergan, we and AbbVie must work together to ensure an orderly transition of this work plan and to continue these commercialization efforts. If we and AbbVie 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.

In addition, as described above, as of the date of this Quarterly Report on Form 10-Q, many of our customer-facing employees have resumed in-person work practices; however, they are limited in the number of in-person details they are able to conduct due to containment and mitigation measures related to the COVID-19 pandemic. We monitor the impact of the COVID-19 pandemic in the territories where our customer-facing employees have resumed in-person

work practices, and in some cases, we have paused the in-person work practices as a result of the impact of the COVID-19 pandemic in those territories. Customer-facing employees who are not providing in-person services continue to support their customers virtually through telephone and web-based technologies. Although we have developed plans to resume in-person work practices for all employees, the extent and duration of our ongoing remote working arrangements remains uncertain. We may delay or otherwise limit in-person work in the future pending relevant health authority guidance and other safety considerations. The virtual support we continue to provide to customers may not be as effective as in-person efforts, and our in-person efforts may be limited in their effectiveness. If this were to occur, or if we, AbbVie or any of our partners were unable to align on our strategy and development and commercial efforts as a result of the COVID-19 pandemic or otherwise, we may not be able to maintain or increase the revenues that we generate or our business may be otherwise materially harmed.

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 depends in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. In determining whether to approve reimbursement for our products and at what level, we expect that third-party payors 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 have faced and expect to continue to face increasing pressure to offer discounts or rebates from list prices or discounts to third-party payors 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 AbbVie will be able to negotiate or continue to negotiate pricing terms with third-party payors at levels that are profitable to us, or at all. Certain third-party payors 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 payors 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 government healthcare programs, private health insurers, including managed care organizations, or other reimbursing bodies or payors limit or reduce the indications for or conditions under which our products may be reimbursed. Moreover, as discussed above, changes in insurance coverage or reimbursement levels by governmental authorities, private health insurers and other third-party payors, or in the type of such coverage held by patients, as well as the impacts to healthcare access or administration (including, for example, limitations on medications or procedures deemed "non-essential," reduced interaction between patients and physicians, and increased unemployment), due to the COVID-19 pandemic may materially harm our business and commercialization efforts.

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 initiatives 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. There has been significant scrutiny of pharmaceutical pricing and the resulting costs of pharmaceutical products that could cause significant operational and reimbursement changes for the pharmaceutical industry. There have been a number of recent federal and state efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices, price increases or other related costs. For example, the Bipartisan Budget Act of 2018 contained various provisions that affect coverage and reimbursement of drugs, including an increase, which began in 2019, in the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap from 50% to 70%. 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, Japan and China, 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 payors, including private insurance and governmental payors. 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 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 payors 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 AbbVie 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 for the treatment of chronic constipation in adults in the third quarter of 2018, and our partner Astellas is currently commercializing LINZESS in Japan. In addition, LINZESS was first launched in China for the treatment of IBS-C in adults in November 2019, and our partner AstraZeneca is currently commercializing LINZESS in China (including Hong Kong and Macau). The pricing and reimbursement strategy is a key component of our partners' commercialization plans for CONSTELLA in Europe and LINZESS in Japan and China. 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 China, 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 linaclotide, we are dependent upon third parties, and our and our partners' relationships with those third parties, in our and our partners' efforts to obtain regulatory approval for, and to commercialize, linaclotide, as well as to comply with regulatory and other obligations with respect to linaclotide.

AbbVie played a significant role in the conduct of the clinical trials for linaclotide and in the subsequent collection and analysis of data, and AbbVie holds the new drug application, or NDA, for LINZESS. In addition, we are

commercializing LINZESS in the U.S. with AbbVie. AbbVie is also responsible for the development, regulatory approval and commercialization of linaclotide in countries worldwide other than Japan and China (including Hong Kong and Macau). AbbVie is commercializing LINZESS in Mexico and CONSTELLA in Canada, as well as commercializing CONSTELLA in certain countries in Europe. Astellas and AstraZeneca are responsible for development and commercialization of LINZESS in Japan and China (including Hong Kong and Macau), respectively. Beginning in 2020, each of our partners for linaclotide will be responsible for API, finished drug product and finished goods manufacturing (including bottling and packaging) for its respective territories and distributing the finished goods to wholesalers. We or our partners have commercial supply agreements with independent third parties to manufacture the linaclotide API.

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, including those arising out of the COVID-19 pandemic, 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, particularly in light of the impact of the COVID-19 pandemic on our partners' operations. If any of our partners fails to devote sufficient time and resources to linaclotide, or if its performance is substandard or otherwise hindered, 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.

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 each of Astellas, AstraZeneca and AbbVie is responsible for reporting adverse event information from its territory to us. An AstraZeneca partner is the holder of the global safety database for lesinurad and is 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 such parties do not report adverse events related to such products, or fail to do so in a timely manner, we may not receive the information that we or our partners are required to report to the U.S. FDA or a foreign regulatory authority regarding such products. Furthermore, we or such parties may fail to adequately monitor, identify or investigate adverse events, or to report adverse events to the U.S. FDA or foreign regulatory authority accurately and within the prescribed timeframe. If we or such parties 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 such products, removal of such products from the market, criminal prosecution, the imposition of civil monetary penalties, seizure of such products, or delay in approval of future products.

Even though LINZESS is approved by the U.S. FDA for use in adult patients, post-approval development and regulatory requirements still remain, which present additional challenges.

In August 2012, the U.S. FDA approved LINZESS as a once-daily treatment for adult men and women suffering from IBS-C or CIC. Although we and AbbVie completed additional nonclinical and clinical studies in adults that were required by the U.S. FDA in connection with the approval of LINZESS, LINZESS remains subject to ongoing U.S. 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 six years of age based on nonclinical data from studies in neonatal mice approximately equivalent to human pediatric patients less than two years of age. There is also a boxed warning advising physicians to avoid the use of LINZESS in pediatric patients six to less than 18 years of age. This

warning is based on data in young juvenile mice and, at the time of approval, the lack of clinical safety and efficacy data in pediatric patients across age groups. We and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatric patients, and clinical pediatric programs in IBS-C and functional constipation currently are ongoing. Our ability to expand the indication or label information for LINZESS to pediatrics will depend on, among other things, our successful completion of pediatric clinical programs. In addition, 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 U.S. 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 U.S. 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 U.S. 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 currently approved, we or our partners must comply with numerous and varying regulatory requirements of other jurisdictions regarding, among other things, 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. Additionally, we cannot be certain of the duration or extent to which the COVID-19 pandemic may impact operations of regulatory authorities in jurisdictions around the world, and any reduction in resources dedicated to review and approval of products in applicable jurisdictions could delay or otherwise impact approval or other regulatory decisions or actions. 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 our approved products, including the sale of linaclotide and lesinurad, 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 our products 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 and enable them to compete more effectively. For example, in March 2019, Bausch Health Companies Inc., or Bausch Health, acquired TRULANCE (plecanatide), which, as referenced below, is a competitor to LINZESS, from Synergy Pharmaceuticals, Inc. Competition may also 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's AMITIZA (lubiprostone) is approved by the U.S. FDA for sale in the U.S. for the treatment of IBS-C, CIC and opioid-induced constipation, Bausch Health's TRULANCE (plecanatide) is approved by the U.S. FDA for sale in the U.S. for the treatment of adults with IBS-C and CIC, Takeda's MOTEGRITY (prucalopride) is approved by the U.S. FDA for sale in the U.S. for the treatment of CIC in adults, and Alfasigma USA's ZELNORM (tegaserod) is approved for sale in the U.S. for treatment of IBS-C in women under the age of 65. Over-the-counter laxatives such as MiraLAX® and DULCOLAX®, and lactulose, a prescription laxative treatment, are also available for the treatment of constipation. Additionally, we believe other companies are developing products which could compete with our products, should they be approved by the U.S. FDA or foreign regulatory authorities and become commercially available. For example, although not currently commercially available, the U.S. FDA approved Ardelyx, Inc.'s IBSRELA™ (tenapanor) for the treatment of IBS-C in adults. In addition, there are other compounds in late stage development and other potential competitors that 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 U.S. 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 U.S. FDA or other applicable regulatory agencies. Such "off-label" uses are common across medical specialties. Although the U.S. FDA and other regulatory agencies do not regulate a physician's choice of treatments, the U.S. FDA and other regulatory agencies do restrict manufacturer communications on off-label use. Companies are not permitted to promote drugs or medical devices for off-label uses or to promote unapproved drugs or medical devices. Accordingly, we do not permit promotion of any product that we develop, license, commercialize, promote, co-promote or otherwise partner prior to approval or for any indication, population or use not described in or consistent with such product's label. The U.S. 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. Even if it is later determined that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

Notwithstanding the regulatory restrictions on off-label promotion, the U.S. 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 payors 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, including the Medicaid Drug Rebate Program, 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 teaching hospitals (and additional categories of healthcare practitioners beginning with reports submitted in 2022) 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 payor, 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. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. For example, the processing of personal data in the European Economic Area, or the EEA, is subject to the General Data Protection Regulation, or the GDPR, which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected

individuals, as well as how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the European Commission to lack an adequate level of data protection, such as the United States. In addition, we are subject to the California Consumer Privacy Act, or CCPA, which became effective on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose the types of personal information collected, specific pieces of information collected by a company, the categories of sources from which such information was collected, the business purpose for collecting or selling the consumer's personal information, and the categories of third parties with whom a company shares personal information. The CCPA also imposes several obligations on companies to provide notice to California consumers regarding a company's data processing activities. Additionally, the CCPA gives California consumers the right to ask companies to delete a consumer's personal information and it places limitations on a company's ability to sell personal information, including providing consumers a right to opt out of sales of their personal information. The compliance obligations imposed by the GDPR and the CCPA have required us to revise our operations. In addition, the GDPR and the CCPA impose substantial fines and other regulatory penalties for breaches of data protection requirements, and they confer a private right of action on data subjects (in the case of the GDPR) and consumers (in the case of the CCPA) and their representatives for breaches of certain 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 payor 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. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019. The ACA has also been subject to judicial challenge. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the ACA unconstitutional in its entirety. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional, but remanded the case back to the district court to assess whether any provisions of the ACA were severable and could survive. In March 2020, the Supreme Court agreed to hear the case. Pending resolution of the litigation, which could take some time, the ACA is still operational in all respects. Additional healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. 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. 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 2029 (except May 1, 2020 to December 31, 2020). 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 U.S. 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 evaluation and mitigation strategies approved by the U.S. FDA. We and AbbVie have established a nonclinical and clinical post-marketing plan with the U.S. FDA to understand the safety and efficacy of LINZESS in pediatrics. The U.S. 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 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 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 that we either develop internally or in-license 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 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 acquire, develop and market additional product candidates or approved products would impair our ability to grow and/or adversely affect our business.

As part of our growth strategy, we intend to explore further linaclotide development opportunities. We and AbbVie are exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in new or existing 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 LINZESS. 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 U.S. FDA or in other countries or harm linaclotide's reputation in the marketplace, each of which could materially harm our revenues from linaclotide.

We are advancing our pipeline, including developing IW-3718, a gastric retentive formulation of a bile acid sequestrant for the potential treatment of refractory GERD, and the strength of our company's pipeline will depend in large part on the outcomes of studies of assets 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 U.S. FDA. To satisfy these standards, we must allocate resources among our various development programs and we must engage in costly and lengthy research 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, including for linaclotide and IW-3718. Many companies in the pharmaceutical industry have suffered significant setbacks in clinical trials even after achieving promising results in earlier nonclinical or clinical trials. For example, in May 2020, we and AbbVie announced that our Phase II trial evaluating MD-7246, a delayed release formulation of linaclotide in adult patients with abdominal pain associated with irritable bowel syndrome with diarrhea, did not meet its primary or key secondary endpoints. Based on these findings, we and AbbVie are discontinuing the development of MD-7246.

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 U.S. FDA and other applicable regulatory authorities, which could delay, limit or prevent regulatory approval. The U.S. FDA or other regulatory authorities also may require additional clinical trials, which may be costly or delay, limit, prevent or otherwise impact regulatory submission or approval. Satisfaction of U.S. 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 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 in-license 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 U.S. 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.

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:

- the ongoing COVID-19 pandemic, including restrictions on activities imposed by government authorities in response;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective 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.

The COVID-19 pandemic has impacted and is expected to continue to impact enrollment in our clinical trials, and specifically our Phase III clinical trials of IW-3718 for the treatment of refractory GERD. Most of the IW-3718 Phase III clinical trial sites were not screening new patients during the second quarter of 2020 due to the suspension of in-person procedures required to enroll patients and lower patient participation compared to pre-COVID levels. In line with new U.S. FDA guidance on statistical considerations for trials impacted by COVID-19, we have stopped enrollment of study subjects into one of our two Phase III clinical trials for IW-3718 to conduct an early efficacy assessment. Many clinical sites have now resumed screening new patients in our ongoing clinical trial for IW-3718; however, enrollment continues to be slower than prior to the COVID-19 pandemic. Moreover, patients who are already enrolled in the trials also may discontinue participation due to the various impacts of the COVID-19 pandemic, including impacts on the healthcare system and daily life. Enrollment impacts to our Phase III clinical trials with IW-3718 delayed the date by which we previously expected to receive top-line data for these trials; we may experience further delays (including delays in the early efficacy assessment or receipt of top-line data from our ongoing clinical trial for IW-3718), which may continue for an extended period of time, or other impacts to the trials, and we expect to incur increased aggregate expenses relating to the trials, each due to the COVID-19 pandemic.

Clinical trials may also be delayed or discontinued 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 U.S. 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 U.S. 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 or otherwise determine 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 incur operational difficulties or be exposed to claims and liabilities as a result of the separation of Cyclerion.

On April 1, 2019, we distributed all of the outstanding shares of Cyclerion Therapeutics, Inc., or Cyclerion, common stock to Ironwood stockholders in connection with the separation of our soluble guanylate cyclase business, or the Separation. In connection with the distribution, we entered into a separation agreement and various other agreements (including a tax matters agreement, an employee matters agreement, transition services agreements, an intellectual property license agreement and a development agreement). These agreements govern the separation and distribution and the relationship between us and Cyclerion going forward, including with respect to potential tax-related losses associated with the separation and distribution. In addition, the development agreement provides for the performance of services by Cyclerion for our benefit for a period of time. If Cyclerion is unable to satisfy its obligations under these agreements, we could incur losses or operational challenges or difficulties and may not have sufficient resources available for such services. These arrangements could also lead to disputes over rights to certain shared property and over the allocation of costs for products and operations.

The separation agreement provides for indemnification obligations designed to make Cyclerion financially responsible for many liabilities that may exist relating to its business activities, whether incurred prior to or after the distribution, including any pending or future litigation, but we cannot guarantee that Cyclerion will be able to satisfy its indemnification obligations. It is also possible that a court would disregard the allocation agreed to between us and Cyclerion and require us to assume responsibility for obligations allocated to Cyclerion. Third parties could also seek to hold us responsible for any of these liabilities or obligations, and the indemnity rights we have under the separation agreement may not be sufficient to fully cover all of these liabilities and obligations. Even if we are successful in obtaining indemnification, we may have to bear costs temporarily. In addition, our indemnity obligations to Cyclerion, including those related to assets or liabilities allocated to us, may be significant. These risks could negatively affect our business, financial condition or results of operations.

If the distribution of the shares of Cyclerion common stock in connection with 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.

The distribution, together with certain related transactions, is intended to qualify for tax-free treatment to us and our stockholders for U.S. federal income tax purposes. We received a favorable private letter ruling from the Internal Revenue Service, or IRS, under the pilot program established in Revenue Procedure 2017-52 relating to the U.S. federal income tax treatment of the distribution. Consistent with the guidelines set forth in Revenue Procedure 2017-52, the IRS private letter ruling does not cover all of the issues that are relevant to determining whether the distribution is generally tax free for U.S. federal income tax purposes. Accordingly, completion of the distribution was conditioned upon, among other things, our receipt of an opinion from an outside tax advisor that the distribution will qualify as a transaction that is generally tax-free to both us and our stockholders for U.S. federal income tax purposes under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code. The private letter ruling and opinion were based on and relied on, among other things, certain facts and assumptions, as well as certain representations, statements and undertakings from us and

Cyclerion (including those relating to the past and future conduct of us and Cyclerion). If any of these facts, assumptions, representations, statements or undertakings is, or becomes, inaccurate or incomplete, or if we or Cyclerion breach any of our respective covenants relating to the distribution, the IRS private letter ruling and any tax opinion may be invalid. Moreover, the opinion is not binding on the IRS or any courts. Accordingly, notwithstanding receipt of the IRS private letter ruling and the opinion, the IRS could determine that the distribution and certain related transactions should be treated as taxable transactions for U.S. federal income tax purposes.

If the distribution, together with certain related transactions, fails to qualify as a transaction that is generally tax-free under Sections 355 and 368(a)(1)(D) of the Internal Revenue Code, in general, for U.S. federal income tax purposes, we would recognize taxable gain with respect to Cyclerion's distributed common stock and our stockholders who received shares of Cyclerion common stock in the distribution would be subject to tax as if they had received a taxable distribution equal to the fair market value of such shares.

We may not achieve some or all of the anticipated benefits of the Separation, which may adversely affect our business.

We may not be able to achieve the full strategic, financial or other benefits expected to result from the Separation, or such benefits may be delayed or not occur at all. If we fail to achieve some or all of the expected benefits of the Separation, or if such benefits are delayed, our business, financial condition, results of operations and the value of our stock could be adversely impacted. 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 Class A Common Stock would have been had the Separation not occurred. In addition, we are smaller and less diversified, with a narrower business focus, than we were before the Separation and therefore 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.

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 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 research, development, regulatory, commercial, financial and other expertise of our management, particularly Mark Mallon, our chief executive officer; Gina Consylman, our senior vice president, chief financial officer, and treasurer; Conor Kilroy, our senior vice president, general counsel and secretary; Thomas A. McCourt, our president; Jason Rickard, our senior vice president and chief operating officer and Michael Shetzline, our senior vice president, chief medical officer and head of drug development. Transitions in our senior management team and other key employees, or the unavailability of any such persons for any reason (including due to the COVID-19 pandemic), may disrupt our operations or otherwise harm our business. In addition to the competition for personnel, the Boston area in particular is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee 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 our products. 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, partner, vendor or third-party 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. Further, while some or all of our workforce, and those of our partners, vendors and other third-party providers, work remotely as a result of the COVID-19 pandemic or otherwise, we may have greater vulnerability to cyberattacks or other losses of confidential information, as well as interruptions in information technology systems. Any such interruptions, losses or breaches would substantially impair our ability to operate our business and would compromise our, or our partners, vendors and other third-party providers, 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 financial or other 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.

Risks Related to Intellectual Property

Limitations on our ability to obtain patent protection and/or 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 sufficient 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 were the first to conceive inventions covered by our patents and pending patent applications or that we 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 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 related to LINZESS include multiple patents relating to our commercial, room temperature stable formulations of the 72 mcg, 145 mcg and 290 mcg doses of linaclotide and methods of using these formulations, the latest of which expires in the early 2030s, as well as other patents covering processes for making LINZESS, formulations 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. In addition, we have several pending patent applications in the U.S. We believe in the strength of our LINZESS patent portfolio and that we have sufficient freedom to operate; however, if any of our present or future patents is

challenged, narrowed, invalidated or circumvented, or our pending patent applications are not granted, our ability to prevent third parties from competing with LINZESS could be limited and our business and financial results may be materially harmed.

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 LINZESS 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 LINZESS or our product candidates may infringe.

We may be exposed to, or threatened with, litigation by third parties alleging that LINZESS or our product candidates infringe their intellectual property rights. If LINZESS 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 LINZESS 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 LINZESS in conjunction with ANDAs filed by generic drug manufacturers, and we may receive additional notices from others in the future. We have, and may continue to, become involved in legal proceedings to protect or enforce intellectual property rights 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 U.S. 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 and seek to commercialize generic versions of one or more LINZESS doses. As such, we have brought, and may bring in the future, legal proceedings against generic drug manufacturers.

We and AbbVie have received Paragraph IV certification notice letters regarding ANDAs submitted to the U.S. 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 U.S. FDA-approved drug LINZESS. In the past, we have filed patent infringement lawsuits against five companies making such ANDA filings, and we have entered into settlement agreements dismissing the lawsuits with each company that has made ANDA filings. Frequently, innovators receive multiple ANDA filings. Consequently, we expect to receive additional notice letters regarding ANDAs submitted to the U.S. FDA, and may receive amendments to those notice letters.

After evaluation, we have in the past filed, and may, in the future, file patent infringement lawsuits or take other action against companies making ANDA filings. If a patent infringement suit has been filed within 45 days of receipt of a notice letter, the U.S. 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. 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 incurred significant losses from our inception in 1998 through the year ended December 31, 2018, and we may incur losses in future periods.

In recent years, we have focused primarily on developing, manufacturing and commercializing linaclotide, 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, and debt issuances, including our June 2015 issuance of our 2.25% Convertible Senior Notes due June 15, 2022, or the 2022 Convertible Notes, and our August 2019 issuance of our 0.75% Convertible Senior Notes due 2024, or the 2024 Convertible Notes, and our 1.50% Convertible Senior Notes due 2026, or the 2026 Convertible Notes (together with the 2022 Convertible Notes and the 2024 Convertible Notes, the Convertible Senior Notes). We currently derive a significant portion of our revenue from our LINZESS collaboration with AbbVie 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. Such revenue is highly dependent on LINZESS demand and other factors such as wholesaler buying patterns. Our collaborative arrangements revenue outside of the U.S. has and may continue to fluctuate as a result of the timing and amount of royalties from sales of linaclotide in the markets in which it is currently approved, or any other markets where linaclotide receives approval, as well as clinical and commercial milestones received and recognized under our current and future strategic partnerships outside of the U.S. Additionally, our sale of API outside of the U.S. has fluctuated in the past and has and will significantly decrease in 2020. Under the terms of our amended and restated agreements with both Astellas and AstraZeneca, entered into in August 2019 and September 2019, respectively, we will no longer be responsible for the supply of linaclotide API to Astellas or AstraZeneca beginning in 2020.

Prior to the year ended December 31, 2019, we incurred net losses in each year since our inception in 1998. As of June 30, 2020, we had an accumulated deficit of approximately $1.5 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, particularly in light of the negative financial impact that the COVID-19 pandemic may have on our business in the future. Further, we expect to continue to incur substantial expenses in connection with our efforts to commercialize linaclotide 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. Failure to achieve sustainable net income and maintain positive cash flows would have an adverse effect on 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.

We have previously raised funds to finance our operations through capital raising activities, including the sale of shares of our Class A Common Stock in public offerings and convertible and other debt issuances. 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 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 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 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 Convertible Senior Notes hold the notes to maturity without conversion into our Class A Common Stock and whether we are required to repurchase any of our Convertible Senior Notes prior to maturity upon a fundamental change, as defined in each of the indentures governing the Convertible Senior 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 AbbVie under our collaboration agreement for North America.

In June 2015, we issued approximately $335.7 million aggregate principal amount of our 2022 Convertible Notes bearing an annual interest rate of 2.25%. In August 2019, we issued $200.0 million aggregate principal amount of our 2024 Convertible Notes bearing an annual interest rate of 0.75% and $200.0 million aggregate principal amount of our 2026 Convertible Notes bearing an annual interest rate of 1.50%, and we used a portion of the proceeds from this offering to repurchase $215.0 million aggregate principal amount of the 2022 Convertible Notes. Semi-annual payments on our 2022 Convertible Notes began on December 15, 2015 and semi-annual payments on each of our 2024 Convertible Notes and 2026 Convertible Notes began on December 15, 2019. We expect that for the next few years, at a minimum, the net quarterly payments from AbbVie will be a significant source of cash flows from operations. If the cash flows derived from the net quarterly payments that we receive from AbbVie 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 AbbVie 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 AbbVie under the collaboration agreement for North America. Accordingly, since we cannot guarantee that our company will maintain net income or positive cash flows, 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 AbbVie, (ii) there will be a net quarterly payment from AbbVie at all or (iii) we will not also be required to make a true-up payment to AbbVie 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, 2020, we had total indebtedness of approximately $520.7 million and available cash and cash equivalents of approximately $253.3 million. Our indebtedness, combined with our other financial obligations and contractual commitments, could have 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 flows to be dedicated to debt service payments instead of other purposes, thereby reducing the amount of cash flows 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 flows 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 Convertible Senior Notes, in connection with a transaction involving us that constitutes a fundamental change under the indentures governing the Convertible Senior 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 none of the indentures governing our Convertible Senior Notes includes covenants restricting the operation of our business except in certain limited circumstances, in the event of a default under any of the Convertible Senior Notes, the applicable noteholders or the trustee under the indenture governing the applicable Convertible Senior Notes may accelerate our payment obligations under such Convertible Senior 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 Convertible Senior 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 Class A Common Stock listed on The Nasdaq Global or Global Select Market or The New York Stock Exchange), subject to the terms of each of the indenture governing the Convertible Senior Notes. 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.

Each of the indentures governing our Convertible Senior Notes also includes cross-default features providing that certain failures to pay for outstanding indebtedness would result in a default under the indentures governing our Convertible Senior Notes. 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 Convertible Notes and capped call transactions entered into in connection with our 2024 Convertible Notes and our 2026 Convertible Notes may affect the value of our Class A Common Stock.

In connection with the issuance of our 2022 Convertible Notes, we entered into convertible note hedge transactions, or the Convertible Note Hedges, and separate note hedge warrant transactions, or the Note Hedge Warrants, with certain financial institutions. The Convertible Note Hedges and Note Hedge Warrants were partially terminated in connection with the repurchase of $215.0 million aggregate principal amount of the 2022 Convertible Notes in August 2019. Additionally, in connection with the issuance of our 2024 Convertible Notes and our 2026 Convertible Notes, we entered into capped call transactions, or the Capped Calls, with certain financial institutions. These transactions are expected generally to reduce the potential dilution upon any conversion of our 2022 Convertible Notes, our 2024 Convertible Notes or our 2026 Convertible Notes, as applicable, or offset any cash payments we are required to make in excess of the principal amount of converted Convertible Senior Notes, as the case may be.

In connection with these transactions, the financial institutions likely 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 Convertible Notes, the 2024 Convertible Notes and the 2026 Convertible Notes, as applicable, 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 Convertible Notes, the 2024 Convertible Notes or the 2026 Convertible Notes, as applicable. In addition, under certain circumstances the counterparties have the right to terminate the Convertible Note Hedges and Capped Calls and settle the Note Hedge Warrants on terms set forth in the applicable confirmations, which may result in us not receiving all or any portion of the anticipated benefit of the Convertible Note Hedges and Capped Calls. 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 and Capped Calls, 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 income (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 or impairments of assets or goodwill, and associated write-downs;
- 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;
- any material lawsuit in which we may become involved; and
- the impact of the COVID-19 pandemic or other public health epidemics, including containment or mitigation measures, or natural disasters.

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.

Prior to the year ended December 31, 2019, we incurred significant net losses since our inception. To the extent that we do not generate federal and state taxable income in the future, 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 Related 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 board of directors is currently divided into three classes serving staggered 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. At our 2019 annual meeting of stockholders, our stockholders approved an amendment to our certificate of incorporation to declassify our board of directors to allow our stockholders to vote on the election of the entire board of directors on an annual basis, rather than on a staggered basis. This declassification will be phased in such that, once completed in 2022, stockholders will have the opportunity to replace the entire board at a single stockholders' meeting. As required by Delaware law, the amendment to our certificate of incorporation also reflects that, once the board of directors is declassified, stockholders may remove directors with or without cause.

- 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, as described above, until our board of directors is declassified, 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 super-majority (80%) of the outstanding shares of Class A 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.

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 AbbVie 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 AbbVie for the U.S., 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 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, including clinical trial results or timelines, 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 Class A Common Stock or sales of securities convertible into Class A 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;
- discussion of us or our stock price in the financial or scientific press or in online investor communities; and
- the impact of the COVID-19 pandemic or other public health epidemics, including containment or mitigation measures, or natural disasters.

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 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	Certificate of Retirement. Incorporated by reference to Exhibit 3.2 of Ironwood Pharmaceuticals, Inc.'s Amendment No. 1 to Form 8-A, filed on January 3, 2019.
3.3	Certificate of Amendment of Eleventh Amended and Restated Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 of Ironwood Pharmaceuticals, Inc.'s Current Report on Form 8-K, filed with the SEC on May 31, 2019.
3.4	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 – The Instance Document does not appear in the Interactive Data Files because its XBRL tags are embedded within the Inline XBRL 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
104	The cover page from this Quarterly Report on Form 10-Q formatted in Inline XBRL.

* 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, 2020

By: /s/ MARK MALLON
Mark Mallon
Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 6, 2020

By: /s/ KELLY MACDONALD
Kelly MacDonald
Vice President, Finance and Chief Accounting Officer
(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, Mark Mallon, 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, 2020

/s/ MARK MALLON
Mark Mallon
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, 2020

/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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Mallon, 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/ MARK MALLON
Mark Mallon
Chief Executive Officer

August 6, 2020

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, 2020 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, 2020

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.