# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-K**

(Mark One)

	ANNUAL REPORT	PURSUANT TO SECTIO	N 13 OR 15(d) OF THE SECUR	RITIES EX	CHANGE ACT OF 193	4	
		For th	e fiscal year ended December 31	, 2019			
			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				
			OD PHARMACEUTI	,	INC.		
		(Exact	name of registrant as specified in i	ts charter)			
Delaware (State or other jurisdiction of incorporation or organization)  100 Summer Street, Suite 2300 Boston, Massachusetts (Address of Principal Executive Offices)				04-3404176 (I.R.S. Employer Identification Number)  02110 (Zip Code)			
	·		(617) 621-7722 ant's telephone number, including	area code)			
Sec	urities registered pursuan	at to Section 12(b) of the Act	:				
	Title of each class A Common Stock, \$0.001		Trading Symbol(s) IRWD			exchange on which registered Global Select Market	
Indi Indi the preceding 1 days. Yes ⊠ N	icate by check mark if the icate by check mark when 12 months (or for such sho $\square$	e registrant is not required to ther the registrant: (1) has file orter period that the registran	reasoned issuer, as defined in Rule file reports pursuant to Section 13 and all reports required to be filed but was required to file such reports; tted electronically every Interactive	or 15(d) of y Section 1 ) and (2) ha	f the Exchange Act. Yes [3] or 15(d) of the Securities s been subject to such fili	□ No ⊠ ss Exchange Act of 1934 during ng requirements for the past 90	
	•	•	nonths (or for such shorter period t		•	-	
	ny. See the definitions of		ccelerated filer, an accelerated file celerated filer," "smaller reporting				
Large a	ccelerated filer ⊠	Accelerated filer $\square$	Non-accelerated filer $\square$	Smalle	r reporting company $\square$	Emerging growth company $\square$	
		•	if the registrant has elected not to 13(a) of the Exchange Act. □	use the exte	ended transition period for	complying with any new or	
Indi	icate by check mark whet	ther the registrant is a shell co	ompany (as defined in Rule 12b-2	of the Excl	nange Act). Yes □ No 🏻		
Agg	gregate market value of v	oting stock held by non-affil	iates of the Registrant as of June 3	0, 2019: \$1	,697,372,212		
As	of February 10, 2020, the	ere were 158,206,912 shares	of Class A Common Stock outstan	ding.			
		DOCUMI	ENTS INCORPORATED BY RE	EFERENC	E:		
Dom	tions of the definitive mus	www.atatamamt.fom.aum.2020.A	nnual Masting of Stockholders are		ad by reference into Part	III of this noment	

#### NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections titled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations", contains forward-looking statements. All statements contained in this Annual Report on Form 10-K 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 Allergan plc 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; and
- other factors discussed elsewhere in this Annual Report on Form 10-K.

Any or all of our forward-looking statements in this Annual Report on Form 10-K 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 Annual Report on Form 10-K. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report on Form 10-K 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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K.

#### 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 Annual Report on Form 10-K are the property of their respective owners. All rights reserved.

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#### PART I

#### Item 1. Business

#### **Our Company**

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, or GC-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.

We have strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world, including with Allergan plc (together with its affiliates), or Allergan, 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 and Allergan are also advancing 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. MD-7246 is designed to have the pain-relieving effect of linaclotide with minimal impact on bowel function. In May 2019, we and Allergan announced the initiation of a Phase II clinical trial evaluating the safety and efficacy of MD-7246 in adult patients with abdominal pain associated with IBS with diarrhea, or IBS-D.

We are advancing another GI development program, 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.

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<sup>TM</sup> (givosiran), an RNAi therapeutic targeting aminolevulinic acid synthase 1, for the treatment of acute hepatic porphyria, or AHP.

We were incorporated in Delaware on January 5, 1998 as Microbia, Inc. On April 7, 2008, we changed our name to Ironwood Pharmaceuticals, Inc. 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.

#### **Recent Corporate Highlights:**

On April 1, 2019, we completed a tax-free spin-off of our soluble guanylate cyclase, or sGC, business into a separate publicly traded company, Cyclerion Therapeutics, Inc., or Cyclerion. In completing the separation of our sGC business into Cyclerion, or the Separation, we advanced our strategy to drive growth as a GI-focused healthcare company, building on our commercial success with LINZESS and advancing our GI development portfolio. Our strategy is focused on three core priorities: drive LINZESS growth, advance our GI development portfolio and strengthen our financial profile.

#### 1. Drive LINZESS Growth

- Grew our share of collaborative arrangements revenue related to sales of LINZESS in the U.S. to \$325.4 million for the year ended December 31, 2019.
- Reported positive topline data from the Phase IIIb clinical trial evaluating LINZESS 290 mcg on
  overall abdominal symptoms (bloating, pain and discomfort) in adult patients with IBS-C. We and
  Allergan began communicating these additional benefits of LINZESS to healthcare practitioners in
  July 2019 and submitted a Supplemental New Drug Application, or sNDA, with the U.S. FDA in
  November 2019 to seek a more comprehensive description of the effects of LINZESS on its approved
  label.
- Entered into settlements resolving LINZESS patent litigation with Sandoz Inc., or Sandoz, and Teva Pharmaceuticals, USA, or Teva, brought in response to Sandoz's and Teva's abbreviated new drug applications, or ANDAs, seeking approval to market generic versions of LINZESS prior to the expiration of our and Allergan's applicable patents. For additional information relating to the resolution of such litigation, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K.

## 2. Advance GI Development Portfolio

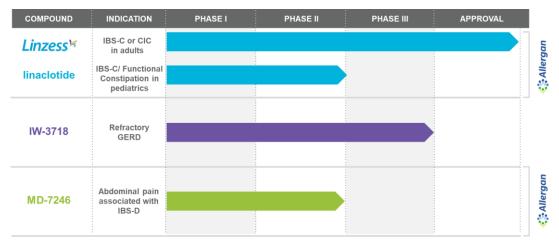
- Continued enrollment in our two pivotal Phase III clinical trials of IW-3718 for the potential treatment of refractory GERD.
- Initiated a Phase II clinical trial with Allergan to evaluate the safety and efficacy of MD-7246 in adult patients with abdominal pain associated with IBS-D. The trial completed enrollment in December 2019.
- Expanded our GI development organization through key roles including Chief Medical Officer, Head of Regulatory and Head of Biostatistics.

## 3. Strengthen Financial Profile

- Issued \$200.0 million in 0.75% Convertible Senior Notes due 2024 and \$200.0 million in 1.50% Convertible Senior Notes due 2026. The proceeds of these issuances were used to pay approximately \$25.2 million in connection with associated capped call transactions, repurchase \$215.0 million aggregate principal amount of our outstanding 2.25% Convertible Senior Notes due 2022 and redeem all of our outstanding 8.375% Notes due 2026.
- Amended and restated our ex-U.S. linaclotide partnerships with Astellas for Japan and AstraZeneca for China (including Hong Kong and Macau). As a result, we recognized \$10.0 million in revenue from Astellas related to upfront payments and approximately \$32.4 million in revenue from AstraZeneca related to non-contingent payments in 2019.
- Announced a new U.S. GI disease education and promotional agreement for Alnylam's GIVLAARI.
- Relocated our headquarters to a new office in downtown Boston, Massachusetts occupying
  approximately 39,000 square feet at 100 Summer Street, from our previous location in Cambridge,
  Massachusetts. Monthly base rent payments were contractually reduced in connection with the
  execution of the 100 Summer Street lease.

## **Our Pipeline**

The following table presents the status of selected key development programs in our pipeline:



This pipeline does not reflect development for candidates for which we have not vet initiated a clinical trial.

The status of our development programs in the table above represents the ongoing phase of development and does not correspond to the completion of a particular phase. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in the "Risk Factors" section of this Annual Report on Form 10-K.

## **GI Programs**

#### IBS-C / CIC

IBS-C and CIC are chronic, functional GI disorders that afflict millions of sufferers worldwide. As many as 11.5 million adults suffer from IBS-C and as many as 28.5 million adults suffer from CIC in the U.S. alone, according to the Lieberman GI Patient Landscape Survey performed in 2010, or the Lieberman Survey. Symptoms of IBS-C include abdominal pain, discomfort or bloating and constipation symptoms (e.g., incomplete evacuation, infrequent bowel movements, hard/lumpy stools), while CIC is primarily characterized by constipation symptoms. Greater than 65% of IBS-C patients suffer from bloating and/or discomfort at least one time per week, according to the Lieberman Survey.

**Linaclotide**—U.S. In August 2012, the U.S. FDA approved LINZESS as a once-daily treatment for adult men and women suffering from IBS-C (290 mcg dose) or CIC (145 mcg dose). We and Allergan began commercializing LINZESS in the U.S. in December 2012. In January 2017, the U.S. FDA approved a 72 mcg dose of linaclotide for the treatment of adult men and women with CIC.

We and Allergan continue to explore ways to enhance the clinical profile of linaclotide by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. In June 2019, we announced positive topline data from our 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. We submitted an sNDA 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 Allergan 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 currently are ongoing.

LINZESS is covered by a U.S. composition of matter patent that expires in 2026, including patent term extension, as well as multiple patents relating to our commercial, room temperature stable formulation of the 145 mcg and 290 mcg doses of linaclotide and methods of using this formulation, 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. We and Allergan have received Paragraph IV certification notice letters, or 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 LINZESS. We and Allergan have entered into settlement agreements with five generic drug manufacturers resolving all outstanding patent infringement litigation brought in response to their ANDAs seeking approval to market generic versions of LINZESS prior to the expiration of our and Allergan's applicable patents. For additional information relating to the resolution of such litigation, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K.

**Linaclotide—Global.** Allergan has rights to develop and commercialize linaclotide in all countries worldwide other than China (including Hong Kong and Macau) and Japan. In November 2012, the European Commission granted marketing authorization to CONSTELLA for the symptomatic treatment of moderate to severe IBS-C in adults. CONSTELLA is the first, and to date, only drug approved in the European Union, or E.U., for IBS-C. CONSTELLA first became commercially available in certain European countries beginning in the second quarter of 2013. Allergan is commercializing CONSTELLA in a number of European countries, including the United Kingdom, Italy and Spain.

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

Astellas has rights to develop, manufacture and commercialize linaclotide in Japan. In December 2016, the Japanese Ministry of Health, Labor and Welfare approved LINZESS for the treatment of adults with IBS-C in Japan. In March 2017, Astellas began commercializing LINZESS for the treatment of adults with IBS-C in Japan. In August 2018, the Japanese Ministry of Health, Labor and Welfare approved LINZESS for the treatment of adults with chronic constipation in Japan. In September 2018, Astellas began commercializing LINZESS for the treatment of adult patients with chronic constipation in Japan.

AstraZeneca has rights to develop, manufacture and commercialize linaclotide in China (including Hong Kong and Macau). In January 2019, the Chinese National Medical Products Administration approved the marketing application for LINZESS for adults with IBS-C in China. AstraZeneca launched LINZESS in China in November 2019.

## Abdominal Pain

**MD-7246.** MD-7246 is a delayed-release formulation of linaclotide being evaluated as an oral, intestinal, non-opioid, pain-relieving agent for patients suffering from abdominal pain associated with certain GI diseases. MD-7246 is designed to provide targeted delivery of linaclotide to the colon, where the majority of abdominal pain is believed to originate, and to limit additional fluid secretion in the small intestine resulting in minimal impact on bowel function.

We and Allergan are initially exploring MD-7246 in a Phase II clinical trial evaluating the safety and efficacy of MD-7246 in adult patients with abdominal pain associated with IBS-D. There are an estimated 16 million Americans who suffer from symptoms of IBS-D, according to Grundmann and Yoon in *Irritable Bowel Syndrome: epidemiology, diagnosis and treatment: an update for health-care practitioners* (published in the Journal of Gastroenterology and Hepatology in 2010) and the United States Census Bureau.

#### Refractory GERD

**IW-3718.** There are an estimated 8 to 10 million Americans who suffer regularly from symptoms of refractory GERD, such as heartburn and regurgitation, despite receiving treatment with the current standard of care, a proton pump inhibitor, to suppress stomach acid, according to the American Community Survey conducted in 2018, Lieberman GERD Survey conducted in 2019, My Total Health Survey conducted in 2018, and the AHRI GERD Survey conducted in 2018. Research suggests some refractory GERD patients may experience reflux of bile from the intestine into the stomach and esophagus. We recently changed our description of the disease from "persistent GERD" to "refractory GERD" to reflect established medical terminology.

We are advancing 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.

## **Collaborations and Partnerships**

As part of our strategy, we have established development and commercial capabilities that we plan to leverage as we seek to bring multiple medicines to patients. We intend to play an active role in the development and commercialization of our products in the U.S., either independently or with partners that have strong capabilities. We also intend to establish strong global brands by out-licensing development and commercialization rights to our products in other key territories to high-performing partners. We believe in the long-term value of our drug candidates, so we seek collaborations that increase the value of our programs by providing meaningful economics and incentives for us and any potential partner. Furthermore, we seek partners who share our values, culture, processes and vision for our products, which we believe will enable us to work with those partners successfully for the entire potential patent life of our drugs. We intend to continue to expand our expertise in GI by accessing innovative externally developed products through strategic transactions and to leverage our existing capabilities to develop and commercialize these products in the U.S.

The following chart shows our revenue for the U.S. and territories outside of the U.S. as a percentage of our total revenue for each of the years ended December 31, 2019, 2018, and 2017.

	Year En	Year Ended December 31,			
	2019	2018	2017		
U.S.	78.0 %	79.0 %	89.0 %		
Japan	13.0 %	20.1 %	10.0 %		
Rest of world	9.0 %	0.9 %	1.0 %		
	100.0 %	100.0 %	100.0 %		

Revenue attributable to our linaclotide partnerships comprised substantially all of our revenue for each of the years indicated. Further, we currently derive a significant portion of our revenue from our LINZESS collaboration with Allergan for the U.S. and believe that the revenues from this collaboration will continue to constitute a significant portion of our total revenue for the foreseeable future. Our revenue from our LINZESS collaboration with Allergan for the U.S. is highly dependent on the responsiveness of patients to fill prescriptions and other factors such as wholesaler buying patterns. Our collaborative arrangements revenue outside of the U.S. has fluctuated for the years ended December 31, 2019, 2018, and 2017 based on timing of milestone and non-contingent payments. Our collaborative arrangements revenue 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 active pharmaceutical ingredient, or API, outside of the U.S. has fluctuated for the years ended December 31, 2019, 2018, and 2017 and will significantly decrease beginning 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.

### Linaclotide

We have pursued a partnering strategy for commercializing linaclotide that has allowed us to focus our commercialization efforts in the U.S. and enabled partners with strong global capabilities to commercialize linaclotide outside of the U.S.

Collaboration Agreement for North America with Allergan

In September 2007, we entered into a collaboration agreement with Allergan to develop and commercialize linaclotide for the treatment of IBS-C, CIC and other GI conditions in North America. Under the terms of the collaboration agreement, we and Allergan are jointly and equally funding the development and commercialization of LINZESS in the U.S., with equal share of any profits or losses. Additionally, we granted Allergan exclusive rights to

develop and commercialize linaclotide in Canada and Mexico for which we receive royalties in the mid-teens' percent on net sales in those countries. Allergan is solely responsible for the further development, regulatory approval and commercialization of linaclotide in those countries and funding any costs.

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

In April 2009, we entered into a license agreement with Almirall S.A., or Almirall, or the European License Agreement, to develop and commercialize linaclotide in Europe (including the Commonwealth of Independent States and Turkey) for the treatment of IBS-C, CIC and other GI conditions. In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to Allergan. In January 2017, we and Allergan entered into an amendment to the European License Agreement. The European License Agreement, as amended, 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, Allergan is obligated to pay us 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.

#### License Agreement for Japan with Astellas

In November 2009, we 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. Pursuant to this license agreement, we were responsible for the supply of linaclotide API to Astellas. On August 1, 2019, we and Astellas amended and restated the license agreement. Under the terms of the amended and restated license agreement, we 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. Beginning in 2020, Astellas is obligated to pay royalties to us 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.

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

In October 2012, we entered into a collaboration agreement with AstraZeneca to co-develop and co-commercialize linaclotide in China (including Hong Kong and Macau). In January 2019, the Chinese National Medical Products Administration approved the marketing application for LINZESS for adults with IBS-C in China. In September 2019, we and AstraZeneca amended and restated the collaboration agreement, under which AstraZeneca obtained the exclusive right to develop, manufacture and commercialize products containing linaclotide in the territory. Under the terms of the amended and restated agreement, we will be transferring all manufacturing responsibilities in China (including Hong Kong and Macau) to AstraZeneca beginning in 2020, and we 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 us 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 territory.

### **Co-Promotion and Other Commercial Agreements**

Co-Promotion Agreement with Allergan

In April 2019, we entered into an agreement with Allergan to promote VIBERZI® (eluxadoline) through December 31, 2019. Under the terms of the agreement, we received approximately \$3.7 million in collaborative arrangements revenue based on the number of VIBERZI sales details performed between April and December 2019. We and Allergan terminated the agreement effective January 1, 2020.

Disease Education and Promotional Agreement with Alnylam

In August 2019, we and Alnylam entered into a disease education and promotional agreement for Alnylam's GIVLAARI for the treatment of AHP. We are 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. We are also eligible to receive a royalty based on a percentage of net sales of GIVLAARI that are directly attributable to our promotional efforts.

#### **Our Strategy**

Our vision is to become the leading U.S. GI-focused healthcare company. To achieve this vision, we are dedicated to leveraging our development and commercial expertise to advance the treatment of GI diseases and redefine the standard of care for millions of patients in the U.S. suffering from GI diseases. Our strategy is focused on three core priorities: drive LINZESS growth, advance our GI development portfolio, and strengthen our financial profile. Key elements of our strategy include:

- assembling a team with a singular passion and documented success in creating, developing and commercializing GI medicines that can make a significant difference in patients' lives;
- successfully and profitably commercializing LINZESS in collaboration with Allergan in the U.S.;
- 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;
- leveraging our U.S.-focused commercial capabilities in marketing, reimbursement, patient engagement and
  sales to expand the commercial potential of LINZESS and our other product candidates in the U.S. and
  collaborating with global partners who share our vision, values, culture, and processes to develop and
  commercialize linaclotide outside of the U.S.;
- investing in our pipeline of novel product candidates IW-3718 and MD-7246;
- evaluating external candidates for in-licensing or acquisition opportunities; and
- executing our strategy with our stockholders' long-term interests in mind by delivering sustainable profits and long-term per share cash flows.

#### Competition

#### Linaclotide

Linaclotide competes globally with certain prescription therapies and over-the-counter, or OTC, products for the treatment of IBS-C and CIC, or their associated symptoms.

OTC and generic laxatives make up the majority of the IBS-C and CIC treatment market, according to the Lieberman Survey and the 2018 U.S. Census. Linaclotide and lactulose account for the majority of prescription treatments in the U.S. IBS-C and CIC markets, according to 2019 data from IQVIA Inc. National Prescription Audit. Given the low barriers to access, many IBS-C and CIC sufferers try OTC fiber and laxatives, such as MiraLAX® and DULCOLAX®, but according to the Lieberman Survey, less than half of them are very satisfied with the ability of OTC products to manage their symptoms.

Until the launch of LINZESS, the only available branded prescription therapy for IBS-C and CIC in the U.S. was AMITIZA® (lubiprostone), which was approved for the treatment of CIC in 2006, for the treatment of IBS-C in 2008, and for the treatment of opioid induced constipation in 2013. AMITIZA is being commercialized in the U.S. by Takeda Pharmaceuticals Limited. AMITIZA also is being commercialized for the treatment of adults with CIC in certain European countries, including the United Kingdom and Switzerland by Sucampo AG, and for the treatment of chronic constipation in Japan by Mylan N.V. Synergy Pharmaceuticals, Inc., or Synergy, obtained approval of TRULANCE® (plecanatide) in the U.S. for the treatment of CIC in adults in January 2017 and for the treatment of IBS-C in adults in

January 2018. In March 2019, Bausch Health Companies acquired substantially all of Synergy's assets, including all rights to TRULANCE, dolcanatide and all related intellectual property in the context of a Chapter 11 bankruptcy process. Shire plc obtained approval of MOTEGRITY<sup>TM</sup> (prucalopride) in the U.S. for the treatment of CIC in adults in December 2018. In April 2019, US WorldMeds, LLC received approval for the reintroduction of ZELNORM<sup>TM</sup> (tegaserod) in the U.S. for the treatment of IBS-C in women under the age of 65. In September 2019, Ardelyx, Inc. received approval for ISBRELA<sup>TM</sup> (tenapanor) in the U.S. for the treatment of IBS-C in adults. ISBRELA is not currently commercially available.

#### Manufacturing and Supply

It is our objective that the supply of linaclotide be safe and effective, with redundancy built into critical steps of the supply chain, and that each of our collaboration partners are in a position to manage the supply and distribution of linaclotide in their respective territories through a combination of contract manufacturers and in-house manufacturing capabilities. Linaclotide production consists of three phases—manufacture of the API (sometimes referred to as drug substance), manufacture of finished drug product and manufacture of finished goods. We or our partners have commercial supply agreements with multiple third-party manufacturers for the production of linaclotide API. We believe the current commercial suppliers have the capabilities to produce linaclotide API in accordance with current good manufacturing practices, or GMP, on a sufficient scale to meet the worldwide development and commercial needs for linaclotide. The commercial suppliers of linaclotide API are subject to routine inspections by regulatory agencies worldwide and also undergo periodic audit and certification by our quality department.

Allergan is responsible for linaclotide API, finished drug product and finished goods manufacturing (including bottling and packaging) and distributing the finished goods to wholesalers for the U.S. and its other territories. Astellas is responsible for linaclotide finished drug product and finished goods manufacturing (including bottling and packaging) and distributing the finished goods to wholesalers for Japan, and in connection with the amended and restated license agreement we and Astellas entered into in August 2019, Astellas became responsible for its own supply of linaclotide API for Japan beginning in 2020. Under our original collaboration with AstraZeneca, we were responsible for linaclotide API, finished drug product and finished goods manufacturing for China and for linaclotide API and finished drug product manufacturing for Hong Kong and Macau, with AstraZeneca accountable for finished goods manufacturing for Hong Kong and Macau. Under the terms of the amended and restated collaboration agreement we and AstraZeneca entered into in September 2019, we will be transferring all manufacturing responsibilities in these territories to AstraZeneca beginning in 2020.

Prior to linaclotide, there was no precedent for long-term room temperature shelf storage formulation for an orally dosed peptide to be produced in millions of capsules per year. Our efforts to date have led to formulations that are both cost effective and able to meet the stability requirements for commercial pharmaceutical products.

### Sales and Marketing

For the foreseeable future, we intend to develop and commercialize our drugs in the U.S. alone or with partners, and expect to rely on partners to develop and commercialize our drugs in territories outside the U.S. In executing our strategy, our goal is to retain oversight over the worldwide development and commercialization of our products by playing an active role in their commercialization or finding partners who share our vision, values, culture and processes.

To date, we have established a high-quality commercial organization dedicated to bringing innovative, highly-valued GI healthcare solutions to our customers, including patients, payors, and healthcare providers. Our GI commercial capabilities, including marketing, patient engagement and sales, are designed to support our existing product as well as potential future internally and externally developed products.

We are also coordinating efforts with our linaclotide partners to launch and maintain an integrated, global linaclotide brand. By leveraging the knowledge base and expertise of our experienced commercial team and the insights of each of our linaclotide commercialization partners, we continually improve our collective marketing strategies.

#### **Patents and Proprietary Rights**

We actively seek to protect the proprietary technology that we consider important to our business, including pursuing patents that cover our products, compositions, and formulations, their methods of use and the processes for

their manufacture, as well as any other relevant inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business; defend our patents; preserve the confidentiality of our trade secrets; and operate without infringing the patents and proprietary rights of third parties.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. We expect to apply, and have applied, for patent term extension in countries where it is available.

#### Linaclotide Patent Portfolio

Our linaclotide patent portfolio is currently composed of ten U.S. patents listed in the U.S. FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", or the Orange Book, five granted European patents, all of which have been validated in all available European countries, ten granted Japanese patents, five granted Chinese patents, 52 issued patents in other foreign jurisdictions, and numerous pending U.S., foreign and Patent Cooperation Treaty, or PCT, patent applications. We own or jointly own all of the issued patents and pending applications.

The issued U.S. patents, which will expire between 2024 and 2033, contain claims directed to the linaclotide molecule, pharmaceutical compositions thereof, methods of using linaclotide to treat GI disorders, processes for making the molecule, and room temperature stable formulations of linaclotide and methods of use thereof. The 72 mcg, 145 mcg and 290 mcg LINZESS doses are covered by various composition of matter patents, the latest of which expires in 2026. In addition, the commercial formulations of the 145 mcg and 290 mcg LINZESS doses are covered by patents that expire in the early 2030s. The granted European patents, which will expire between 2024 and 2031, some of which are subject to potential patent term extension, contain claims directed to the linaclotide molecule, pharmaceutical compositions thereof, uses of linaclotide to prepare medicaments for treating GI disorders, and room temperature stable formulations of linaclotide and their use in treating IBS-C and chronic constipation. The granted Chinese patents, which will expire between 2024 and 2032, the granted Japanese patents, which will expire between 2025 and 2036, some of which are subject to potential patent term extension, and the granted patents in other foreign jurisdictions, which will expire between 2024 and 2032, some of which may be subject to potential patent term extension, contain claims directed to the linaclotide molecule, pharmaceutical compositions of linaclotide for use in treating GI disorders, and room temperature stable formulations of linaclotide.

We have pending patent applications in certain countries worldwide that, if issued, will expire between 2024 and 2032 and which include claims covering the linaclotide molecule, methods of using linaclotide to treat GI disorders, the current commercial formulation of linaclotide and uses thereof to treat GI disorders. We have multiple additional U.S. patent applications covering commercial formulations related to our 72 mcg LINZESS dose that, if issued, would expire in 2029 and 2031.

MD-7246 is covered by several granted patents covering linaclotide the latest of which expires in 2026 in the U.S. and the latest of which expires in 2029 outside the U.S. In addition, we have pending patent applications in the U.S., PCT and foreign jurisdictions directed to formulations of MD-7246 and methods of using MD-7246 to treat various diseases and disorders, such as IBS-D, that, if issued, will expire between 2029 and 2037.

The patent term of a patent that covers an U.S. FDA approved drug is also eligible for patent term extension, which permits patent term restoration as compensation for some of the patent term lost during the U.S. FDA regulatory review process. The Hatch Waxman Act permits a patent term extension of a single patent applicable to an approved drug for up to five years beyond the expiration of the patent but the extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the U.S. FDA. The United States Patent and Trademark Office, or USPTO, has issued a Certificate of Patent Term Extension for U.S. Patent 7,304,036, which covers linaclotide and methods of use thereof. As a result, the patent term of this patent was extended to August 30, 2026, 14 years from the date of linaclotide's approval by the U.S. FDA. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. We have received patent term

extensions in Japan for several of our linaclotide patents. We have also received patent term extensions, called supplementary protection certificates, for certain linaclotide patents from several national patent offices in Europe.

We and Allergan received Notice Letters regarding ANDAs submitted to the U.S. FDA by five generic drug manufacturers requesting approval to engage in commercial manufacture, use, sale and offer for sale of linaclotide capsules, proposed generic versions of LINZESS. All five manufacturers requested approval for their 145 mcg and 290 mcg generic doses of LINZESS and two requested additional approval for their 72 mcg generic doses of LINZESS. We and Allergan have entered into settlement agreements with all five of these generic drug manufacturers providing for licenses to market their 145 mcg and 290 mcg generic versions of LINZESS, beginning as early as March 2029 (subject to U.S. FDA Approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. In addition, we and Allergan entered into a settlement agreement providing one generic drug manufacturer a license to market its 72 mcg generic version of LINZESS beginning in August 2030 (subject to U.S. FDA Approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. For additional information relating to such ANDAs and any resolution of related litigation, see Item 3. *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K.

#### IW-3718

Our patent portfolio relating to our IW-3718 development program is currently composed of one issued U.S. patent and ten issued patents in foreign jurisdictions, which are directed to a sustained-release, gastro-retentive dosage form of a bile acid sequestrant and its use in treating disorders related to the bile acid in the upper GI tract, such as refractory GERD; and numerous pending U.S., foreign and PCT patent applications. We own all of the issued patents and pending applications. The issued U.S. patent expires in 2031. The foreign issued patents expire between 2027 and 2034. The pending patent applications, if issued, will expire between 2027 and 2038.

#### **Government Regulation**

Our business is subject to government regulation in both the U.S. and in other countries. In the U.S., pharmaceutical products are subject to extensive regulation by the U.S. FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations, as well as similar foreign regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-marketing requirements and assessments, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. The U.S. FDA and other regulatory authorities have very broad enforcement authority and failure to abide by applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution, disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approval, refusal to approve pending applications, and civil or criminal prosecution.

#### U.S. FDA Approval Process

We believe that our product candidates will be regulated by the U.S. FDA as drugs. No company may market a new drug until it has submitted an NDA to the U.S. FDA, and the U.S. FDA has approved it. The steps required before the U.S. FDA may approve an NDA generally include:

- conducting nonclinical laboratory tests and animal tests in compliance with U.S. FDA's good laboratory practice, or GLP, requirements;
- development, manufacture and testing of active pharmaceutical product and dosage forms suitable for human use in compliance with current GMP;
- conducting adequate and well-controlled human clinical trials that establish the safety and efficacy of the product for its specific intended use(s);
- in order to evaluate a drug in humans in the U.S., an Investigational New Drug Application, or IND, must be submitted and come into effect before human clinical trials may begin;

- the submission to the U.S. FDA of an NDA;
- satisfactory completion of one or more U.S. FDA inspections of the manufacturing facility or facilities at
  which the product, or components thereof, are produced to assess compliance with current GMP
  requirements and to assure that the facilities, methods and controls are adequate to preserve the product's
  identity, strength, quality and purity;
- inspections of other sources of data in the NDA, such as inspection of clinical trial sites to assess compliance with good clinical practice, or GCP, requirements are also generally required; and
- U.S. FDA review and approval of the NDA.

Nonclinical tests include laboratory evaluation of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLP. We must submit the results of the nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the U.S. FDA as part of an IND, which must become effective before we may commence human clinical trials in the U.S. The IND will automatically become effective 30 days after its receipt by the U.S. FDA, unless the U.S. FDA raises concerns or questions before that time about the conduct of the proposed trial. In such a case, we must work with the U.S. FDA to resolve any outstanding concerns before the clinical trial can proceed. We cannot be sure that submission of an IND will result in the U.S. FDA allowing clinical trials to begin, or that, once begun, issues will not arise that will cause us or the U.S. FDA to modify, suspend or terminate such trials. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB requirements or if the trial has been associated with unexpected serious harm to subjects. An IRB may also impose other conditions on the trial. For studies conducted outside of the U.S., similarly, we are subject to local regulations which may differ from the U.S. and local regulations must be followed appropriately.

Clinical trials involve the administration of the product candidate to humans under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are typically conducted in three sequential phases, though the phases may overlap or be combined. In Phase I, the initial introduction of the drug into healthy human subjects, the drug is usually tested for safety (adverse effects), dosage tolerance and pharmacologic action, as well as to understand how the drug is taken up by and distributed within the body. Phase II usually involves studies in a limited patient population (individuals with the disease under study) to:

- evaluate preliminarily the efficacy of the drug for specific, targeted conditions;
- determine dosage tolerance and appropriate dosage as well as other important information about how to design larger Phase III trials; and
- identify possible adverse effects and safety risks.

Phase III trials generally further evaluate clinical efficacy and test for safety within an expanded patient population. The conduct of clinical trials is subject to extensive regulation, including compliance with GCP regulations and guidance, and regulations designed to protect the rights and safety of subjects involved in investigations.

The U.S. FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with U.S. FDA requirements or presents an unacceptable risk to the clinical trial patients. We may also suspend clinical trials at any time on various grounds.

The results of the nonclinical and clinical studies, together with other detailed information, including the manufacture and composition of the product candidate, are submitted to the U.S. FDA in the form of an NDA requesting approval to market the drug. The U.S. FDA approval of the NDA is required before marketing of the product may begin in the U.S. If the NDA contains all pertinent information and data, the U.S. FDA will "file" the application and begin review. The review process, however, may be extended by U.S. FDA requests for additional information, nonclinical or

clinical studies, clarification regarding information already provided in the submission, or submission of a risk evaluation and mitigation strategy. The U.S. FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The U.S. FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the U.S. FDA will typically inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless current GMP compliance is satisfactory. The U.S. FDA also typically inspects facilities responsible for performing animal testing, as well as clinical investigators who participate in clinical trials. The U.S. FDA may refuse to approve an NDA if applicable regulatory criteria are not satisfied or may require additional testing or information. The U.S. FDA may also limit the indications for use and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The testing and approval process requires substantial time, effort and financial resources, and our product candidates may not be approved on a timely basis, if at all. The time and expense required to perform the clinical testing necessary to obtain U.S. FDA approval for regulated products can frequently exceed the time and expense of the research and development initially required to create the product. The results of nonclinical studies and initial clinical trials of our product candidates are not necessarily predictive of the results from large-scale clinical trials, and clinical trials may be subject to additional costs, delays or modifications due to a number of factors, including difficulty in obtaining enough patients, investigators or product candidate supply. Failure by us or our collaborators, licensors or licensees, including Allergan, Astellas and AstraZeneca, to obtain, or any delay in obtaining, regulatory approvals or in complying with requirements could adversely affect commercialization and our ability to receive product or royalty revenues.

#### Hatch-Waxman Act

The Hatch-Waxman Act established abbreviated approval procedures for generic drugs. Approval to market and distribute these drugs is obtained by submitting an ANDA with the U.S. FDA. The application for a generic drug is "abbreviated" because it need not include nonclinical or clinical data to demonstrate safety and effectiveness and may instead rely on the U.S. FDA's previous finding that the brand drug, or reference drug, is safe and effective. In order to obtain approval of an ANDA, an applicant must, among other things, establish that its product is bioequivalent to an existing approved drug and that it has the same active ingredient(s), strength, dosage form, and route of administration. A generic drug is considered bioequivalent to its reference drug if testing demonstrates that the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the reference drug when administered under similar experimental conditions.

The Hatch-Waxman Act also provides incentives by awarding, in certain circumstances, certain legal protections from generic competition. This protection comes in the form of a non-patent exclusivity period, during which the U.S. FDA may not accept, or approve, an application for a generic drug, whether the application for such drug is submitted through an ANDA or a through another form of application, known as a 505(b)(2) application.

The Hatch-Waxman Act grants five years of exclusivity when a company develops and gains NDA approval of a new chemical entity that has not been previously approved by the U.S. FDA. This exclusivity provides that the U.S. FDA may not accept an ANDA or 505(b)(2) application for five years after the date of approval of previously approved drug, or four years in the case of an ANDA or 505(b)(2) application that challenges a patent claiming the reference drug (see discussion below regarding Paragraph IV Certifications). The Hatch-Waxman Act also provides three years of exclusivity for approved applications for drugs that are not new chemical entities, if the application contains the results of new clinical investigations (other than bioavailability studies) that were essential to approval of the application. Examples of applications that may require new clinical investigations essential to approval and receive three-year exclusivity include applications for new indications, dosage forms (including new drug delivery systems), strengths, or conditions of use for an already approved product. This three-year exclusivity period only protects against U.S. FDA approval of ANDAs and 505(b)(2) applications for generic drugs for the conditions of approval (for example, indication or dosage form) that required new clinical investigations that were essential to approval; it does not prohibit the U.S. FDA from accepting or approving ANDAs or 505(b)(2) NDAs for generic drugs that do not include such conditions of approval.

Paragraph IV Certifications. Under the Hatch-Waxman Act, NDA applicants and NDA holders must provide information about certain patents claiming their drugs, or methods of use of the drug that is the subject of the NDA, for listing in the Orange Book. When an ANDA or 505(b)(2) application is submitted, it must contain one of several possible certifications regarding each of the patents listed in the Orange Book for the reference drug. A certification that a listed patent is invalid, unenforceable or will not be infringed by the sale of the proposed product is called a "Paragraph IV" certification. A certification that provides the date a listed patent will expire, but does not challenge the validity, enforceability or infringement of the patent, is called a "Paragraph III" certification. FDA can approve the ANDA or 505(b)(2) application containing the Paragraph III certification upon expiration of the patent.

Within 20 days of the acceptance by the U.S. FDA of an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must notify the NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed. The NDA holder or patent holder may then initiate a patent infringement suit in response to the Paragraph IV notice. If this is done within 45 days of receiving notice of the Paragraph IV certification, a 30-month stay of the U.S. FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The U.S. FDA may approve the proposed product before the expiration of the 30-month stay only if a court finds the patent invalid or not infringed, and the court may shorten or lengthen the 30-month stay under certain limited circumstances.

Patent Term Restoration. Under the Hatch-Waxman Act, a portion of the patent term lost during product development and U.S. FDA review of an NDA or 505(b)(2) application is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of U.S. FDA approval of the product. The maximum period of patent term extension is five years, and the patent cannot be extended to more than 14 years from the date of U.S. FDA approval of the product. Only one unexpired patent claiming the drug product, a method of using the product or a method of manufacturing the product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The U.S. Patent and Trademark Office, in consultation with the U.S. FDA, reviews and approves the application for patent term restoration.

## Other Regulatory Requirements

After approval, finished drug products are subject to extensive continuing regulation by the U.S. FDA, which include company obligations to manufacture products in accordance with current GMP, maintain and provide to the U.S. FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain U.S. FDA approval of certain manufacturing or labeling changes, and comply with U.S. FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and U.S. FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or NDA holder.

We and our partners and any third-party manufacturers we or our partners engage are required to comply with applicable U.S. FDA manufacturing requirements contained in the U.S. FDA's current GMP regulations. Current GMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet current GMP requirements to the satisfaction of the U.S. FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers are also subject to periodic inspections of facilities by the U.S. FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the U.S. FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting drugs for uses, conditions or diseases, or in patient populations that are not consistent with the drug's approved labeling (known as "off-label use"), and principles governing industry-sponsored scientific and educational activities. Failure to comply with U.S. FDA requirements can have negative consequences, including adverse publicity, warning or untitled letters from the U.S. FDA, mandated

corrective advertising or communications with doctors or patients, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and U.S. FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar in type and quality to the clinical data supporting the original application for the original indication, and the U.S. FDA uses similar procedures and actions in reviewing such NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following U.S. FDA approval of an NDA. The U.S. FDA also may require post-marketing testing, known as Phase IV testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or to place conditions on an approval that restrict the distribution or use of the product.

Outside the U.S., our and our collaborators' abilities to market a product are contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from jurisdiction to jurisdiction. At present, foreign marketing authorizations are applied for at a national level, although within the E.U. registration procedures are available to companies wishing to market a product in more than one E.U. member state. We are subject to U.S. federal and foreign anti-corruption laws. Those laws include the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. corporations and their representatives from offering, promising, authorizing, or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA encompasses certain healthcare professionals in many countries. We are also subject to similar laws of other countries that have enacted anti-corruption laws and regulations.

#### Pricing and Reimbursement

Within the U.S., significant uncertainty exists regarding the coverage and reimbursement status of products approved by the U.S. FDA. Sales of our products depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. The process for determining whether a third-party payor will provide coverage for a finished drug product typically is separate from the process for setting the price of a finished drug product or for establishing the reimbursement rate that the payor will pay for the finished drug product once coverage is approved. Third-party payors may limit coverage to specific finished drug products on an approved list, also known as a formulary, which might not include all of the U.S. FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our products or to restrict coverage of our products could reduce utilization of our products. Moreover, a third-party payor's decision to provide coverage for a finished drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for finished drug product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. Federal and state governments have shown significant interest in implementing cost-containment programs, including restrictions on reimbursement and requirements for substitution of generic products. Adoption of new or enhanced cost-containment measures could limit our net revenue and results. Third party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy. Restrictions in coverage or decreases in third-party reimbursement for our products could have a material adverse effect on our sales, results of operations and financial condition. We expect that the pharmaceutical industry will experience pricing pressures due to the increasing influence of managed care (and related implementation of managed care strategies to control utilization), additional federal and state legislative and regulatory proposals to regulate pricing of drugs, limit coverage of drugs or reduce reimbursement for drugs, and public scrutiny of drug pricing. While we cannot predict what executive, legislative and regulatory proposals will be adopted or other actions will occur, such events could have a material adverse effect on our business, financial condition and profitability. For additional information relating to pricing and reimbursement, see Item 1A, Risk Factors, elsewhere in this Annual Report on Form 10-K.

#### Sales and Marketing

The marketing and sale of pharmaceutical products are subject to comprehensive governmental regulation both within and outside the U.S.

Within the U.S., numerous federal, state and local authorities have jurisdiction over, or enforce laws related to, such activities, including the U.S. FDA, U.S. Drug Enforcement Agency, Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services Office of Inspector General, the U.S. Department of Justice, state Attorneys General, state departments of health and state pharmacy boards.

We are subject to the requirements of the Federal Food, Drug, and Cosmetic Act and accompanying regulations that prohibit pharmaceutical companies from promoting a drug prior to approval from the U.S. FDA and from promoting an approved drug in a manner inconsistent with the approved label.

We are also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws, for activities related to sales of any of our products or product candidates that may in the future receive marketing approval. Anti-kickback laws generally prohibit persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. False claims laws 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. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid).

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation.

#### **Our Legacy Business**

#### **Separation**

On April 1, 2019, we completed the Separation. At the time of the Separation, Cyclerion's portfolio was comprised of several sGC stimulators, including olinciguat, a vascular sGC stimulator in Phase II development, praliciguat, a systemic sGC stimulator in Phase II development, and IW-6463, a central nervous system-penetrant sGC stimulator in Phase I development. In connection with the Separation, certain assets and liabilities related to the sGC business were transferred to Cyclerion, including various U.S. and foreign patents and Patent Cooperation Treaty patent applications.

## **Uncontrolled Gout Programs**

In June 2016, we closed a transaction with AstraZeneca pursuant to which we received an exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient, including ZURAMPIC® and DUZALLO®. In January 2018, we commenced an initiative to evaluate the optimal mix of investments for our lesinurad franchise for uncontrolled gout, including ZURAMPIC and DUZALLO. As part of this effort, in 2018 we began re-allocating resources within our lesinurad franchise to systematically explore a more comprehensive marketing mix in select test markets (with paired controls), while continuing to build market presence for the lesinurad franchise across the country. In July 2018, we obtained and analyzed the results from the lesinurad franchise test markets. Data from the test markets did not meet expectations. In connection with the results, we determined on July 31, 2018 to terminate the lesinurad license agreement. In August 2018, we delivered to AstraZeneca a notice of termination of the lesinurad license agreement. The post-marketing clinical study to further evaluate the renal and cardiovascular safety of lesinurad was terminated following the termination of the lesinurad license agreement.

#### **Employees**

As of December 31, 2019, we had 317 employees. Approximately 60 were in our drug development team, 196 were in our sales and commercial team, and 61 were in general and administrative functions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

During the years ended December 31, 2019 and 2018, we commenced certain reductions in our workforce. Refer to Note 19, *Workforce Reduction*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for further details.

#### **Available Information**

You may obtain free copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to those reports, as soon as reasonably practicable after they are electronically filed or furnished to the SEC, on the Investors section of our website at www.ironwoodpharma.com or by contacting our Investor Relations department at (617) 374-5082. The contents of our website are not incorporated by reference into this report and you should not consider information provided on our website to be part of this report.

#### Item 1A. Risk Factors

In addition to the other information in this Annual Report on Form 10-K, any of the factors described below could significantly and negatively affect our business, financial condition, results of operations or prospects. The trading price of our Class A Common Stock may decline due to these risks.

#### Risks Related to Our Business and Industry

We are highly dependent on the commercial success of LINZESS® (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, Allergan plc (together with its affiliates), or Allergan, began selling LINZESS in the U.S. during December 2012. Revenues from our LINZESS collaboration constitute a significant portion of our total revenue, and we believe they will continue to do so for the foreseeable future. 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 Allergan;
- 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 costeffective 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 reapprovals 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. Food and Drug Administration, or 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 the lack of clinical safety and efficacy data in pediatric patients of any age group. We and Allergan have established a nonclinical and clinical post-marketing plan with the 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 active pharmaceutical ingredient, or 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, 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 and natural disasters. In addition, the raw materials necessary to make API for our products are acquired from a limited number of sources. Any delay or disruption in the availability of these raw materials or a change in raw material suppliers could result in production disruptions, delays or higher costs with consequent adverse effects on us.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations and the challenges associated with complex supply chain management. Even if our 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 June 2019, Allergan and AbbVie, Inc., or AbbVie, entered into a definitive agreement providing for the combination of the two companies. If the transaction is completed, or if any of our linaclotide partners otherwise undergo a change of control or in management, we would need to reestablish many relationships and confirm continued alignment on our development and commercialization strategy for linaclotide. Further, in connection with any change of control or 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. 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 Allergan was previously providing to the collaboration. Any such transition might result in a period of reduced efficiency or performance by our operations and commercialization teams, which could adversely affect our ability to commercialize LINZESS.

Although many members of our global operations, commercial and medical affairs teams have strategic oversight of, and a certain level of involvement in, their functional areas globally, we do not have corresponding operational capabilities in these areas outside of the U.S. If Allergan, Astellas 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 Allergan to market and sell LINZESS in the U.S. for it to achieve its maximum commercial potential.

We are working closely with Allergan to execute our joint commercialization plan for LINZESS. The commercialization plan includes an agreed upon marketing campaign that targets the physicians who see patients who could benefit from LINZESS treatment. Our marketing campaign also targets the adult men and women who suffer from IBS-C or CIC. Our commercialization plan also includes an integrated call plan for our sales forces to optimize the education of specific gastroenterologists and primary care physicians on whom our and Allergan's sales representatives call, and the frequency with which the representatives meet with them.

In order to optimize the commercial potential of LINZESS, we and Allergan must execute upon this commercialization plan effectively and efficiently. In addition, we and Allergan must continually assess and modify our commercialization plan in a coordinated and integrated fashion in order to adapt to the promotional response. Further, we and Allergan must continue to focus and refine our marketing campaign to ensure a clear and understandable physician-patient dialogue around IBS-C, CIC and the potential for LINZESS as an appropriate therapy. In addition, we and Allergan must provide our sales forces with the highest quality support, guidance and oversight for them to continue to effectively promote LINZESS to gastroenterologists and primary care physicians. Should the merger of Allergan and AbbVie be consummated, we and AbbVie must work together to ensure an orderly transition of this work plan and to continue these commercialization efforts. If we and Allergan (or AbbVie, should the merger be consummated) fail to perform these commercial functions in the highest quality manner and in accordance with our joint commercialization plan and related agreements, LINZESS will not achieve its maximum commercial potential and we may suffer financial harm. Our efforts to further target and engage adult patients with IBS-C or CIC may not effectively increase appropriate patient awareness or patient/physician dialogue and may not increase the revenues that we generate from LINZESS.

## We are subject to uncertainty relating to pricing and reimbursement policies in the U.S. which, if not favorable for our products, could hinder or prevent our products' commercial success.

Our and our partner's ability to commercialize our products successfully depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party 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 may face increasing pressure to offer discounts or rebates from list prices or discounts to a greater number of 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 Allergan 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.

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 Allergan is currently commercializing CONSTELLA in a number of European countries, including the United Kingdom, Italy and Spain. LINZESS was first launched in Japan for the treatment of IBS-C in adults in the first quarter of 2017, and 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 the first quarter of 2019, the Chinese National Medical Products Administration approved the marketing application for LINZESS for adults with IBS-C in China, and our partner, AstraZeneca, launched LINZESS in November 2019. 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.

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

commercializing LINZESS in the U.S. with Allergan. Allergan is also responsible for the development, regulatory approval and commercialization of linaclotide in countries worldwide other than Japan and China (including Hong Kong and Macau). Allergan is commercializing LINZESS in Mexico and CONSTELLA in Canada, as well as commercializing CONSTELLA in certain countries in Europe. Astellas 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 that arise in those regions. These integrated functions may not be carried out effectively and efficiently if we fail to communicate and coordinate with our linaclotide partners, and vice versa. Our linaclotide partnering strategy imposes obligations, risks and operational requirements on us as the central node in our global network of partners. If we do not effectively communicate with each partner and ensure that the entire network is making integrated and cohesive decisions focused on the global brand for linaclotide, linaclotide will not achieve its maximum commercial potential. Further, we have limited ability to control the amount or timing of resources that our partners devote to linaclotide. If any of our partners fails to devote sufficient time and resources to linaclotide, or if its performance is substandard, it will delay the potential submission or approval of regulatory applications for linaclotide, as well as the manufacturing and commercialization of linaclotide in the particular territory. A material breach by any of our partners of our collaboration or license agreement with such partner, or a significant disagreement between us and a partner, could also delay the regulatory approval and commercialization of linaclotide, potentially lead to costly litigation, and could have a material adverse impact on our financial condition. Moreover, although we have noncompete 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 Allergan 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 Allergan 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 the lack of clinical safety and efficacy data in pediatric patients of

any age group. We and Allergan have established a nonclinical and clinical post-marketing plan with the 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. 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 US WorldMeds, LLC'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 ISBRELA<sup>TM</sup> (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 health care 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 includes provisions to eliminate 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. Pending appeals, which could take some time, the ACA is still operational in all respects. 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. 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 Allergan 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 inlicense 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 Allergan 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 also pursuing various other programs in our pipeline, including MD-7246, a delayed release form of linaclotide that is being developed as an oral, intestinal, non-opioid, pain relieving agent for patients suffering from abdominal pain associated with certain GI diseases, the potential treatment of IBS-D, and IW-3718, a gastric retentive formulation of a bile acid sequestrant for the potential treatment of persistent gastroesophageal reflux disease, and the strength of our company's pipeline will depend in large part on the outcomes of these studies. 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 for linaclotide and our product candidates, including MD-7246 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. 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. 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:

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

Clinical trials may also be delayed 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 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. They also provide for the performance of services by each company for the benefit of the other 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 taxfree 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; and Thomas A. McCourt, our president. Transitions in our senior management team and other key employees may result in operational disruptions, and our business may be harmed as a result. In addition to the competition for personnel, the Boston area in particular is characterized by a high cost of living. 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 error, malfeasance or other disruptions. We, our partners, vendors and other third-party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. While we have invested in information technology and security and the protection of confidential information, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruptions or breach would substantially impair our ability to operate our business and would compromise our, and their, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business. While we maintain cyber liability insurance, this insurance may not be sufficient to cover the losses that may result from an interruption or breach of our (or our partners', vendors' and third-party providers') systems.

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

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

#### **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 (linaclotide), 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 formulation of the 145 mcg and 290 mcg doses of linaclotide and methods of using this formulation, 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. For example, we are pursuing patent applications that cover the commercial formulation of the 72 mcg dose of LINZESS. 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 invalidated, 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 Allergan have received Paragraph IV certification notice letters, or 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. For additional information relating to such ANDAs, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K. 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. 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. For additional information relating to such lawsuits and settlements, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K. 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 Allergan for the U.S. We believe that the revenues from the LINZESS collaboration will continue to constitute a significant portion of our total revenue for the foreseeable future. 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 will significantly decrease beginning 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. For the year ended December 31, 2019, we recorded net income of approximately \$21.5 million. We incurred net losses of approximately \$282.4 million and approximately \$116.9 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of approximately \$1.6 billion. We cannot be certain that sales of our products, and the revenue from our other commercial activities will not fall short of our projections or be delayed. Further, we expect to continue to incur substantial expenses in connection with our efforts to commercialize linaclotide and 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 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 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 linaclotide product
  development programs, including our post-approval nonclinical and clinical studies of linaclotide in
  pediatrics and our investment to enhance the clinical profile of LINZESS within IBS-C and CIC, as well as
  to study linaclotide in additional indications, populations and formulations to assess its potential to treat
  various conditions;
- the 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 Allergan 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 Allergan will be a significant source of cash flows from operations. If the cash flows derived from the net quarterly payments that we receive from Allergan under the collaboration agreement for North America are insufficient on any particular payment date to fund the interest payment on our outstanding indebtedness, at a minimum, we will be obligated to pay the amounts of such shortfall out of our general funds. The determination of whether Allergan will be obligated to make a net quarterly payment to us in respect of a particular quarterly period is a function of the revenue generated by LINZESS in the U.S. as well as the development, manufacturing and commercialization expenses incurred by each of us and Allergan under the collaboration agreement for North America. Accordingly, since we cannot guarantee that our company will maintain net income or generate and maintain 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 Allergan, (ii) there will be a net quarterly payment from Allergan at all or (iii) we will not also be required to make a true-up payment to Allergan under the collaboration agreement for North America, in each case, in respect of a particular quarterly period.

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

As of December 31, 2019, we had total indebtedness of approximately \$520.7 million and available cash and cash equivalents of approximately \$177.0 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 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; and
- any material lawsuit in which we may become involved.

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 Allergan and involves the use of estimates and judgments, which could be modified in the future. We are highly dependent on our linaclotide partners for timely and accurate information regarding any revenues realized from sales of linaclotide in their respective territories, and in the case of Allergan for the U.S., 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 results, including clinical trial results, or intellectual property rights of us or others;
- actual and anticipated fluctuations in our quarterly and annual operating results;
- deviations in our operating results from any guidance we may provide or the estimates of securities analysts;
- sales of additional shares of our 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;
   and
- discussion of us or our stock price in the financial or scientific press or in online investor communities.

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

## Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

Our corporate headquarters and operations are located in Boston, Massachusetts, where, as of December 31, 2019, we occupied approximately 39,000 square feet of office space under our lease expiring in June 2030. We believe that our facilities are suitable and adequate for our needs for the foreseeable future.

## Item 3. Legal Proceedings

We and Allergan plc (together with its affiliates), or Allergan, have received Paragraph IV certification notice letters, or Notice Letters, regarding Abbreviated New Drug Applications, or ANDAs, submitted to the U.S. Food and Drug Administration, or U.S. FDA, by generic drug manufacturers requesting approval to engage in commercial

manufacture, use, sale and offer for sale of (i) 145 mcg and 290 mcg linaclotide capsules, or the Potential Generic Products, and/or (ii) 72 mcg linaclotide capsules, or the Potential 72mcg Generic Products, each proposed generic versions of our U.S. FDA-approved drug LINZESS.

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

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

In response to the ANDAs for which we received Notice Letters in 2016, we and Allergan filed a lawsuit against the generic drug manufacturers in Delaware District Court in November 2016. We asserted that the Challenged Patents are valid and infringed by Teva and Sandoz. In accordance with the Hatch-Waxman Act, the timely filing of the lawsuits against the ANDA filers with respect to the Challenged Patents triggered an automatic stay of the U.S. FDA's approval of the ANDAs until as early as February 29, 2020 (unless there is a final court decision adverse to us and Allergan sooner). In October 2017 and January 2018, we and Allergan filed lawsuits against Teva and Sandoz, respectively, each in Delaware District Court, related to each of their respective second Notice Letters. We asserted that U.S. Patent No. 9,708,371 is valid and infringed by each of Teva and Sandoz. The lawsuits filed in October 2017 and January 2018 against Teva and Sandoz, respectively, have been consolidated with the lawsuit filed in November 2016.

In January 2017, each of Teva and Sandoz filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of the Challenged Patents. In November 2017 and February 2018, each of Teva and Sandoz, respectively, filed an answer and counterclaims seeking declaratory judgment of invalidity and non-infringement of U.S. Patent No. 9,708,371. In February 2018, we and Allergan filed a lawsuit against Teva in Delaware District Court asserting that the 72mcg Challenged Patents are valid and infringed. This lawsuit was consolidated with the lawsuit filed in November 2016.

In May 2018 and August 2018, we, Allergan, Teva and Sandoz stipulated to dismiss without prejudice all claims, counterclaims and defenses with respect to U.S. Patent Nos. 9,708,371 and 8,933,030, respectively. In May 2019, we, Allergan, Teva and Sandoz stipulated to dismiss without prejudice all claims, counterclaims and defenses with respect to U.S. Patent Nos. 7,745,409 and 8,110,553.

The trial for the action involving Teva and Sandoz was originally scheduled to begin in June 2019. However, the trial was postponed as a result of the unavailability of one of the expert witnesses for Teva and Sandoz to testify in person at the trial due to a serious health issue. In July 2019, we, Allergan, Teva and Sandoz filed a proposed stipulation with the Delaware District Court, and, in August 2019, the court entered an order approving the stipulation. The stipulation and order provided for the trial to be rescheduled to begin on January 7, 2020. In an effort to preserve the status quo, the stipulation and order prohibited Teva and Sandoz from commercially selling or importing into the U.S. any proposed generic version of LINZESS until the earlier of (i) the date the court issued its trial decision in the lawsuit, and (ii) September 20, 2020. However, in January 2020, we and Allergan entered into settlements with Sandoz and Teva resolving the action. We and Allergan previously entered into settlement agreements with Aurobindo Pharma Ltd. and an affiliate of Aurobindo; Mylan Pharmaceuticals Inc., or Mylan; and Sun Pharma Global FZE. Pursuant to the terms of

the settlements, we and Allergan granted each generic drug manufacturer a license to market their respective 145 mcg and 290 mcg generic versions of LINZESS in the U.S. beginning as early as March 31, 2029 (subject to U.S. FDA approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. We also previously entered into a settlement agreement with Mylan pursuant to which we granted Mylan a license to market its 72 mcg generic version of LINZESS beginning August 5, 2030 (subject to U.S. FDA approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. The settlement with Teva does not grant any license to Teva with regard to its 72 mcg generic version of LINZESS.

## Item 4. Mine Safety Disclosures

Not applicable.

#### **PART II**

# Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Shares of our Class A Common Stock are traded on the Nasdaq Global Select Market under the symbol "IRWD." Our shares have been publicly traded since February 3, 2010. As of February 10, 2020, there were 70 stockholders of record of our Class A Common Stock. The number of record holders is based upon the actual number of holders registered on the books of the company at such date and does not include holders of shares in "street names" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depositories.

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of Class A Common Stock are entitled to share equally in any dividends that our board of directors may determine to issue from time to time. In the event a dividend is paid in the form of shares of common stock or rights to acquire shares of common stock, the holders of Class A Common Stock will receive Class A Common Stock, or rights to acquire Class A Common Stock, as the case may be.

We have never declared or paid any cash dividends on our capital stock, and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is referenced under Item 12 of Part III of this Annual Report on Form 10-K.

## Corporate Performance Graph

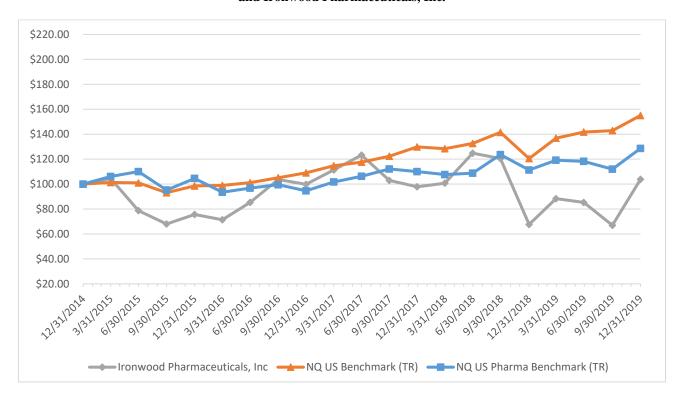
The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

On April 1, 2019, we completed the separation, or the Separation, of our soluble guanylate cyclase 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 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 following graph compares the performance of our Class A Common Stock to the Nasdaq Benchmark TR Index (U.S.) and to the Nasdaq Pharmaceutical Benchmark TR Index (U.S.) from December 31, 2014 through December 31, 2019. The comparison assumes \$100 was invested after the market closed on December 31, 2014 in our Class A Common Stock and in each of the presented indices, and it assumes reinvestment of dividends, if any (other than any Cyclerion common stock distributed in connection with the Separation). Total returns reflected in the following graph for periods prior to the date of the Separation have been adjusted for the effect of the Separation to exclude the sGC business.

# COMPARISON OF QUARTERLY CUMULATIVE TOTAL RETURN

Among The Nasdaq Benchmark TR Index (U.S.), the Nasdaq Pharmaceutical Benchmark TR Index (U.S.) and Ironwood Pharmaceuticals, Inc.



#### Item 6. Selected Financial Data

You should read the following selected financial data together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2019, 2018 and 2017 and the consolidated balance sheet data as of December 31, 2019 and 2018 from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016, and 2015 from our audited financial statements not included in this Annual Report on Form 10-K. During the year ended December 31, 2019, we completed the separation of our soluble guanylate cyclase, or sGC, business, or the Separation. Results of operations related to our sGC business have been reclassified to reflect discontinued operations for all periods presented. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenues:					
Collaborative arrangements revenue <sup>(1)</sup>	\$ 379,652	\$ 272,839	\$ 265,533	\$ 263,923	149,040
Product revenue, net	_	3,445	3,061	109	_
Sale of active pharmaceutical ingredient	48,761	70,355	29,682	9,925	515
Total Revenues	428,413	346,639	298,276	273,957	149,555
Cost and expenses:					
Cost of revenues <sup>(2)</sup>	23,875	32,751	19,097	1,868	12
Write-down of commercial supply and inventory to net realizable value and					
(settlement) loss on non-cancellable purchase commitments <sup>(3)</sup>	(3,530)	247	309	374	17,638
Research and development	115,044	101,060	88,145	101,903	78,326
Selling, general and administrative	172,450	219,676	231,184	169,169	120,927
Amortization of acquired intangible asset <sup>(4)</sup>	_	8,111	6,214	981	_
(Gain) loss on fair value remeasurement of contingent consideration <sup>(4)</sup>	_	(31,045)	(31,310)	9,831	_
Gain on lease modification <sup>(5)</sup>	(3,169)	_	_	_	_
Restructuring expenses <sup>(6)</sup>	3,620	14,715	_	_	_
Impairment of intangible assets <sup>(4)</sup>		151,794			
Total cost and expenses	308,290	497,309	313,639	284,126	216,903
Income (loss) from operations	120,123	(150,670)	(15,363)	(10,169)	(67,348)
Other (expense) income:					
Interest expense	(36,602)	(37,724)	(36,370)	(39,153)	(31,096)
Interest and investment income	2,862	2,991	2,111	1,169	443
Gain (loss) on derivatives <sup>(7)</sup>	3,023	(8,743)	(3,284)	8,146	(9,928)
Loss on extinguishment of debt (8)	(30,977)	_	(2,009)	_	_
Other income <sup>(9)</sup>	514				
Other expense, net	(61,180)	(43,476)	(39,552)	(29,838)	(40,581)
Net income (loss) from continuing operations	58,943	(194,146)	(54,915)	(40,007)	(107,929)
Net loss from discontinued operations	(37,438)	(88,222)	(62,022)	(41,701)	(34,740)
Net income (loss)	\$ 21,505	\$ (282,368)	\$ (116,937)	\$ (81,708)	(142,669)
Net income (loss) per share from continuing operations—basic and diluted	\$ 0.38	\$ (1.27)	\$ (0.37)	\$ (0.28)	\$ (0.76)
Net loss per share from discontinued operations—basic and diluted	(0.24)	(0.58)	(0.42)	(0.29)	\$ (0.24)
Net income (loss) per share—basic and diluted	0.14	(1.85)	(0.78)	(0.56)	\$ (1.00)
Weighted average number of common shares—basic and diluted:	156,023	152,634	148,993	144,928	142,155

<sup>(1)</sup> Collaborative arrangements revenue for the year ended December 31, 2019 included approximately \$325.4 million related to our share of sales of LINZESS® (linaclotide) in the U.S., approximately \$32.4 million in non-contingent payments from AstraZeneca AB (together with its affiliates), and \$10.0 million related to the upfront fee from Astellas Pharma Inc.

Collaborative arrangements revenue for the year ended December 31, 2018 included approximately \$264.2 million related to our share of sales of LINZESS in the U.S., which included an approximately \$29.9 million adjustment related to a change in estimate of gross-to-net sales reserves and allowances, primarily associated with governmental and contractual rebates.

Collaborative arrangements revenue for the year ended December 31, 2016 included approximately \$217.7 million related to our share of sales of LINZESS in the U.S. and \$30.0 million related to the receipt of milestone payments.

(2) Cost of revenues for the year ended December 31, 2019 included approximately \$23.9 million related to sales of linaclotide API and finished drug product.

Cost of revenues for the year ended December 31, 2018 included approximately \$31.6 million related to sales of linaclotide API and finished drug product.

Cost of revenues for the year ended December 31, 2017 included approximately \$2.6 million related to ZURAMPIC and DUZALLO product sales.

(3) During the year ended December 31, 2019, we recorded settlements of approximately \$3.5 million as write-down of commercial supply to net realizable value and (settlement) loss on non-cancelable purchase commitments related to the reversal of certain previously accrued non-cancelable purchase commitments.

During the year ended December 31, 2018, we wrote down approximately \$0.2 million of ZURAMPIC® commercial supply as a result of revised demand forecasts due to the exit of the exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient, or the Lesinurad License, including ZURAMPIC and DUZALLO®.

During the years ended December 31, 2017 and 2016, we wrote down approximately \$0.3 million and approximately \$0.4 million, respectively, of prepaid ZURAMPIC commercial supply primarily as a result of revised demand forecasts.

During the year ended December 31, 2015, we recorded expenses of approximately \$17.6 million for the write-down of inventory and an accrual for excess non-cancelable inventory purchase commitments related to linaclotide API.

These charges are more fully described in Note 8, *Inventory*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

- (4) Amortization of acquired intangible assets was based on the economic consumption of intangible assets. Our amortization was related to the ZURAMPIC and DUZALLO intangible assets. (Gain) loss on fair value remeasurement of contingent consideration was related to our contingent consideration liability pursuant to our exclusive license to develop, manufacture, and commercialize products containing lesinurad as an active ingredient, including ZURAMPIC and DUZALLO, in the U.S. During the year ended December 31, 2018, we delivered to AstraZeneca a notice of termination of the lesinurad license agreement. As a result, we recorded an impairment charge of approximately \$151.8 million due to the impairment of the ZURAMPIC and DUZALLO intangible assets. As a result, a gain on fair value remeasurement of contingent consideration of approximately \$31.0 million was recorded during the year ended December 31, 2018.
- (5) During the year ended December 31, 2019, we recorded a gain on lease modification of approximately \$3.2 million related to the modification of our 301 Binney Street lease in April 2019.
- (6) During the year ended December 31, 2019, we incurred approximately \$3.6 million in restructuring expenses, primarily due to costs associated with the February 2019 workforce reduction.
  - During the year ended December 31, 2018, we incurred approximately \$14.7 million in restructuring expenses, primarily due to costs associated with the workforce reductions in 2018 as a result of our evaluation of the optimal mix of investments for the lesinurad franchise, our subsequent decision to terminate the Lesinurad License and the associated contract termination costs, as well as our intention to separate into two independent publicly traded companies.
- (7) Gain (loss) on derivatives consists of the change in fair value of our 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

consolidated statements of operations. In connection with the partial repurchase of our 2.25% Convertible Senior Notes due 2022, or the 2022 Convertible Notes, we also terminated the respective portion of our existing Convertible Note Hedges and Note Hedge Warrants. The Convertible Note Hedges and Note Hedge Warrants are more fully described in Note 7, *Fair Value of Financial Instruments*, and Note 12, *Notes Payable*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

(8) For the year ended December 31, 2019, we recorded a loss on extinguishment of debt of approximately \$31.0 million due to the write-off of unamortized debt issuance costs and debt discount related to the partial repurchase of the 2022 Convertible Notes in August 2019 and the prepayment premium and write-off of the remaining unamortized debt issuance costs and debt discount on the 2026 Notes as part of the redemption of all of the outstanding principal amount of the 8.375% Notes due 2026, or the 2026 Notes, in September 2019.

For the year ended December 31, 2017, we recorded a loss on extinguishment of debt of approximately \$2.0 million due to the write-off of remaining unamortized debt issuance costs on the 11% PhaRMA Notes due 2024, or the PhaRMA Notes, as part of the redemption in January 2017.

(9) For the year ended December 31, 2019, we recorded other income of approximately \$0.5 million related to a transition services agreement with Cyclerion Therapeutics, Inc., or Cyclerion, in connection with the Separation.

	Year Ended December 31,					
	2019	2018	2017	2016	2015	
		(in thousands)				
Consolidated Balance Sheet Data:						
Cash, cash equivalents and available-for-sale						
securities	\$ 177,023	\$ 173,172	\$ 221,416	305,216	\$ 439,394	
Working capital (excluding deferred revenue)	266,798	146,911	245,569	289,050	430,931	
Assets of discontinued operations, including current						
portion (1)		10,490	7,256	6,097	9,631	
Right-of-use assets <sup>(2)</sup>	17,743	_	_	_		
Total assets	402,748	332,050	605,674	709,821	619,121	
Deferred revenue, including current portion	875	_	_	_	8,989	
Current liabilities of discontinued operations <sup>(1)</sup>		15,739	9,997	6,618	3,659	
Debt financing and convertible notes, including						
current portion (3)	407,994	413,692	396,091	366,492	378,548	
Capital lease obligations, including current portion	_	231	4,077	6,309	2,937	
Operating lease obligations, including current						
portion <sup>(2)</sup>	23,228	_	_	_		
Total liabilities	495,999	528,421	595,826	643,105	523,996	
Total stockholders' (deficit) equity	(93,251)	(196,371)	9,848	66,716	95,125	
· · · · · · · ·						

<sup>(1)</sup> During the year ended December 31, 2019, we completed the Separation. Assets and liabilities related to Cyclerion have been reclassified as assets and liabilities of discontinued operations for the periods presented.

<sup>(2)</sup> During the year ended December 31, 2019, we implemented Accounting Standards Codification, Topic 842, *Leases*, or ASC 842. As a result, we recorded right-of-use assets and associated lease liabilities for operating leases on our consolidated balance sheet as of December 31, 2019.

<sup>(3)</sup> In August 2019, we issued \$200.0 million in aggregate principal amount of the 0.75% Convertible Senior Notes due 2024, or the 2024 Convertible Notes, and \$200.0 million in aggregate principal amount of the 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 to pay the cost of the associated capped call transactions, redeem all of the outstanding principal balance of the 2026 Notes, and repurchase \$215.0 million aggregate principal amount of the 2022 Convertible Notes.

#### Item 7. 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 consolidated financial statements and the notes to those financial statements appearing elsewhere in this 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 Annual Report on Form 10-K, 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, or GC-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.

We have strategic partnerships with leading pharmaceutical companies to support the development and commercialization of linaclotide throughout the world, including with Allergan plc (together with its affiliates), or Allergan 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 and Allergan are also advancing 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. MD-7246 is designed to have the pain-relieving effect of linaclotide with minimal impact on bowel function. In May 2019, we and Allergan announced the initiation of a Phase II clinical trial evaluating the safety and efficacy of MD-7246 in adult patients with abdominal pain associated with IBS with diarrhea, or IBS-D.

We are advancing another GI development program, 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.

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<sup>TM</sup> (givosiran), an RNAi therapeutic targeting aminolevulinic acid synthase 1, for the treatment of acute hepatic porphyria, or AHP.

In January 2020, we and Allergan entered into settlement agreements with Sandoz Inc., or Sandoz, and Teva Pharmaceuticals, USA, or Teva, resolving patent litigation brought in response to Sandoz's and Teva's abbreviated new drug applications seeking approval to market generic versions of LINZESS prior to the expiration of our and Allergan's applicable patents. For additional information relating to the resolution of such litigation, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K.

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, we incurred net losses in each year since our inception in 1998. For the year ended December 31, 2019, we recorded net income of approximately \$21.5 million. As of December 31, 2019, we had an accumulated deficit of

approximately \$1.6 billion. We are unable to predict the extent of any future losses or guarantee that our company will be able to achieve or maintain positive cash flows.

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.

# **Key 2019 Financial Highlights:**

Issued \$400.0 million in Convertible Senior Notes.

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, on September 16, 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 12, *Notes Payable*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

 Amended and restated our ex-U.S. linaclotide partnerships with Astellas in Japan and AstraZeneca in China (including Hong Kong and Macau).

On August 1, 2019, we amended and restated our license agreement with Astellas, or the Amended Astellas License Agreement. As a result, we recognized \$10.0 million in revenue from Astellas related to upfront payments. Beginning in 2020, we will no longer be responsible for the supply of linaclotide active pharmaceutical ingredient, or API, to Astellas.

On September 16, 2019, we amended and restated our collaboration agreement with AstraZeneca, or the Amended AstraZeneca Agreement, under which AstraZeneca obtained the exclusive right to develop, manufacture, and commercialize products containing linaclotide in the AstraZeneca license territory, or the AstraZeneca License. As a result, we recognized approximately \$32.4 million in revenue from AstraZeneca related to non-contingent payments in 2019. Beginning in 2020, we will no longer be responsible for API, finished drug product and finished goods manufacturing for China and Macau and for finished drug product manufacturing for Hong Kong.

These agreements are more fully described in Note 6, *Collaboration, License, Co-Promotion and Other Commercial Agreements*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Announced a new U.S. GI disease education and promotional agreement for GIVLAARI.

In August 2019, we entered into a disease education and promotional agreement with Alnylam for Alnylam's GIVLAARI. GIVLAARI was approved by the U.S. FDA in December 2019. Under the agreement, we will perform disease awareness activities related to AHP and sales detailing activities for GIVLAARI. This

agreement is more fully described in Note 6, *Collaboration, License, Co-Promotion and Other Commercial Agreements*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

• Relocated our headquarters to a new office in downtown Boston, Massachusetts.

On June 11, 2019, we entered into a non-cancelable operating lease, or the Summer Street Lease, for approximately 39,000 square feet of office space on the 23rd floor of 100 Summer Street, Boston, Massachusetts, or the Summer Street Property. The Summer Street Property began serving as our new headquarters in October 2019, replacing our prior headquarters at 301 Binney Street in Cambridge, Massachusetts. Monthly base rent payments were contractually reduced in connection with the execution of the Summer Street Lease. This agreement is more fully described in Note 9. *Leases*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

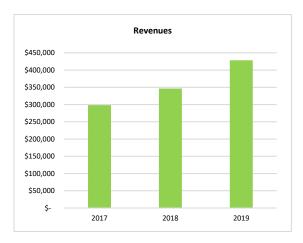
## **Our Legacy Business**

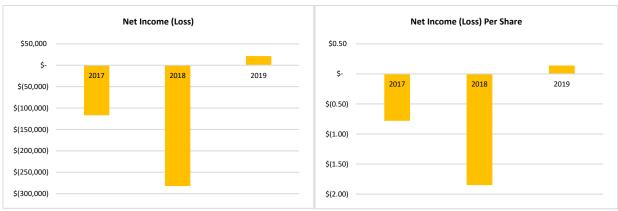
On April 1, 2019, we completed the separation, or the Separation, of our soluble guanylate cyclase, or sGC, business, and certain other assets and liabilities, into a separate, independent publicly traded company, Cyclerion Therapeutics, Inc., or Cyclerion. The Separation was effected by means of a distribution of all 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.

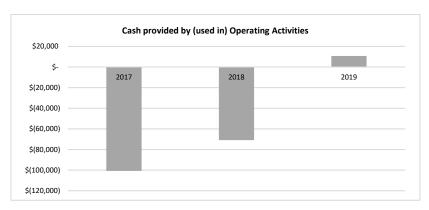
The separation agreement with Cyclerion, dated as of March 30, 2019, sets forth, among other things, our agreements with Cyclerion regarding the principal actions to be taken in connection with the Separation, including the dividend, which was effective as of April 1, 2019. In connection with the Separation, we also entered into certain other agreements with Cyclerion, including transition services agreements and a development agreement. Pursuant to the transition service agreements, we are obligated to provide and are entitled to receive certain transition services related to corporate functions, such as finance, procurement, facilities and development. Pursuant to the development agreement, Cyclerion is obligated to provide us with certain research and development services with respect to certain of our products and product candidates, including MD-7246 and IW-3718. The Separation and the aforementioned agreements are more fully described in Note 3, *Cyclerion Separation*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

# **Key Performance Indicators**

The following charts summarize key metrics of revenue, earnings (losses), and operating cash use (dollars in thousands, per share amounts in dollars):







These metrics are more fully described in the *Results of Operations* and *Liquidity and Capital Resources* sections below.

#### **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. Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606, using the modified retrospective transition method. The adoption of ASC 606 represented a change in accounting principle that aims to more closely align revenue recognition with the delivery of our services and will provide financial statement readers with enhanced disclosures. In accordance with ASC 606, we recognize revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration which we expect to receive in exchange for the good or service. Upon adoption of ASC 606, we concluded that no cumulative-effect adjustment to the accumulated deficit as of January 1, 2018 was necessary. The adoption of ASC 606 had no impact on our consolidated statement of operations, consolidated balance sheets, or consolidated statement of cash flows. The reported results for the year ended as of December 31, 2019 and 2018 reflect the application of ASC 606 guidance, while the reported results for the year ended December 31, 2017 were prepared in accordance with ASC 605, Revenue Recognition, or ASC 605.

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, 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 AstraZeneca Agreement, we received our share of the net profits or bore our share of the net losses from the 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 Allergan as collaboration expense or collaborative arrangements revenue, as applicable. Net profits or losses consist of net sales to third-party customers and sublicense income in the U.S. less the cost of goods sold as well as selling, general and administrative expenses. Although we expect net sales to increase over time, the settlement payments between Allergan and us, resulting in collaborative arrangements revenue or collaboration expense, are subject to fluctuation based on the ratio of selling, general and administrative expenses incurred by each party. In addition, our collaborative arrangements revenue may fluctuate as a result of the timing and amount of license fees and clinical and commercial milestones received and recognized under our current and future strategic partnerships as well as timing and amount of royalties from the sales of linaclotide in the European, Canadian or Mexican markets or any other markets where linaclotide receives approval.

Product revenue consisted of sales of ZURAMPIC <sup>®</sup> and DUZALLO <sup>®</sup>, or the Lesinurad Products, in the U.S. through the date of the termination of our exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient, or the Lesinurad License, in January 2019. Product revenue was recognized when a particular national wholesaler or a selected regional wholesaler, or a Distributor, obtained control of our product, which occurred at a point in time, typically upon shipment of the Lesinurad Products to the Distributor. When we performed shipping and handling activities after the transfer of control to the Distributor (e.g., when control transferred prior to delivery), they were considered fulfillment activities, and accordingly, the costs were accrued for when the related revenue was recognized. Taxes collected from customers relating to product sales and remitted to governmental authorities were excluded from revenues. We expensed incremental costs of obtaining contracts with Distributors as and when incurred if the expected amortization period of the asset that we would have recognized was one year or less.

Cost of Revenues. Cost of revenues primarily includes cost of collaborative arrangements revenue related to our collaborative arrangements, the sales of linaclotide API and finished drug product, as well as the cost of product revenue related to the sales of ZURAMPIC and DUZALLO in the U.S. 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. Cost of product revenue related to the sales of ZURAMPIC and DUZALLO in the U.S. included the cost of producing finished goods that corresponded with product revenue for the reporting period, such as third party supply and overhead costs, as well as certain period costs related to freight, packaging, stability and quality testing, and customer acquisition.

Write-down of Inventory to Net Realizable Value and (Settlement) Loss on Non-cancelable Inventory and Commercial Supply Purchase Commitments. During the year ended December 31, 2019, we recorded settlements of approximately \$3.5 million as write-down of commercial supply to net realizable value and (settlement) loss on non-cancelable purchase commitments related to reversal of certain previously accrued non-cancelable purchase commitments.

During the year ended December 31, 2018, we wrote down approximately \$0.3 million primarily related to lesinurad inventory and commercial supply purchase commitments as a result of revised demand forecasts and the notice of termination of the Lesinurad License. During the year ended December 31, 2018, we assigned to Allergan certain linaclotide excess non-cancelable purchase commitments for which we previously accrued. Accordingly, we relieved the previous accrual of approximately \$2.5 million.

During the year ended December 31, 2017, we wrote down approximately \$0.3 million of lesinurad commercial supply purchase commitments as a result of revised demand forecasts.

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 Allergan 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 Allergan 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 advancing innovative product opportunities in areas of large unmet need, including IBS-C and CIC, abdominal pain associated with lower GI disorders, and refractory GERD.

<u>Linaclotide</u>. 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 Japan and in a number of E.U. and other countries. In January 2019, the Chinese National Medical Products Administration approved the marketing application for LINZESS for adults with IBS-C in China. AstraZeneca launched LINZESS in China in November 2019.

We and Allergan 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 Allergan 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.

<u>MD-7246</u>. MD-7246 is a delayed-release formulation of linaclotide being evaluated as an oral, intestinal, non-opioid, pain-relieving agent for patients suffering from abdominal pain associated with certain GI diseases. MD-7246 is

designed to provide targeted delivery of linaclotide to the colon, where the majority of the abdominal pain is believed to originate, and to limit additional fluid secretion in the small intestine resulting in minimal impact on bowel function.

We and Allergan are initially exploring MD-7246 in a Phase II clinical trial evaluating the safety and efficacy of MD-7246 in adult patients with abdominal pain associated with IBS-D.

<u>IW-3718</u>. We are advancing 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.

<u>Early research and development</u>. 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 years ended December 31, 2019, 2018, and 2017. These expenses relate primarily to internal compensation, benefits and other employee-related expenses and external costs associated with nonclinical studies and clinical trial costs for our product candidates. We allocate costs related to facilities, depreciation, share-based compensation, research and development support services, laboratory supplies and certain other costs directly to programs.

	Yea	Year Ended December 31,					
	2019 2018			2017			
		(ir	thousands)				
Linaclotide <sup>(1)</sup>	\$ 39,061	\$	33,749	\$	33,042		
Lesinurad <sup>(2)</sup>	524		5,184		17,764		
IW-3718	65,771		37,789		16,160		
Early research and development	9,688		24,338		21,179		
Total research and development expenses	\$ 115,044	\$	101,060	\$	88,145		

- (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 \$501.7 million of research and development expenses related to linaclotide. The expenses for linaclotide include both our portion of the research and development costs incurred by Allergan for the U.S. and AstraZeneca for China (including Hong Kong and Macau) prior to the execution of the Amended AstraZeneca Agreement, 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 Allergan 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 Allergan 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 Allergan are also exploring development opportunities to enhance the clinical profile of LINZESS by studying linaclotide in additional indications, populations and formulations to assess its potential to treat various conditions. 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 Annual Report on Form 10-K, 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, we were reimbursed for certain selling, general and administrative expenses and we netted these reimbursements against our selling, general and administrative expenses as incurred. Under the Amended AstraZeneca Agreement, AstraZeneca is responsible for all costs and expenses incurred under the AstraZeneca License. We include Allergan's selling, general and administrative cost-sharing payments in the calculation of the net profits and net losses from the sale of LINZESS in the U.S. and present the net payment to or from Allergan as collaboration expense or collaborative arrangements revenue, respectively.

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

Gain on Fair Value Remeasurement of Contingent Consideration. We closed a transaction with AstraZeneca, or the Lesinurad Transaction, in June 2016, pursuant to which we received an exclusive license to develop, manufacture and commercialize products containing lesinurad as an active ingredient, including ZURAMPIC and DUZALLO, in the U.S. Our contingent consideration obligation related to the Lesinurad Transaction consisted of the fair value of estimated future milestone and royalty payments. This liability was revalued at each reporting date. Changes in the fair value of our contingent consideration, other than changes due to payments, were recognized as a (gain) loss on fair value remeasurement of contingent consideration in our consolidated statement of operations. Adjustments were recorded when there were changes in significant assumptions, including net sales projections, probability weighted net cash outflow projections, the discount rate, passage of time, and the yield curve equivalent to our credit risk, which was based on the estimated cost of debt for market participants.

*Gain on lease modification.* During the year ended December 31, 2019, we recorded a gain on lease modification of approximately \$3.2 million related to a modification of our 301 Binney Street lease in April 2019.

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.

Impairment of intangible assets. During the year ended December 31, 2018, we recorded an impairment charge of approximately \$151.8 million related to our ZURAMPIC and DUZALLO intangible assets. For additional information relating to the impairment of these assets, see Note 5, *Goodwill and Intangible Assets*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K

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

Gain (loss) on derivatives consists of the change in fair value of the Convertible Note Hedges and Note Hedge Warrants, which are recorded as derivative assets and liabilities. The Convertible Note Hedges and the Note Hedge Warrants are recorded at fair value at each reporting period and changes in fair value are recorded in our consolidated statements of operations. The Convertible Note Hedges and Note Hedge Warrants are more fully described in Note 12, *Notes Payable*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

In August 2019, we issued \$200.0 million in aggregate principal amount of the 2024 Convertible Notes and \$200.0 million in aggregate principal amount of 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 to redeem all of the outstanding principal balance of the 2026 Notes, repurchase \$215.0 million aggregate principal amount of the 2022 Convertible Notes and pay approximately \$25.2 million for the purchase of the Capped Calls. 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 and Note Hedge Warrants. These transactions are more fully described in Note 12, *Notes Payable*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

In connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, we entered into 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 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, and have a cap price of approximately \$17.05 per share. These instruments meet the conditions outlined in ASC Topic 815, *Derivatives and Hedging*, or 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. These transactions are more fully described in Note 12, *Notes Payable*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Interest income consists of interest earned on our cash, cash equivalents and marketable securities as well as significant financing components identified under ASC 606.

Discontinued Operations. We have recast all 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 3, Cyclerion Separation, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

## **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based upon our 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 consolidated financial statements, and the amounts of revenues and expenses during the reported periods. Significant estimates and assumptions in our 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 our acquired intangible assets and goodwill; valuation procedures for right-of-use assets and operating lease liabilities; valuation procedures for the issuance and repurchase of convertible notes; valuation of assets and liabilities held for disposition and losses related to discontinued operations; fair value of derivatives; balance sheet classification of notes payable and convertible notes; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; 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.

We believe that our application of the following accounting policies, each of which require significant judgments and estimates on the part of management, are the most critical to aid in fully understanding and evaluating our reported financial results. Our significant accounting policies are more fully described in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Reclassifications and Revisions to Prior Period Financial Statements

Certain prior period financial statement items have been reclassified to conform to current period presentation. We have presented our sGC business as discontinued operations in our consolidated financial statements for all periods presented. The historical financial statements and footnotes have been recast accordingly.

## **Discontinued Operations**

During the three months ended June 30, 2019, we determined that the separation of our sGC business on April 1, 2019 met the criteria for classification as a discontinued operation in accordance with ASC Subtopic 205-20, *Discontinued Operations*. Accordingly, the accompanying consolidated financial statements for all periods presented have been recast to present the assets and liabilities associated with the sGC business as held for disposition and the expenses directly associated with the sGC business as discontinued operations. For additional information related to discontinued operations, refer to Note 3, *Cyclerion Separation*, to these consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Fair Value Measurements

We have certain assets and liabilities that are measured at fair value on a recurring basis, and which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in ASC 820, *Fair Value Measurement*. 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 us to develop our own assumptions for the asset or liability.

Our investment portfolio includes mainly fixed income securities that do not always trade on a daily basis. As a result, the pricing services we use 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. We validate the prices provided by our third party pricing services by obtaining market values from other pricing sources and analyzing pricing data in certain instances.

We classify our derivative financial instruments and contingent consideration as Level 3 under the fair value hierarchy. The derivatives are not actively traded and are valued using the Black-Scholes option pricing model, which requires the use of subjective assumptions, primarily the expected stock price volatility assumption and expected term. The contingent consideration was not actively traded and was valued using the Monte-Carlo, simulation which requires the use of subjective assumptions, including probability weighted net cash outflow projections, discounted using a yield curve equivalent to our credit risk, which was the estimated cost of debt financing for market participants. Adjustments are recorded when there are changes in significant assumptions, including net sales projections, probability weighted net cash outflow projections, the discount rate, passage of time, and the yield curve equivalent to our credit risk, which is based on the estimated cost of debt for market participants.

## Leases

Effective January 1, 2019, we adopted ASC Topic 842, *Leases*, or ASC 842, using the optional transition method. The adoption of ASC 842 represents a change in accounting principle that aims to increase transparency and comparability among organizations by requiring the recognition of right-of-use, assets and lease liabilities on the balance sheet for both operating and finance leases. In addition, the standard requires enhanced disclosures that meet the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. The reported results for the year ended December 31, 2019 reflect the application of ASC 842 guidance, while the reported results for prior periods were prepared in conjunction with ASC Topic 840, *Leases*, or ASC 840. Because there were no material changes to the values of existing capital leases as a result of the adoption of ASC 842, we concluded that no cumulative-effect adjustment to the accumulated deficit as of January 1, 2019 was necessary. The

recognition of right-of-use assets and lease liabilities related to our operating leases under ASC 842 had a material impact on our consolidated financial statements.

As part of the ASC 842 adoption, we elected certain practical expedients outlined in the guidance. These practical expedients include:

- A policy election to use the short-term lease exception by asset class; and
- Election of the practical expedient package during transition, which includes:
  - An entity need not reassess whether any expired or existing contracts are or contain leases.
  - An entity need not reassess the classification for any expired or existing leases. As a result, all
    leases that were classified as operating leases in accordance with ASC 840 are classified as
    operating leases under ASC 842, and all leases that were classified as capital leases in accordance
    with ASC 840 are classified as finance leases under ASC 842.
  - o An entity need not reassess initial direct costs for any existing leases.

Subsequent to our adoption of ASC 842, we elected the post-transition practical expedient, by class of underlying asset, to account for lease components and non-lease components together as a single component for the asset class of operating lease right-of-use real estate assets.

Our lease portfolio for the year ended December 31, 2019 includes: leases for our prior and current headquarters locations, a data center colocation lease, vehicle leases for our salesforce representatives, and leases for computer and office equipment. We determine if an arrangement is a lease at the inception of the contract. The asset component of our operating leases is recorded as the operating lease right-of-use asset, and the liability component is recorded as the current portion of operating lease liabilities and operating lease liabilities, net of current portion in our consolidated balance sheet. As of December 31, 2019, we did not record any finance leases.

Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term at the lease inception date. Existing leases in our lease portfolio as of the adoption date were valued as of January 1, 2019. We use an incremental borrowing rate based on the information available at lease inception in determining the present value of lease payments if an implicit rate of return is not provided with the lease contract. Operating lease right-of-use assets are adjusted for incentives expected to be received.

Right-of-use assets and operating lease liabilities are remeasured upon certain modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate upon lease modification.

Lease cost is recognized on a straight-line basis over the lease term, and includes amounts related to short-term leases. We recognize variable lease payments as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by us.

## Derivative Assets and Liabilities

In June 2015, in connection with the issuance of the 2022 Convertible Notes, we entered into the Convertible Note Hedges. Concurrently with entering into the Convertible Note Hedges, we also entered into certain warrant transactions in which we sold Note Hedge Warrants to the Convertible Note Hedge counterparties to acquire shares of our Class A Common Stock, subject to customary anti-dilution adjustments. In connection with the partial repurchase of the 2022 Convertible Notes in August 2019, we terminated our Convertible Note Hedges and Note Hedge Warrants proportionately. These instruments are derivative financial instruments under ASC 815.

These derivatives are recorded as assets or liabilities at fair value at the end of each reporting period and the fair value is determined using the Black-Scholes option-pricing model. The changes in fair value are recorded as a component of other (expense) income in the consolidated statements of operations. Significant inputs used to determine the fair value include the price per share of our Class A Common Stock on the date of valuation, expected term of the derivative instruments, the strike prices of the derivative instruments, the risk-free interest rate, and the expected

volatility of our Class A Common Stock. Changes to these inputs could materially affect the valuation of the Convertible Note Hedges and Note Hedge Warrants in future periods.

In August 2019, in connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, we entered into the Capped Calls. 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 (subject to anti-dilution and certain other adjustments). 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.

## Revenue Recognition

Effective January 1, 2018, we adopted ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* and related amendments, or ASU 2014-09, using the modified retrospective transition method. The adoption of ASU 2014-09 represented a change in accounting principle that aims to more closely align revenue recognition with the delivery of our products or services and will provide financial statement readers with enhanced disclosures. ASU 2014-09 also included Subtopic 340-40, *Other Assets and Deferred Costs—Contracts with Customers*, which required the deferral of incremental costs of obtaining a contract with a customer. In accordance with ASC 606, we recognize revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration which we expect to receive in exchange for the good or service. Upon adoption of ASC 606, we concluded that no cumulative-effect adjustment to the accumulated deficit as of January 1, 2018 was necessary. There were no remaining or ongoing deliverables or unrecognized consideration as of December 31, 2017 that required an adjustment to the accumulated deficit. The adoption of ASC 606 had no impact on our consolidated statement of operations, consolidated balance sheets, or consolidated statement of cash flows. The reported results for the years ended December 30, 2019 and 2018 reflect the application of ASC 606 guidance, while the reported results for the year ended December 31, 2017 were prepared in accordance with ASC 605, *Revenue Recognition*, or ASC 605.

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

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

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

Our revenues are generated primarily through collaborative arrangements and license agreements related to the development and commercialization of linaclotide, as well as co-promotion arrangements in the U.S. The terms of the collaborative arrangements and other agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, including participation on joint steering committees, (iii) the manufacture of finished drug product, API, or development materials for a partner, which are reimbursed at a contractually determined rate, and (iv) education or co-promotion activities by our clinical sales specialists. Non-refundable payments to us under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API, or development materials, (iv)

payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives, and (vi) royalties on product sales. Additionally, we may receive our share of the net profits or bear our share of the net losses from the sale of linaclotide in the U.S. Prior to the execution of the Amended AstraZeneca Agreement in September 2019, we received our share of the net profits and bore our share of the net losses from the sale of linaclotide in China (including Hong Kong and Macau). We have adopted a policy to recognize revenue net of tax withholdings, as applicable.

#### Revenue recognition under ASC 606

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

#### Collaboration, License, Co-Promotion and Other Commercial Agreements

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

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

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

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

## Net Profit or Net Loss Sharing

In accordance with ASC 808 Topic, *Collaborative Arrangements*, or ASC 808, we considered the nature and contractual terms of the arrangement and the nature of our business operations to determine the classification of payments under our collaboration agreements. While ASC 808 provides guidance on classification, the standard is silent on matters of separation, initial measurement, and recognition. Therefore, we, consistent with our accounting policies prior to the adoption of ASC 606, apply the separation, initial measurement, and recognition principles of ASC 606 to our collaboration agreements. We adopted ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, during the three months ended December 31, 2018 and confirmed that,

consistent with our initial conclusions, we will continue to analogize to ASC 606 for further guidance on areas such as separation, initial measurement, and recognition for our existing collaborative arrangements where applicable.

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

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

## Product revenue, net

Product revenue consisted of sales of the Lesinurad Products in the U.S. through the date of the termination of the Lesinurad License in January 2019. We sold the Lesinurad Products principally to a limited number of national wholesalers and selected regional wholesalers, or the Distributors. The Distributors resold the Lesinurad Products to retail pharmacies and healthcare providers, who then sold to patients.

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

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

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

Product revenue was recorded net of the trade discounts, allowances, rebates, chargebacks, discounts, product returns, and other incentives. Certain of these adjustments were recorded as an accounts receivable reserve, while certain of these adjustments were recorded as accrued expenses.

#### Other

Through December 31, 2019, we produced linaclotide finished drug product, API and development materials for certain of our partners.

We recognize revenue on linaclotide finished drug product, API and development materials when control has transferred to the partner, which generally occurs upon shipment for sales of API and finished drug product, after the material has passed all quality testing required for collaborator acceptance. As it relates to development materials and API produced for Astellas, we are reimbursed at a contracted rate. Such reimbursements are considered as part of revenue generated pursuant to the Astellas license agreement and are presented as collaborative arrangements revenue. Any linaclotide finished drug product, API and development materials currently produced for Allergan for the U.S. are recognized in accordance with the cost-sharing provisions of the collaboration agreement with Allergan for North America. Prior to the execution of the Amended AstraZeneca Agreement in September 2019, any linaclotide finished drug product, API and development materials produced for AstraZeneca for China (including Hong Kong and Macau), were recognized in accordance with the cost-sharing provisions of the AstraZeneca collaboration agreement. Beginning in 2020, we will no longer be responsible for the supply of linaclotide finished drug product or API to our partners.

Our deferred revenue balance consists of advance billings and payments received from customers in excess of revenue recognized.

Revenue recognition prior to the adoption of ASC 606

## Agreements Entered into Prior to January 1, 2011

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

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

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

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

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

When evaluating multiple element arrangements under ASU 2009-13, we considered whether the deliverables under the arrangement represented separate units of accounting. This evaluation required subjective determinations and required management to make judgments about the individual deliverables and whether such deliverables were separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluated certain criteria, including whether the deliverables had standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination included the research, manufacturing

and commercialization capabilities of the partner and the availability of relevant research and manufacturing expertise in the general marketplace. In addition, we considered whether the collaborator can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, and whether the value of the deliverable was dependent on the undelivered items and whether there were other vendors that could provide the undelivered items.

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

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

## Up-Front License Fees prior to January 1, 2018

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

## Milestones prior to January 1, 2018

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

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

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

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

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

We recorded our share of the net profits or net losses from the sales of LINZESS in the U.S. on a net basis and presented the settlement payments to and from Allergan as collaboration expense or collaborative arrangements revenue,

as applicable, as we were not the primary obligor and did not have the risks and rewards of ownership in the collaboration agreement with Allergan for North America. We and Allergan settle the cost sharing quarterly, such that our consolidated statements of operations reflect 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

## Royalties on Product Sales prior to January 1, 2018

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

## Product Revenue, Net prior to January 1, 2018

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

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

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

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

## Other

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

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

The agreements above are more fully described in Note 6, *Collaboration, License, Co-promotion and Other Commercial Agreements*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Research and Development Expense

We have committed significant resources into the research and development of our product candidates and intend to continue to do so for the foreseeable future. All research and development expenses are expensed as incurred. We capitalize nonrefundable advance payments we make for research and development activities and defer expense recognition until the related goods are received or the related services are performed.

Research and development expenses are comprised of costs incurred in performing research and development activities, including salary, benefits, share-based compensation, and other employee-related expenses; laboratory supplies and other direct expenses; facilities expenses; overhead expenses; third-party contractual costs relating to nonclinical studies and clinical trial activities and related contract manufacturing expenses, development of manufacturing processes and regulatory registration of third-party manufacturing facilities; licensing fees for our product candidates; and other outside expenses.

Clinical trial expenses include expenses associated with contract research organizations, or CROs. The invoicing from CROs for services rendered can lag several months. We accrue the cost of services rendered in connection with CRO activities based on our estimate of site management, monitoring costs, project management costs, and investigator fees. We maintain regular communication with our CRO vendors to gauge the reasonableness of our estimates. Differences between actual clinical trial expenses and estimated clinical trial expenses recorded have not been material and are adjusted for in the period in which they become known. However, if we incorrectly estimate activity levels associated with the CRO services at a given point in time, we could be required to record material adjustments in future periods. Prior to the execution of the Amended AstraZeneca Agreement in September 2019, under our collaboration agreement with AstraZeneca for China (including Hong Kong and Macau), we were reimbursed for certain research and development expenses and we netted these reimbursements against our research and development expenses as incurred. Under our collaboration agreement with Allergan for North America, we are reimbursed for certain research and development expenses and we net these reimbursements against our research and development expenses as incurred. Amounts owed to Allergan or AstraZeneca under our respective collaboration agreements are recorded as incremental research and development expense. Nonrefundable advance payments for research and development activities are capitalized and expensed over the related service period or as goods are received. In connection with the execution of the Amended AstraZeneca Agreement, AstraZeneca is fully responsible for all research and development costs incurred related to the development, manufacture, and commercialization of linaclotide in China (including Hong Kong and Macau).

## Share-Based Compensation Expense

We grant awards under our share-based compensation programs, including stock awards, restricted stock awards, or RSAs, restricted stock units, or RSUs, stock options, and shares issued under our employee stock purchase plan, or ESPP. Share-based compensation is recognized as expense in the consolidated statements of operations based on the grant date fair value over the requisite service period, net of estimated forfeitures. We estimate the fair value of stock options and ESPP shares using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility and expected term, among others. The fair value of stock awards, RSAs, and RSUs is based on the market value of our Class A Common Stock on the date of grant. For awards that vest based on service conditions, we use the straight-line method to allocate compensation expense to reporting periods. For awards that contain performance conditions, we determine the appropriate amount to expense based on the anticipated achievement of performance targets, which requires judgment, including forecasting the achievement of future specified targets. We make certain assumptions in order to value and record expense associated with awards made to employees and non-employees under our share-based compensation arrangements. Changes in these assumptions may lead to variability with respect to the amount of expense we recognize in connection with share-based payments.

We estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We estimate forfeitures over the requisite service period using historical forfeiture activity and record share-based compensation expense only for those awards that are expected to vest.

Compensation expense related to modified awards is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite remaining service period, as appropriate.

We record the expense for stock option grants subject to performance-based milestone vesting using the accelerated attribution method over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates whether the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

Compensation expense for discounted purchases under the ESPP is measured using the Black-Scholes model to compute the fair value of the lookback provision plus the purchase discount and is recognized as compensation expense over the offering period.

While the assumptions used to calculate and account for share-based compensation awards represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment. As a result, if revisions are made to our underlying assumptions and estimates, our share-based compensation expense could vary significantly from period to period.

#### **Contingent Consideration**

In accordance with ASC Topic 805, *Business Combinations*, we recognize assets acquired and liabilities assumed in business combinations, including contingent liabilities and non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. The consideration for our business acquisitions may include future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in our consolidated statements of operations. Adjustments are recorded when there are changes in significant assumptions, including net sales projections, probability weighted net cash outflow projections, the discount rate, passage of time, and the yield curve equivalent to our credit risk, which is based on the estimated cost of debt for market participants. For further details related to contingent consideration, refer to Note 7, *Fair Value of Financial Instruments*, to our consolidated financial statements appearing elsewhere in this 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 consolidated financial statements.

	Year Ended December 31,		
	2019	2018	2017
		(in thousands)	
Revenues:			
Collaborative arrangements revenue	\$ 379,652	\$ 272,839	\$ 265,533
Product revenue, net	_	3,445	3,061
Sale of active pharmaceutical ingredient	48,761	70,355	29,682
Total revenues	428,413	346,639	298,276
Cost and expenses:			
Cost of revenues, excluding amortization of acquired intangible assets	23,875	32,751	19,097
Write-down of commercial supply and inventory to net realizable value and			
(settlement) loss on non-cancellable purchase commitments	(3,530)	247	309
Research and development	115,044	101,060	88,145
Selling, general and administrative	172,450	219,676	231,184
Amortization of acquired intangible assets	_	8,111	6,214
Gain on fair value remeasurement of contingent consideration	_	(31,045)	(31,310)
Gain on lease modification	(3,169)		
Restructuring expenses	3,620	14,715	_
Impairment of intangible assets		151,794	
Total cost and expenses	308,290	497,309	313,639
Income (loss) from operations	120,123	(150,670)	(15,363)
Other (expense) income:			
Interest expense	(36,602)	(37,724)	(36,370)
Interest and investment income	2,862	2,991	2,111
Gain (loss) on derivatives	3,023	(8,743)	(3,284)
Loss on extinguishment of debt	(30,977)	_	(2,009)
Other income	514		
Other expense, net	(61,180)	(43,476)	(39,552)
Net income (loss) from continuing operations	58,943	(194,146)	(54,915)
Net loss from discontinued operations	(37,438)	(88,222)	(62,022)
Net income (loss)	\$ 21,505	\$ (282,368)	\$ (116,937)

#### Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

#### Revenues

		Ended	ou.	
	Decem	ber 31,	Chang	<u>e</u>
	2019	2018	\$	%
		(dollars in th	ousands)	
Revenues:				
Collaborative arrangements revenue	\$ 379,652	\$ 272,839	\$ 106,813	39 %
Product revenue, net		3,445	(3,445)	(100)%
Sale of active pharmaceutical ingredient	48,761	70,355	(21,594)	(31)%
Total revenues	428,413	346,639	81,774	24 %

Collaborative arrangements revenue. The increase in revenue from collaborative arrangements of approximately \$106.8 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily related to approximately \$32.4 million in revenue recognized related to non-contingent payments outlined in the Amended AstraZeneca Agreement; an approximately \$31.3 million increase in our share of the net profits from the sale of LINZESS in the U.S. driven by increased prescription demand; an approximately \$29.9 million negative adjustment during the year ended December 31, 2018 related to a change in estimate of gross-to-net sales reserves and

allowances, primarily associated with governmental and contractual rebates; \$10.0 million from an up-front payment received in connection with the Amended Astellas License Agreement; an approximately \$2.3 million increase in copromotion and royalty revenue; and an approximately \$0.5 million increase from an up-front license payment received.

*Product revenue, net.* The decrease in net product revenue of approximately \$3.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, was due to our termination of the Lesinurad License in January 2019. As a result of this termination, we are no longer commercializing the Lesinurad Products.

Sale of active pharmaceutical ingredient. The decrease in sale of API of approximately \$21.6 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily due to an approximately \$23.8 million decrease in shipments of linaclotide API to Astellas for Japan pursuant to the Amended Astellas License Agreement; and an approximately \$0.8 million decrease in shipments of linaclotide API to Allergan, partially offset by an approximately \$3.0 million increase in sale of finished drug product to AstraZeneca.

#### Cost and Expenses

	Year Ended December 31.		Change	
	2019	2018	\$	%
C-+1		(dollars in	thousands)	
Cost and expenses:	e 22.075	e 20.751	e (0.07 <i>c</i> )	(27)0/
Cost of revenues, excluding amortization of acquired intangible assets	\$ 23,875	\$ 32,751	\$ (8,876)	(27)%
Write-down of commercial supply and inventory to net realizable value and (settlement)				
loss on non-cancellable purchase commitments	(3,530)	247	(3,777)	(1,529)%
Research and development	115,044	101,060	13,984	14 %
Selling, general and administrative	172,450	219,676	(47,226)	(21)%
Amortization of acquired intangible assets	_	8,111	(8,111)	(100)%
Gain on fair value remeasurement of contingent consideration	_	(31,045)	31,045	(100)%
Gain on lease modification	(3,169)	_	(3,169)	(100)%
Restructuring expenses	3,620	14,715	(11,095)	(75)%
Impairment of intangible assets	_	151,794	(151,794)	(100)%
Total cost and expenses	\$ 308,290	\$ 497,309	\$ (189,019)	(38)%

Cost of revenues, excluding amortization of acquired intangible assets. The decrease of approximately \$8.9 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily related to a decrease of approximately \$10.7 million due to a decrease in linaclotide API sales to Astellas pursuant to the Amended Astellas License Agreement and a decrease of approximately \$0.4 million related to sales of the Lesinurad Products, partially offset by an increase of approximately \$2.7 million due to an increase in API sales to AstraZeneca.

Write-down of commercial supply and inventory to net realizable value and (settlement) loss on non-cancellable purchase commitments. The decrease in write-down of commercial supply and inventory to net realizable value and loss on non-cancellable purchase commitments of approximately \$3.8 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, was primarily due to the settlement of certain commercial supply purchase commitments that occurred during the year ended December 31, 2019, which resulted in an overall gain. In connection with the Amended AstraZeneca Agreement, certain of our previously written-down linaclotide excess purchase commitments were assumed by AstraZeneca and resulted in a settlement of approximately \$2.5 million. Additionally, certain previously written-down linaclotide purchase commitments were satisfied through API purchases at pricing terms favorable to the pricing estimates at the time of the write-down, resulting in a gain of approximately \$0.7 million upon purchase. During the year ended December 31, 2018, we recorded approximately \$0.2 million of write-downs of lesinurad inventory and purchase commitments.

Research and development. The increase in research and development expense of approximately \$14.0 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily related to an increase of approximately \$26.4 million in external development costs related to IW-3718; an increase of approximately \$9.2 million related to linaclotide development; and an increase of approximately \$0.7 million in professional services fees, including consulting and temporary support costs. These increases were partially offset by a decrease of approximately \$16.0 million in compensation, benefits and other employee-related expenses primarily associated with decreased headcount; a decrease of approximately \$4.8 million in operating expenses, including facilities and IT related expenses; and a decrease of approximately \$1.3 million related to lesinural development due to the termination of the Lesinural License.

Selling, general and administrative. Selling, general and administrative expenses decreased for the year ended December 31, 2019 compared to the year ended December 31, 2018 primarily as a result of the Separation which was completed on April 1, 2019, and the termination of the Lesinurad License in January 2019. The decrease of approximately \$47.2 million was primarily due to decreases in non-Separation costs of approximately \$56.6 million, partially offset by an approximately \$9.4 million increase in costs associated with the Separation. The approximately \$56.6 million decrease in non-Separation costs primarily includes an approximately \$27.7 million decrease in other compensation, benefits and employee-related expenses as a result of a decrease in headcount related to the 2018 workforce reductions; an approximately \$19.4 million decrease in sales and marketing programs; an approximately \$6.2 million decrease in costs associated with the lesinurad post-marketing clinical study; an approximately \$4.0 million decrease in professional services fees; and an approximately \$1.3 million decrease in legal costs. These decreases were partially offset by an approximately \$2.0 million increase in facilities and other operating expenses. The approximately \$9.4 million increase in costs associated with the Separation includes an approximately \$6.6 million increase in operating expenses, including facilities, primarily due to asset disposals related to the change in headquarters location and an approximately \$4.9 million increase in compensation, benefits and other employee-related expenses. These increases were partially offset by an approximately \$2.1 million decrease in Separation-related legal, accounting, consulting and investment banking expenses.

Amortization of acquired intangible assets. The decrease in amortization of acquired intangible assets of approximately \$8.1 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was due to the impairment of the intangible assets related to the Lesinurad Products as a result of revised cash flow assumptions and the exit of the Lesinurad License.

Gain on fair value remeasurement of contingent consideration. The decrease in the gain on fair value of the contingent consideration obligation of approximately \$31.0 million for the year end December 31, 2019 compared to the year ended December 31, 2018 was due to the termination of the Lesinurad License. During the three months ended September 30, 2018, the Company reduced its projected revenue assumptions associated with the sales of ZURAMPIC and DUZALLO and delivered to AstraZeneca a notice of termination of the lesinurad license agreement.

*Gain on lease modification.* The increase in the gain on lease modification of approximately \$3.2 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was due to the modification of the 301 Binney Street lease in connection with the Separation.

Restructuring expenses. The decrease in restructuring expenses of approximately \$11.1 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, was primarily due to costs associated with the workforce reductions that occurred in January 2018, June 2018, and August 2018, which exceeded the costs incurred in the February 2019 workforce reduction.

Impairment of intangible assets. The decrease in the impairment of intangible assets of approximately \$151.8 million for each of the year ended December 31, 2019 compared to the year ended December 31, 2018 was due to the full asset impairment of the intangible assets that occurred in 2018 related to the Lesinurad Products as a result of revised net cash flow assumptions and the exit of the Lesinurad License.

Other (Expense) Income, Net

	Year I Decem	Chang	e	
	2019	2018 (dollars in the	\$ ousands)	%
Other (expense) income:		(a. a. a		
Interest expense	\$ (36,602)	\$ (37,724)	\$ 1,122	(3)%
Interest and investment income	2,862	2,991	(129)	(4)%
Gain (loss) on derivatives	3,023	(8,743)	11,766	(135)%
Loss on extinguishment of debt	(30,977)	_	(30,977)	(100)%
Other income	514		514	100 %
Total other expense, net	\$ (61,180)	\$ (43,476)	\$ (17,704)	41 %

Interest expense. Interest expense decreased by approximately \$1.1 million during the year ended December 31, 2019 compared to the year ended December 31, 2018, mainly due to a decrease of approximately \$4.7 million and approximately \$3.7 million in interest expense associated with the 2026 Notes and the 2022 Convertible Notes, respectively, due to the redemption of the outstanding principal balance of the 2026 Notes in September 2019 and the repurchase of \$215.0 million aggregate principal amount of the 2022 Convertible Notes in August 2019, partially offset by an increase of approximately \$7.3 million in interest expense associated with the 2024 Convertible Notes and the 2026 Convertible Notes issued in August 2019.

Interest and investment income. Interest and investment income decreased by an insignificant amount for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to lower average cash and cash equivalent balances throughout the year.

Gain (loss) on derivatives. For the year ended December 31, 2019, we recorded a gain of approximately \$3.0 million on derivatives as a result of the partial termination of the Convertible Note Hedges and Note Hedge Warrants and the change in fair value of the remaining Convertible Note Hedges and Note Hedge Warrants during the year. For the year ended December 31, 2018, we recorded a loss on derivatives of approximately \$8.7 million resulting from the change in fair value of the Convertible Note Hedges and the Note Hedge Warrants.

Loss on extinguishment of debt. The loss on extinguishment of debt was approximately \$31.0 million during the year ended December 31, 2019 and pertained to the write-off of unamortized debt issuance costs and debt discount related to the partial repurchase of the 2022 Convertible Notes in August 2019 and the prepayment premium and write-off of the unamortized debt issuance costs and debt discount on the 2026 Notes as part of the redemption of all of the outstanding principal amount of the 2026 Notes in September 2019.

*Other income*. Other income increased approximately \$0.5 million during the year ended December 31, 2019 compared to year ended December 31, 2018, primarily due to income related to a transition service agreement with Cyclerion.

#### Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

#### Revenue

	Year	Ended		
	Decem	ber 31,	Chang	e
	2018	2017	\$	%
	(dollars in thousands)			
Revenues:				
Collaborative arrangements revenue	\$ 272,839	\$ 265,533	\$ 7,306	3 %
Product revenue, net	3,445	3,061	384	13 %
Sale of active pharmaceutical ingredient	70,355	29,682	40,673	137 %
Total revenues	346,639	298,276	48,363	16 %

Collaborative arrangements revenue. The increase in revenue from collaborative arrangements of approximately \$7.3 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily related to an approximately \$36.2 million increase in our share of the net profits from the sale of LINZESS in the U.S. driven by increased prescription demand; an approximately \$1.5 million increase in revenue related to VIBERZI® (eluxadoline) co-promotion activities; an approximately \$1.3 million increase due to the recognition of the VIBERZI sales-based milestone; and an approximately \$1.0 million increase in revenue related to royalty payments received in relation to all partner activities. The increases were partially offset by an adjustment to our share of the net profits from the sale of LINZESS in the U.S. of approximately \$29.9 million related to a change in estimate of gross-to-net sales reserves and allowances, primarily associated with governmental and contractual rebates; and approximately \$2.5 million decrease attributable to the decrease in revenue under the Co-Promotion Agreement with Exact Sciences Corp. due to the end of the royalty period.

*Product revenue, net.* The increase in net product revenue of approximately \$0.4 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to net product sales of DUZALLO in the U.S. in 2018. We began commercializing DUZALLO in September 2017.

Sale of active pharmaceutical ingredient. The increase in sale of API of approximately \$40.7 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to increased shipments of linaclotide API to Astellas for Japan. In March 2017, Astellas began commercializing LINZESS for the treatment of adults with IBS-C in Japan, and in September 2018, Astellas began commercializing LINZESS for the treatment of adults with chronic constipation in Japan.

#### Cost and Expenses

	Year	Ended		
	Decem	ber 31,	Change	
	2018	2017	\$	%
		(dollars in tho	usands)	
Cost and expenses:				
Cost of revenues, excluding amortization of acquired intangible				
assets	\$ 32,751	\$ 19,097	\$ 13,654	71 %
Write-down of commercial supply and inventory to net realizable				
value and loss on non-cancellable purchase commitments	247	309	(62)	(20)%
Research and development	101,060	88,145	12,915	15 %
Selling, general and administrative	219,676	231,184	(11,508)	(5)%
Amortization of acquired intangible assets	8,111	6,214	1,897	31 %
Gain on fair value remeasurement of contingent consideration	(31,045)	(31,310)	265	(1)%
Restructuring expenses	14,715		14,715	100 %
Impairment of intangible assets	151,794		151,794	100 %
Total cost and expenses	\$ 497,309	\$ 313,639	\$ 183,670	59 %

Cost of revenues, excluding amortization of acquired intangible assets. The increase of approximately \$13.7 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily related to an increase of approximately \$15.2 million due to an increase in linaclotide API sales to Astellas, partially offset by approximately \$1.5 million of one-time period related costs incurred during the year ended December 31, 2017.

Write-down of commercial supply and inventory to net realizable value and loss on non-cancelable purchase commitments. The insignificant decrease in write-down of lesinurad commercial supply and loss on non-cancelable purchase commitments for the year ended December 31, 2018 compared to the year ended December 31, 2017 was driven by write-downs of inventory, overhead, and purchase commitments of approximately \$2.8 million primarily due to revisions to the lesinurad commercial supply demand forecasts as a result of exiting the lesinurad franchise and additional insignificant adjustments related to linaclotide inventory; offset by an approximately \$2.5 million settlement related to linaclotide excess non-cancelable purchase commitment accruals that were assigned to Allergan during the year ended December 31, 2018.

Research and development. The increase in research and development expense of approximately \$12.9 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily related to an increase of approximately \$17.2 million in research costs related to our early research and development; an increase of approximately \$4.2 million in compensation, benefits and other employee-related expenses; and an increase of approximately \$1.4 million in operating costs, including facilities. These increases were partially offset by a decrease of \$9.5 million in costs related to lesinural development and transition services agreement expenses with AstraZeneca, which ended in 2017.

Selling, general and administrative. Selling, general and administrative expenses decreased by approximately \$11.5 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 primarily as a result of an approximately \$5.4 million decrease in transitional support service costs which ended in 2017 associated with the Lesinurad Transaction; an approximately \$4.2 million decrease in costs associated with product samples; an approximately \$3.5 million decrease in costs related to facilities and operating costs; an approximately \$1.9 million decrease in cost as a result of gains recorded in association with the disposal of the salesforce fleet vehicles; an

approximately \$1.2 million decrease in costs associated with professional services; an approximately \$0.9 million decrease in costs related to sales and marketing programs; and an approximately \$0.8 million decrease in compensation, benefits, and employee-related expenses. These decreases were partially offset by an approximately \$3.8 million increase in legal and consulting costs associated with the 2018 proxy statement and an approximately \$2.9 million increase in other legal costs.

Amortization of acquired intangible assets. The increase in amortization of acquired intangible assets expense of approximately \$1.9 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to the amortization of the DUZALLO intangible asset which began amortizing in August 2017 upon U.S. FDA approval. During the year ended December 31, 2018, the ZURAMPIC and DUZALLO intangible assets were written down and considered fully impaired.

Gain on fair value remeasurement of contingent consideration. Fair value remeasurement of contingent consideration includes significant estimates related to probability weighted net cash outflow projections, discounted using a yield curve equivalent to our credit risk which estimates the probability weighted analysis of expected future milestone and royalty payments based on net sales to be made to AstraZeneca in connection with the Lesinurad Transaction. Changes to these inputs are re-evaluated each reporting period. The decrease in the gain on fair value of the contingent consideration obligation of approximately \$0.3 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was due to revised projected revenue assumptions associated with the sales of ZURAMPIC and DUZALLO. During the three months ended September 30, 2018, the Company reduced its projected revenue assumptions associated with the sales of ZURAMPIC and DUZALLO and delivered to AstraZeneca a notice of termination of the lesinurad license agreement.

Restructuring expenses. The increase in restructuring expenses of approximately \$14.7 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was due to approximately \$8.3 million of workforce reduction and contract termination costs incurred during the year ended December 31, 2018 associated with the exit of the Lesinurad License; approximately \$4.0 million of costs related to the workforce reduction in June 2018 associated with the determination of the initial organizational designs of the two new companies that resulted from the Separation; and approximately \$2.4 million of costs incurred with the reduction in field-based workforce in January 2018 associated with an initiative to evaluate the optimal mix of investments for the lesinurad franchise.

*Impairment of intangible assets.* The increase in the impairment of intangible assets of approximately \$151.8 million for the year ended December 31, 2018 compared to the year ended December 31, 2017 was due to the full asset impairment of the ZURAMPIC and DUZALLO intangible assets as a result of revised net cash flow assumptions and the exit of the Lesinurad License.

Other (Expense) Income

	Year	Ended		
	Decem	ber 31,	Chang	ge
	2018	2017	2017 \$	
		(dollars in tho	usands)	
Other (expense) income:				
Interest expense	\$ (37,724)	\$ (36,370)	\$ (1,354)	4 %
Interest and investment income	2,991	2,111	880	42 %
Loss on derivatives	(8,743)	(3,284)	(5,459)	166 %
Loss on extinguishment of debt		(2,009)	2,009	(100)%
Total other expense, net	\$ (43,476)	\$ (39,552)	\$ (3,924)	10 %

*Interest expense*. Interest expense increased by approximately \$1.4 million during the year ended December 31, 2018 compared to the year ended December 31, 2017, mainly due to an increase of approximately \$1.5 million in interest expense associated with the 2022 Convertible Notes.

*Interest and investment income.* Interest and investment income increased approximately \$0.9 million for the year ended December 31, 2018 compared to the year ended December 31, 2017, mainly due to higher returns on investment securities in 2018, and partially offset by lower average investment balances in 2018 versus 2017.

Loss on derivatives. For the year ended December 31, 2018 we recorded a loss on derivatives of approximately \$8.7 million resulting from an approximately \$67.1 million decrease in fair value of the Convertible Note Hedges and an approximately \$58.4 million increase in the fair value of the Note Hedge Warrants. For the year ended December 31, 2017, we recorded a loss on derivatives of approximately \$3.3 million resulting from an approximately \$24.3 million decrease in fair value of the Convertible Note Hedges and an approximately \$21.0 million increase in the fair value of the Note Hedge Warrants.

Loss on extinguishment of debt. Loss on extinguishment of debt was approximately \$2.0 million for the year ended December 31, 2017 due to the write-off of the remaining unamortized debt issuance costs on the 11% PhaRMA Notes due 2024, or the PhaRMA Notes, as part of the redemption in January 2017.

#### **Liquidity and Capital Resources**

Until the year ended December 31, 2019, we had incurred losses since our inception in 1998 and, as of December 31, 2019, we had an accumulated deficit of approximately \$1.6 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 \$167.3 million of net proceeds from the private placement of our PhaRMA Notes in January 2013, approximately \$324.0 million of net proceeds from the private placement of our 2022 Convertible Notes in June 2015, approximately \$11.2 million of net proceeds from the private placement of our 2026 Notes in January 2017, and approximately \$391.0 million of net proceeds from the private placement of our 2024 Convertible Notes and 2026 Convertible Notes in August 2019. In connection with the issuance of the 2026 Notes, we redeemed the PhaRMA Notes in full and, in connection with the issuance of the 2024 Convertible Notes, we repurchased \$215.0 million aggregate principal amount of our 2022 Convertible Notes and redeemed all of our 2026 Notes.

At December 31, 2019, we had approximately \$177.0 million of unrestricted cash and cash equivalents. Our cash equivalents include amounts held in money market funds and repurchase agreements. We invest cash in excess of immediate requirements in accordance with our investment policy, which limits the amounts we may invest in certain types of investments and requires all investments held by us to be at least AA- rated, with a remaining maturity when purchased of less than twenty-four months, so as to primarily achieve liquidity and capital preservation.

During the year ended December 31, 2019, our balances of cash and cash equivalents decreased approximately \$1.6 million. This decrease is primarily due to approximately \$7.2 million in capital expenditures as well as approximately \$1.2 million used in financing activities, primarily due to payments of approximately \$227.3 million to repurchase \$215.0 million aggregate principal amount of the 2022 Convertible Notes. Financing activities also included principal and prepayment premium payments totaling \$156.4 million to fully redeem the outstanding principal balance of the 2026 Notes, and payments for the purchase of the Capped Calls for approximately \$25.2 million. These financing activities cash outflows were partially offset by approximately \$391.0 million in net proceeds from the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, after deducting the initial purchaser's commissions, as well as offering expenses, approximately \$13.6 million in proceeds from the exercise of stock options and the issuance of shares under our ESPP, and approximately \$3.2 million in proceeds from partial termination of the Convertible Notes Hedges and Note Hedge Warrants. Cash and cash equivalents used in investing and financing activities was offset by approximately \$10.7 million of cash provided by operating our business.

#### **Cash Flows From Operating Activities**

Net cash provided by operating activities totaled approximately \$10.7 million for the year ended December 31, 2019, of which approximately \$0.6 million related to cash used in continuing operations and approximately \$11.3 million related to cash provided by discontinued operations. The use of approximately \$0.6 million in cash for continuing operations primarily related to cash flows from our net income of approximately \$21.5 million and non-cash items of approximately \$77.8 million, partially offset by changes in assets and liabilities of approximately \$100.0 million, primarily resulting from a decrease in accounts receivable and related party accounts receivable, a decrease in prepaid expenses and other current assets, an increase in operating right-of-use assets, a decrease in accounts payable and related party accounts payable and accrued expenses, a decrease in accrued research and development costs, and a

decrease in operating lease liabilities. Non-cash items included approximately \$31.3 million in share-based compensation expense, approximately \$31.0 million of loss on extinguishment of debt, approximately \$19.6 million in non-cash interest expense, approximately \$5.6 million in depreciation and amortization expense of property and equipment, partially offset by approximately \$3.5 million related to the settlement on non-cancellable purchase commitments, approximately \$3.2 million gain on lease modification, and an approximate \$3.0 million net increase due to the change in fair value of the Convertible Note Hedges and Note Hedge Warrants.

Net cash used in operating activities totaled approximately \$70.9 million for the year ended December 31, 2018, of which approximately \$82.7 million related to cash used in continuing operations and approximately \$11.8 million related to cash provided by discontinued operations. The primary use of cash was our net loss of approximately \$282.4 million, partially offset by non-cash items of approximately \$198.2 million and changes in assets and liabilities of approximately \$1.5 million, primarily resulting from an increase in accounts receivable and related party accounts receivable, a decrease in prepaid expenses and other current assets, a decrease in inventory and other assets, an increase in accounts payable and related party accounts payable and accrued expenses, an increase in accrued research and development costs, and an increase in deferred rent. Non-cash items included approximately \$151.8 million of intangible asset impairment related to the termination of the lesinurad license agreement, approximately \$40.5 million in share-based compensation expense, approximately \$17.6 million in non-cash interest expense, an approximate \$8.7 million net decrease due to the change in fair value of the Convertible Note Hedges and Note Hedge Warrants, approximately \$8.1 million in amortization of acquired intangible assets, and approximately \$3.9 million in depreciation and amortization expense of property and equipment; partially offset by an approximately \$31.0 million due to the non-cash change in fair value of contingent consideration, and approximately \$1.9 million due to the gain on disposal of property and equipment.

Net cash used in operating activities totaled approximately \$100.8 million for the year ended December 31, 2017, of which approximately \$108.0 million related to cash used in continuing operations and approximately \$7.3 million related to cash provided by discontinued operations. The primary uses of cash were our net loss of approximately \$116.9 million and changes in assets and liabilities of approximately \$25.4 million resulting primarily from a decrease in related party accounts receivable, an increase in restricted cash associated with the release of the line of credit related to our lease amendment in 2017, a decrease in accounts payable, related party accounts payable, and accrued expenses, an increase in prepaid expenses and other assets, an increase in inventory and other assets, a decrease in deferred rent and an increase in accrued research and development costs. These uses of cash were primarily offset by non-cash items of approximately \$34.3 million, including approximately \$30.9 million in share-based compensation expense, approximately \$16.1 million in non-cash interest expense, approximately \$6.4 million in depreciation and amortization expense of property and equipment, approximately \$6.2 million in amortization of acquired intangible assets, an approximately \$3.3 million increase due to the change in fair value of the Convertible Note Hedges and Note Hedge Warrants, approximately \$2.0 million loss on extinguishment of debt, approximately \$1.3 million in write-down of excess non-cancelable product sample purchase commitment, and approximately \$0.7 million in loss on disposal of property and equipment; partially offset by an approximately \$31.3 million due to the non-cash change in fair value of contingent consideration, and approximately \$1.6 million due to the gain on facility subleases.

#### **Cash Flows From Investing Activities**

Cash used in investing activities for the year ended December 31, 2019 totaled approximately \$11.1 million, of which approximately \$6.9 million related to cash used in continuing operations and approximately \$4.2 million related to cash used in discontinued operations. Cash used in investing activities pertained primarily to the purchase of approximately \$7.2 million of property and equipment, primarily laboratory space and leasehold improvements on the second floor of our prior headquarters purchased prior to the Separation and transferred to Cyclerion, and leasehold improvements, equipment, and furniture at our current headquarters.

Cash provided by investing activities for the year ended December 31, 2018 totaled approximately \$88.9 million, of which approximately \$97.1 million related to cash provided by continuing operations and approximately \$8.3 million related to cash used in discontinued operations. Cash provided by investing activities was primary related to maturities of approximately \$99.2 million of available-for-sale securities, and approximately \$0.4 million in proceeds from the purchases of property and equipment. This was partially offset by the sale of approximately \$1.5 million of property and equipment, primarily laboratory equipment as well as hardware and software related to our information technology infrastructure, and the purchase of approximately \$3.2 million of available-for-sale securities.

Cash provided by investing activities for the year ended December 31, 2017 totaled approximately \$151.5 million, of which approximately \$152.9 million related to cash provided by continuing operations and approximately \$1.4 million related to cash used in discontinued operations. Cash provided by investing activities was primary related to the sales and maturities of approximately \$346.9 million of available-for-sale securities, and an insignificant amount of proceeds from the sale of property and equipment. This was partially offset by the purchase of approximately \$191.4 million of available-for-sale securities and the purchase of approximately \$2.8 million of property and equipment, primarily laboratory equipment as well as hardware and software related to our information technology infrastructure.

#### **Cash Flows From Financing Activities**

Cash used in financing activities for the year ended December 31, 2019 totaled approximately \$1.2 million and resulted from approximately \$227.3 million in payments to repurchase \$215.0 million aggregate principal amount of the 2022 Convertible Notes. Financing activities also included principal and prepayment premium payments totaling \$156.4 million to fully redeem the outstanding principal balance of the 2026 Notes. We also purchased Capped Calls for approximately \$25.2 million. These cash outflows were partially offset by approximately \$391.0 million in net proceeds from the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes, after deducting fees and expenses of approximately \$9.0 million, approximately \$13.6 million in proceeds from the exercise of stock options and the issuance of shares under our ESPP, and approximately \$3.2 million in proceeds from the partial termination of the Convertible Notes Hedges and Note Hedge Warrants.

Cash provided by financing activities for the year ended December 31, 2018 totaled approximately \$30.1 million and resulted primarily from approximately \$32.1 million in cash provided by stock option exercises and the issuance of shares under our ESPP, partially offset by approximately \$1.8 million in cash used for payments on our capital leases.

Cash provided by financing activities for the year ended December 31, 2017 totaled approximately \$19.8 million and resulted primarily from approximately \$146.3 million in proceeds from issuance of the 2026 Notes, and approximately \$26.4 million in cash provided by stock option exercises and the issuance of shares under our ESPP, partially offset by approximately \$134.3 million in cash paid to redeem our outstanding PhaRMA Notes, approximately \$15.1 million in cash used for payments on contingent purchase consideration, including a milestone payment to AstraZeneca for the approval of DUZALLO, approximately \$3.2 million in cash used for payments on our capital leases, and approximately \$0.2 million in costs associated with the issuance of the 2026 Notes.

#### **Funding Requirements**

We began commercializing LINZESS in the U.S. with our collaboration partner, Allergan, in the fourth quarter of 2012, and we currently derive 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, abdominal pain associated with IBS 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 Allergan for North America, total net sales of LINZESS in the U.S., as recorded by Allergan, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between us and Allergan. Additionally, we receive royalties from Allergan based on sales of linaclotide in its licensed territories outside of the U.S. We believe revenues from our LINZESS partnership for the U.S. with Allergan will continue to constitute a significant portion of our total revenue for the foreseeable future and we cannot be certain that such revenues, as well as the revenues from our other commercial activities, will enable us to 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 December 31, 2019 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), as well as 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 Annual Report on Form 10-K. 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.

#### **Contractual Commitments and Obligations**

#### Lease Obligations

The following table summarizes our lease and commercial supply obligations at December 31, 2019 (excluding interest, except as otherwise noted):

		Payments Due by Period			
		Less Than			More Than
	Total	1 Year	1 - 3 Years	3 - 5 Years	5 Years
			(in thousands	s)	
Operating lease obligations	31,638	1,146	6,257	6,191	18,044

Our commitments for operating leases relate to our office space in Boston, Massachusetts and our data storage space in Boston, Massachusetts.

#### Notes Payable

In June 2015, we issued approximately \$335.7 million in aggregate principal amount of the 2022 Convertible Notes. The 2022 Convertible Notes are governed by an indenture between us and U.S. Bank National Association, as trustee, or the 2022 Indenture. The 2022 Convertible Notes are senior unsecured obligations and bear cash interest at a rate of 2.25% per year, 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. In August 2019, we repurchased \$215.0 million aggregate principal amount of the 2022 Convertible Notes, and we partially terminated the proportionate portion of the Convertible Note Hedges and Note Hedge Warrants we entered into in connection with the issuance of the 2022 Convertible Notes. 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 consolidated statements of operations. During the year ended December 31, 2019, the Company recorded a gain on derivatives of approximately \$3.0 million as a result of the partial termination of the Convertible Note Hedges and Note Hedge Warrants and the change in fair value of the remaining Convertible Note Hedges and Note Hedge Warrants.

In August 2019, we issued \$200.0 million in aggregate principal amount of the 2024 Convertible Notes and \$200.0 million in aggregate principal amount of the 2026 Convertible Notes. The 2024 Convertible Notes and 2026 Convertible Notes are governed by separate indentures, each dated as of August 12, 2019, each an Indenture and collectively the Indentures, between us and U.S. Bank National Association, as trustee. The 2024 Convertible Notes and the 2026 Convertible Notes are senior unsecured obligations. 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. To minimize the impact of potential dilution to our Class A common stockholders upon conversion of the 2024 Convertible Notes and the 2026 Convertible Notes, we entered into separate Capped Calls in connection with the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes. We paid the counterparties approximately \$25.2 million to enter into the Capped Calls.

The following table summarizes our obligations under our convertible senior notes at December 31, 2019 (in thousands):

	Payments Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
2022 Convertible Notes (including interest)	127,488	2,716	124,772	_	_
2024 Convertible Notes (including interest)	206,750	1,500	3,000	202,250	_
2026 Convertible Notes (including interest)	219,500	3,000	6,000	6,000	204,500
Total payments on convertible senior notes	\$ 553,738	\$ 7,216	\$ 133,772	\$ 208,250	\$ 204,500

The convertible senior notes, Convertible Note Hedges, Note Hedge Warrants and Capped Calls are more fully described in Note 12, *Notes Payable*, in the accompanying notes to our financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Commitments Related to Our Collaboration and License Agreements

We have certain collaboration and license agreements that are not individually significant to our business. We may be required to pay up to \$18.0 million for regulatory milestones, none of which had been paid as of December 31, 2019. Our license and collaboration agreements are more fully described in Note 6, *Collaboration, License, Co-Promotion and Other Commercial Agreements*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Tax-related Obligations

We exclude liabilities or obligations pertaining to uncertain tax positions from our summary of contractual commitments and obligations as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. As of December 31, 2019, we have approximately \$53.1 million of uncertain tax positions, and we cannot reasonably estimate the potential adjustment to our net operating loss and credit carryforwards. These uncertain tax positions are more fully described in Note 16, *Income Taxes*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Other Funding Commitments

As of December 31, 2019, we have several ongoing studies in various clinical trial stages. Our most significant clinical trial expenditures are to CROs. The contracts with CROs generally are cancellable, with notice, at our option and do not have any significant cancellation penalties. These items are not included in the table above.

#### **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 consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. We did not otherwise adopt any new accounting pronouncements during the fiscal year ended December 31, 2019 that had a material effect on our consolidated financial statements included in this report.

#### Item 7A. 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 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 December 31, 2019, the fair value of the 2022 Convertible Notes was estimated by us to be \$141.3 million. During the year ended December 31, 2019, we repurchased \$215.0 million aggregate principal amount of the 2022 Convertible Notes and the remaining outstanding principal as of December 31, 2019 was approximately \$120.7 million. The 2022 Convertible Notes are more fully described in Note 7, *Fair Value of Financial Instruments*, and Note 12, *Notes Payable*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

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 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 consolidated statements of operations. The Convertible Note Hedges and Note Hedge Warrants are more fully described in Note 12, *Notes Payable*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

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 December 31, 2019, the fair value of the 2024 Convertible Notes and 2026 Convertible Notes was estimated by us to be approximately \$235.7 million and approximately \$240.1 million, respectively. The 2024 Convertible Notes and 2026 Convertible Notes are more fully described in Note 7, *Fair Value of Financial Instruments*, and Note 12, *Notes Payable*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### 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 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 815 to be classified in stockholders' deficit on our 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 12, *Notes Payable*, in the accompanying notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

#### Foreign Currency Risk

We have no significant monetary assets or liabilities expected to be settled in foreign currencies 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 years ended December 31, 2019, 2018 and 2017 had a significant impact on our results of operations.

#### Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, together with the independent registered public accounting firm report thereon, appear at pages F-1 through F-72, of this Annual Report on Form 10-K.

#### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A. Controls and Procedures

#### **Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, or 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 Annual Report on Form 10-K 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.

#### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and directors; and
- (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Ernst and Young LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

#### **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 quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Based on that evaluation, our principal executive officer and principal financial officer concluded no changes during the quarter ended December 31, 2019 materially affected, or were reasonably likely to materially affect, our internal controls over financial reporting.

#### Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Ironwood Pharmaceuticals, Inc.

#### **Opinion on Internal Control over Financial Reporting**

We have audited Ironwood Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Ironwood Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of comprehensive income (loss), shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 13, 2020 expressed an unqualified opinion thereon.

#### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

#### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts February 13, 2020

#### Item 9B. Other Information

None.

#### **PART III**

#### Item 10. Directors, Executive Officers and Corporate Governance

We have adopted a code of business conduct and ethics applicable to our directors, executive officers and all other employees. A copy of that code is available on our corporate website at http://www.ironwoodpharma.com. Any amendments to the code of business conduct and ethics, and any waivers thereto involving our executive officers, also will be available on our corporate website. A printed copy of these documents will be made available upon request. The content on our website is not incorporated by reference into this Annual Report on Form 10-K.

The other information required by this item is incorporated by reference from our proxy statement for our 2020 Annual Meeting of Stockholders.

#### Item 11. Executive Compensation

The information required by this item is incorporated by reference from our proxy statement for our 2020 Annual Meeting of Stockholders.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information relating to security ownership of certain beneficial owners of our common stock and information relating to the security ownership of our management required by this item is incorporated by reference from our proxy statement for our 2020 Annual Meeting of Stockholders.

The table below sets forth information with regard to securities authorized for issuance under our equity compensation plans as of December 31, 2019. As of December 31, 2019, we had four active equity compensation plans, each of which was approved by our stockholders:

- Our Amended and Restated 2005 Stock Incentive Plan:
- Our Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan;
- Our 2019 Equity Incentive Plan; and
- Our Amended and Restated 2010 Employee Stock Purchase Plan.

		Weighted-	Number of
		average	securities remaining
		exercise	available for future
	Number of	price of	issuance under
	securities to be	outstanding	equity
	issued upon exercise	options,	compensation plans
	of outstanding	warrants,	(excluding securities
	options, warrants	and rights	reflected in column
Plan Category	and rights (1)	(2)	(a))
	(a)	<b>(b)</b>	(c)
Equity compensation plans approved by security holders	20,401,328	\$ 12.13	10,954,595
Equity compensation plans not approved by security holders			
Total	20,401,328	\$ 12.13	10,954,595

- (1)Amount includes the number of shares subject to issuance upon exercise of 17,194,239 outstanding stock options and vesting of 3,207,089 restricted stock units.
- (2)Amount includes all outstanding stock options but does not include restricted stock units, which do not have an exercise price.

#### Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from our proxy statement for our 2020 Annual Meeting of Stockholders.

#### Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from our proxy statement for our 2020 Annual Meeting of Stockholders.

#### **PART IV**

#### Item 15. Exhibits and Financial Statement Schedules

- 1. List of documents filed as part of this report
  - 1. Consolidated Financial Statements listed under Part II, Item 8 and included herein by reference.
  - 2. Consolidated Financial Statement Schedules

No schedules are submitted because they are not applicable, not required or because the information is included in the Consolidated Financial Statements or Notes to Consolidated Financial Statements.

#### 3. Exhibits

		Incorporated by reference herein			
Number	Description	Form	Date		
3.1	Eleventh Amended and Restated Certificate of Incorporation	Annual Report on Form 10-K (File No. 001-34620)	March 30, 2010		
3.2	Certificate of Retirement	Registration Statement on Form 8-A/A (File No. 001-34620)	January 3, 2019		
3.3	Certificate of Amendment	Current Report on Form 8-K (File No. 001-34620)	May 31, 2019		
3.4	Fifth Amended and Restated Bylaws	Annual Report on Form 10-K (File No. 001-34620)	March 30, 2010		
2.1	Separation Agreement, dated as of March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cyclerion Therapeutics, Inc.	Current Report on Form 8-K (File No. 001-34620)	April 4, 2019		
4.1	Specimen Class A Common Stock certificate	Registration Statement on Form S-1, as amended (File No. 333-163275)	January 20, 2010		
4.2	Indenture, dated as of June 15, 2015, by and between Ironwood Pharmaceuticals, Inc. and U. S. Bank National Association (including the form of the 2.25% Convertible Senior Note due 2022)	Current Report on Form 8-K (File No. 001-34620)	June 15, 2015		
4.2.1	Supplemental Indenture dated as of April 5, 2019 by and between Ironwood Pharmaceuticals, Inc. and U.S. Bank National Association	Current Report on Form 8-K (File No. 001-34620)	April 8, 2019		
4.2.2	Form of 2.25% Convertible Senior Note due 2022	Current Report on Form 8 K (File No. 001 34620)	June 15, 2015		

		Incorporated by reference	herein
Number	Description	Form	Date
4.3	Indenture, dated as of August 12, 2019, by and between Ironwood Pharmaceuticals, Inc. and U.S. Bank National Association (including the form of the 0.75% Convertible Senior Note due 2024)	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019
4.3.1	Form of 0.75% Convertible Senior Note due 2024	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019
4.4	Indenture, dated as of August 12, 2019, by and between Ironwood Pharmaceuticals, Inc. and U.S. Bank National Association (including the form of the 1.50% Convertible Senior Note due 2026)	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019
4.4.1	Form of 1.50% Convertible Senior Note due 2026	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019
4.5*	Description of Securities of Ironwood Pharmaceuticals, Inc.		
10.1#	Amended and Restated 2005 Stock Incentive Plan and form agreements thereunder	Registration Statement on Form S-1, as amended (File No. 333-163275)	January 29, 2010
10.2#	Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan	Registration Statement on Form S-8, as amended (File No. 333-184396)	October 12, 2012
10.2.1#	Form of Stock Option Agreement under the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	November 6, 2018
10.2.2#	Form of Non-employee Director Restricted Stock Agreement under the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	July 30, 2019
10.2.3#	Form of Restricted Stock Unit Agreement under the Amended and Restated 2010 Employee, Director and Consultant Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	November 6, 2018

		Incorporated by reference herein			
Number	Description	Form	Date		
10.3#	2019 Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	July 30, 2019		
10.3.1#	Form of Non-statutory Stock Option Agreement under the 2019 Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	July 30, 2019		
10.3.2#	Form of Restricted Stock Unit Agreement under the 2019 Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	July 30, 2019		
10.3.3#	Form of Restricted Stock Agreement under the 2019 Equity Incentive Plan	Quarterly Report on Form 10-Q (File No. 001-34620)	July 30, 2019		
10.4*#	Amended and Restated 2010 Employee Stock Purchase Plan				
10.5#	Change of Control Severance Benefit Plan, as amended and restated	Quarterly Report on Form 10-Q (File No. 001-34620)	April 29, 2014		
10.6#	Form of Executive Severance Agreement	Annual Report on Form 10-K (File No. 001-34620)	February 25, 2019		
10.7#	Non-employee Director Compensation Policy, effective May 20, 2019	Quarterly Report on Form 10-Q (File No. 001-34620)	July 30, 2019		
10.8#	Form of Indemnification Agreement with Directors and Officers	Registration Statement on Form S-1, as amended (File No. 333-163275)	December 23, 2009		
10.9#	Offer Letter, dated January 3, 2019, between Ironwood Pharmaceuticals, Inc. and Mark Mallon	Current Report on Form 8-K (File No. 001-34620)	January 4, 2019		
10.10+	Collaboration Agreement, dated as of September 12, 2007, as amended on November 3, 2009, by and between Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc.	Registration Statement on Form S-1, as amended (File No. 333-163275)	February 2, 2010		
10.10.1	Amendment No. 2 to the Collaboration Agreement, dated as of January 8, 2013, by and between Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc.	Annual Report on Form 10-K (File No. 001-34620)	February 21, 2013		

		Incorporated by reference herein				
Number	Description	Form	Date			
10.11+	Commercial Agreement, dated as of January 31, 2017, by and among Allergan USA, Inc., Forest Laboratories, LLC and Ironwood Pharmaceuticals, Inc.	Quarterly Report on Form 10-Q (File No. 001-34620)	May 8, 2017			
10.12+	License Agreement, dated as of April 30, 2009, by and between Allergan Pharmaceuticals International Ltd. (formerly with Almirall, S.A.) and Ironwood Pharmaceuticals, Inc.	Registration Statement on Form S-1, as amended (File No. 333-163275)	February 2, 2010			
10.12.1+	Amendment No. 1 to License Agreement, dated as of June 11, 2013, by and between Allergan Pharmaceuticals International Ltd. (formerly with Almirall, S.A.) and Ironwood Pharmaceuticals, Inc.	Quarterly Report on Form 10-Q (File No. 001-34620)	August 8, 2013			
10.12.2+	Amendment to the License Agreement, dated as of October 26, 2015, by and between Allergan Pharmaceuticals International Ltd. and Ironwood Pharmaceuticals, Inc.	Annual Report on Form 10-K (File No. 001-34620)	February 19, 2016			
10.12.3+	Amendment to the License Agreement dated as of January 31, 2017, by and between Allergan Pharmaceuticals International Ltd., and Ironwood Pharmaceuticals, Inc.	Quarterly Report on Form 10-Q (File No. 001-34620)	May 8, 2017			
10.13+	Novation Agreement, dated as of October 26, 2015, by and among Almirall, S.A., Allergan Pharmaceuticals International Ltd. and Ironwood Pharmaceuticals, Inc.	Annual Report on Form 10-K (File No. 001-34620)	February 19, 2016			
10.14+	Amended and Restated License Agreement, dated as of August 1, 2019, by and between Ironwood Pharmaceuticals, Inc. and Astellas Pharma Inc.	Current Report on Form 8-K (File No. 001-34620	August 1, 2019			

		Incorporated by reference herein				
Number	Description	Form	Date			
10.15+	Amended and Restated License and Collaboration Agreement, dated as of September 16, 2019, by and between AstraZeneca AB and Ironwood Pharmaceuticals, Inc.	Current Report on Form 8-K (File No. 001-34620)	September 18, 2019			
10.16+	Commercial Supply Agreement, dated as of June 23, 2010, by and among PolyPeptide Laboratories, Inc. and Polypeptide Laboratories (SWEDEN) AB, Forest Laboratories, Inc. and Ironwood Pharmaceuticals, Inc.	Quarterly Report on Form 10-Q (File No. 001-34620)	August 10, 2010			
10.17+	Commercial Supply Agreement, dated as of March 28, 2011, by and among Corden Pharma Colorado, Inc. (f/k/a Roche Colorado Corporation), Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc.	Quarterly Report on Form 10-Q (File No. 001-34620)	May 13, 2011			
10.17.1+	Amendment No. 3 to Commercial Supply Agreement, dated as of November 26, 2013, by and between Corden Pharma Colorado, Inc. (f/k/a Roche Colorado Corporation), Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc.	Annual Report on Form 10-K (File No. 001-34620)	February 7, 2014			
10.18	Lease Agreement for facilities at 100 Summer Street, Boston, Massachusetts, dated as of June 11, 2019, by and between Ironwood Pharmaceuticals, Inc. and MA-100 Summer Street Owner, L.L.C.	Current Report on Form 8-K (File No. 001-34620)	June 13, 2019			
10.19	Lease Termination Agreement for facilities at 301 Binney Street, Cambridge, Massachusetts, dated as of June 11, 2019, by and between Ironwood Pharmaceuticals, Inc. and BMR-Rogers Street LLC.	Current Report on Form 8-K (File No. 001-34620)	June 13, 2019			
10.20	Tax Matters Agreement, dated as of March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cyclerion Therapeutics, Inc.	Current Report on Form 8-K (File No. 001-34620)	April 4, 2019			

		Incorporated by reference herein				
Number	Description	Form	Date			
10.21	Employee Matters Agreement, dated as of March 30, 2019, by and between Ironwood Pharmaceuticals, Inc. and Cyclerion Therapeutics, Inc.	Current Report on Form 8-K (File No. 001-34620)	April 4, 2019			
10.22	Base Call Option Transaction Confirmation, dated as of June 10, 2015, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.23	Base Call Option Transaction Confirmation, dated as of June 10, 2015, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC, through its agent Credit Suisse Securities (USA) LLC	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.24	Base Warrants Confirmation, dated as of June 10, 2015, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.25	Base Warrants Confirmation, dated as of June 10, 2015, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC, through its agent Credit Suisse Securities (USA) LLC	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.26	Additional Call Option Transaction Confirmation, dated as of June 22, 2015, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.27	Additional Call Option Transaction Confirmation, dated as of June 22, 2015, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC, through its agent Credit Suisse Securities (USA) LLC	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			

		Incorporated by reference herein				
Number	Description	Form	Date			
10.28	Additional Warrants Confirmation, dated as of June 22, 2015, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.29	Additional Warrants Confirmation, dated as of June 22, 2015, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC, through its agent Credit Suisse Securities (USA) LLC	Quarterly Report on Form 10-Q (File No. 001-34620)	August 7, 2015			
10.30	Base Call Option Transaction Confirmation for the 2024 Notes, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.31	Base Call Option Transaction Confirmation for the 2026 Notes, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.32	Base Call Option Transaction Confirmation for the 2024 Notes, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.33	Base Call Option Transaction Confirmation, for the 2026 Notes, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.34	Additional Call Option Transaction Confirmation for the 2024 Notes, dated as of August 12, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			

		Incorporated by reference herein				
Number	Description	Form	Date			
10.35	Additional Call Option Transaction Confirmation for the 2026 Notes, dated as of August 12, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.36	Additional Call Option Transaction Confirmation for the 2024 Notes, dated as of August 12, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.37	Additional Call Option Transaction Confirmation for the 2026 Notes, dated as of August 12, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC	Current Report on Form 8-K (File No. 001-34620)	August 13, 2019			
10.38*	Call Spread Unwind Agreement, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association					
10.39*	Call Spread Unwind Agreement, dated as of August 7, 2019, between Ironwood Pharmaceuticals, Inc. and Credit Suisse Capital LLC					
21.1*	Subsidiaries of Ironwood Pharmaceuticals, Inc.					
23.1*	Consent of Independent Registered Public Accounting Firm					
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					

		Incorporated by reference herein		
Number	Description	Form	Date	
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 Annual			
	Report on Form 10-K, formatted in			
	Inline XBRL			

<sup>\*</sup> Filed herewith.

<sup>‡</sup> Furnished herewith.

<sup>+</sup> Confidential treatment granted under 17 C.F.R. §§200.80(b)(4) and 230.406. The confidential portions of this exhibit have been omitted and are remeasured accordingly. The confidential portions have been provided separately to the SEC pursuant to the confidential treatment request.

<sup>#</sup> Management contract or compensatory plan, contract, or arrangement.

#### Item 16. Form 10-K Summary

None.

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on the 13<sup>th</sup> day of February 2020.

Ironwood Pharmaceuticals, Inc.			
By:	/s/ MARK MALLON		
Mark Mallon			
Chief Executive Officer			

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ MARK MALLON Mark Mallon	Chief Executive Officer and Director (Principal Executive Officer)	February 13, 2020
/s/ GINA CONSYLMAN Gina Consylman	Senior Vice President, Chief Financial Officer (Principal Financial Officer)	February 13, 2020
/s/ KELLY MACDONALD  Kelly MacDonald	Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)	February 13, 2020
/s/ JULIE H. MCHUGH Julie H. McHugh	Chair of the Board	February 13, 2020
/s/ MARK CURRIE  Mark Currie	Director	February 13, 2020
/s/ Andrew Dreyfus Andrew Dreyfus	Director	February 13, 2020
/s/ JON DUANE  Jon Duane	Director	February 13, 2020
/s/ MARLA KESSLER Marla Kessler	Director	February 13, 2020
/s/ CATHERINE MOUKHEIBIR Catherine Moukheibir	Director	February 13, 2020
/s/ LAWRENCE S. OLANOFF Lawrence S. Olanoff	Director	February 13, 2020
/s/ EDWARD P. OWENS Edward P. Owens	Director	February 13, 2020

# Index to Consolidated Financial Statements of Ironwood Pharmaceuticals, Inc.

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Consolidated Statements of Comprehensive Income (Loss) for the Years Ended December 31, 2019, 2018, and	
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#### **Report of Independent Registered Public Accounting Firm**

To the Shareholders and the Board of Directors of Ironwood Pharmaceuticals, Inc.

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Ironwood Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 13, 2020 expressed an unqualified opinion thereon.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### **Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

#### Collaboration Agreement for North America with Allergan plc

Description of the Matter

Revenue recognized from the Collaboration Agreement for North America with Allergan plc (together with its affiliates, or "Allergan") was \$325.4 million for the sale of LINZESS in the U.S for the year ended December 31, 2019. As discussed in Note 6 to the consolidated financial statements, the Company generates the majority of its revenue from a collaboration arrangement with Allergan related to linaclotide (LINZESS). The Company records its share of the net profits or net losses from the sales of LINZESS in the U.S., less commercial expenses, and presents the settlement payments to and from Allergan as collaboration arrangements revenue or collaborative arrangements expense, as applicable.

Auditing revenue recognition under the Allergan collaboration is especially challenging and requires significant auditor judgment because complete and accurate information regarding net profits realized from sales of LINZESS in the U.S. and the costs incurred in selling it may not be available at the time the financial statements are prepared.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's internal controls over its collaboration revenue process. The Company maintains and operates a suite of controls over the Company's evaluation of the completeness and accuracy of its quarterly reporting from Allergan.

Our audit procedures included, among others, reviewing the Company's contract with Allergan, reviewing information provided by Allergan, performing auditing procedures over gross sales, adjustments to arrive at net sales, cost of goods sold, and selling and marketing costs contributing to Ironwood's share of net profits and obtaining confirmation directly from Allergan.

#### Valuation of Convertible Notes

Description of the Matter

As more fully described in Note 12 to the consolidated financial statements, in August 2019, Ironwood issued \$200 million of 0.75% Convertible Senior Notes due 2024 (the "2024 Convertible Notes") and \$200 million of 1.50% Convertible Senior Notes due 2026 (the "2026 Convertible Notes"). Ironwood used some of the proceeds from the offering to repurchase \$215 million aggregate principal of the existing 2.25% Convertible Senior Notes due 2022 (the "2022 Convertible Notes"). The Company separately accounted for the liability and equity components of the 2022 Convertible Notes, the 2024 Convertible Notes and the 2026 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 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 estimated fair value of the 2022 Convertible Notes, the 2024 Convertible Notes and the 2026 Convertible Notes was \$141.3 million, \$235.7 million and \$240.1 million as of December 31, 2019.

Auditing the Company's valuation of the fair value of the debt component associated with the 2022, 2024 and 2026 Convertible Notes was especially judgmental because 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.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's internal controls over the significant assumptions underlying the determination of the interest rates used to calculate the fair value of the 2022, 2024 and 2026 Convertible Notes and the conversion option that was recorded in stockholders' equity.

To test the interest rates used to calculate the fair value of debt, our audit procedures included testing the Company's valuation methodology, evaluating the significant assumptions used by the Company, and evaluating the completeness and accuracy of the underlying data supporting the significant assumptions and estimates. In addition, we involved a valuation professional to assist in our evaluation of the methodology used by the Company and significant assumptions.

/s/ Ernst & Young LLP We have served as the Company's auditor since 1998. Boston, Massachusetts February 13, 2020

# Ironwood Pharmaceuticals, Inc. Consolidated Balance Sheets (In thousands, except share and per share amounts)

(22 viousumus, eneepe sinite una per sinite una sums)	December 31, 2019		Dec	December 31, 2018	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	177,023	\$	173,172	
Accounts receivable, net		11,279		20,991	
Related party accounts receivable, net		105,967		59,959	
Inventory, net		648			
Prepaid expenses and other current assets		10,685		10,216	
Restricted cash		1,250		1,250	
Current assets of discontinued operations		_		847	
Total current assets		306,852		266,435	
Restricted cash, net of current portion		971		6,426	
Accounts receivable, net of current portion		32,597			
Property and equipment, net		12,429		7,652	
Operating lease right-of-use assets		17,743			
Convertible note hedges		31,366		41,020	
Goodwill		785		785	
Other assets		5		89	
Non-current assets of discontinued operations		_		9,643	
Total assets	\$	402,748	\$	332,050	
LIABILITIES AND STOCKHOLDERS' DEFICIT	<del></del>	7.	<u> </u>	,,,,,,,	
Current liabilities:					
Accounts payable	\$	3,978	\$	14,891	
Related party accounts payable, net	Ψ	1,509	Ψ	14,071	
Accrued research and development costs		2,956		2,963	
Accrued expenses and other current liabilities		30,465		38,001	
Capital lease obligations		50,105		73	
Current portion of deferred rent				252	
Current portion of 2026 Notes				47,554	
Current portion of contingent consideration		_		51	
Current portion of operating lease liabilities		1,146			
Deferred revenue		875			
Current liabilities of discontinued operations				15,739	
Total current liabilities		40,929		119,524	
Capital lease obligations, net of current portion		-10,727		158	
Deferred rent, net of current portion		_		6,308	
Note hedge warrants		24,260		33,763	
Convertible senior notes		407,994		265,601	
2026 Notes, net of current portion				100,537	
Operating lease obligations, net of current portion		22,082			
Other liabilities		734		2,530	
Commitments and contingencies		,		2,000	
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 157,535,962					
issued and outstanding at December 31, 2019 and 500,000,000 shares authorized and					
154,414,691 shares issued and outstanding at December 31, 2018		158		154	
Additional paid-in capital		1,478,823		1,394,603	
Accumulated deficit		(1,572,232)		(1,591,128)	
Total stockholders' deficit		(93,251)		(196,371)	
Total liabilities and stockholders' deficit	\$	402,748	\$	332,050	
Total hadilities and stockholders deficit	φ	402,748	φ	332,030	

# Ironwood Pharmaceuticals, Inc.

# **Consolidated Statements of Operations**

# (In thousands, except per share amounts)

	Years Ended December 31,				ι,	
	2	019		2018		2017
Revenues:						
Collaborative arrangements revenue	\$ 37	9,652	\$	272,839	2	265,533
Product revenue, net		—		3,445		3,061
Sale of active pharmaceutical ingredient	4	8,761		70,355		29,682
Total revenues	42	8,413		346,639		298,276
Cost and expenses:						
Cost of revenues, excluding amortization of acquired intangible assets	2	3,875		32,751		19,097
Write-down of commercial supply and inventory to net realizable value and						
(settlement) loss on non-cancellable purchase commitments	(	(3,530)		247		309
Research and development	11	5,044		101,060		88,145
Selling, general and administrative	17	2,450		219,676	2	231,184
Amortization of acquired intangible assets		_		8,111		6,214
Gain on fair value remeasurement of contingent consideration				(31,045)		(31,310)
Gain on lease modification	(	(3,169)		_		_
Restructuring expenses		3,620		14,715		
Impairment of intangible assets				151,794		
Total cost and expenses	_ 30	8,290		497,309		313,639
Income (loss) from operations	12	0,123	(	150,670)		(15,363)
Other (expense) income:						
Interest expense	(3	6,602)		(37,724)		(36,370)
Interest and investment income		2,862		2,991		2,111
Gain (loss) on derivatives		3,023		(8,743)		(3,284)
Loss on extinguishment of debt	(3	0,977)		_		(2,009)
Other income		514				
Other expense, net	(6	1,180)		(43,476)		(39,552)
Net income (loss) from continuing operations	5	8,943	(	194,146)		(54,915)
Net loss from discontinued operations	(3	7,438)		(88,222)		(62,022)
Net income (loss)		1,505	\$ (	282,368)	\$ (	116,937)
				<u> </u>		
Net income (loss) per share from continuing operations—basic and diluted	\$	0.38	\$	(1.27)	\$	(0.37)
Net loss per share from discontinued operations—basic and diluted	\$	(0.24)	\$	(0.58)	\$	(0.42)
Net income (loss) per share—basic and diluted		0.14	\$	(1.85)	\$	(0.78)
, /1	\$					, ,
Weighted average common shares outstanding used in computing net income						
(loss) per share—basic and diluted:	15	6,023		152,634		148,993

# Ironwood Pharmaceuticals, Inc.

# Consolidated Statements of Comprehensive Income (Loss)

# (In thousands)

	Year	Years Ended December 31,				
	2019	2018	2017			
Net income (loss)	\$ 21,505	\$(282,368)	\$(116,937)			
Other comprehensive income (loss):						
Unrealized gains (losses) on available-for-sale securities		79	(72)			
Total other comprehensive income (loss)		79	(72)			
Comprehensive income (loss)	\$ 21,505	\$(282,289)	\$(117,009)			

# Ironwood Pharmaceuticals, Inc.

# **Consolidated Statements of Stockholders' Equity (Deficit)**

# (In thousands, except share amounts)

	Class A Common Stock		Class B Common Stock		Additional paid-in	Accumulated	Accumulated other comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	deficit	income (loss)	equity (deficit)
Balance at December 31, 2016	132,631,387	133	14,484,077	15	1,258,398	(1,191,823)	(7)	66,716
Issuance of common stock upon exercise of stock options and employee stock purchase plan	2,156,152	3	1,042,047		26,318	_	_	26,321
Issuance of common stock awards	135,625	_	_	_	14	_	_	14
Conversion of Class B Common Stock to Class A Common Stock	1,542,362	1	(1,542,362)	(1)	_	_	_	_
Share-based compensation expense related to share-based awards to non-employees	_	_	_	_	301	_	_	301
Share-based compensation expense related to share-based awards to employees and employee								
stock purchase plan	_	_	_		33,505	_	_	33,505
Unrealized gains on available-for-sale securities	_	_	_	_	_	_	(72)	(72)
Net loss					_	(116,937)		(116,937)
Balance at December 31, 2017	136,465,526	137	13,983,762	14	1,318,536	(1,308,760)	(79)	9,848
Issuance of common stock upon exercise of stock options and employee stock purchase plan	3,070,139	3	764,361	_	32,058	_	_	32,061
Issuance of common stock awards	130,903	_	_	_	_	_	_	_
Conversion of Class B Common Stock to Class A Common Stock	14,748,123	14	(14,748,123)	(14)	_	_	_	_
Share-based compensation expense related to share-based awards to employees and employee								
stock purchase plan	_	_	_	_	44,009	_	_	44,009
Unrealized losses on available-for-sale securities	_	_	_		_	_	79	79
Net loss						(282,368)		(282,368)
Balance at December 31, 2018	154,414,691	\$ 154		<u>\$</u>	\$ 1,394,603	\$ (1,591,128)	<u> </u>	\$ (196,371)

# Ironwood Pharmaceuticals, Inc.

# **Consolidated Statements of Stockholders' Equity (Deficit)**

# (In thousands, except share amounts)

	Class A		Additional		Total	
	Common Stock		paid-in Accumulated		Stockholders'	
	Shares	Amount	<u>capital</u>	deficit	deficit	
Balance at December 31, 2018	154,414,691	154	1,394,603	(1,591,128)	(196,371)	
Issuance of common stock upon exercise of stock options and employee stock purchase plan, net of cancellations	3,121,271	4	13,597	_	13,601	
Share-based compensation expense related to share-based awards and employee stock purchase plan	_	_	32,331	_	32,331	
Equity component of convertible senior notes	_	_	92,502	_	92,502	
Equity component of issuance costs for convertible senior notes	_	_	(2,092)	_	(2,092)	
Purchase of capped calls	_	_	(25,159)	_	(25,159)	
Equity component of partial repurchase of 2022 Convertible Notes	_	_	(26,959)	_	(26,959)	
Dividend of SGC business	_	_	_	(2,609)	(2,609)	
Net income				21,505	21,505	
Balance at December 31, 2019	157,535,962	\$ 158	\$ 1,478,823	\$ (1,572,232)	\$ (93,251)	

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

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

			Ende	d Decembe	er 31,		
	2019			2018		2017	
Cash flows from operating activities:							
Net Income (Loss)	\$ 21,5	505	\$	(282,368)	\$	(116,937)	
Adjustments to reconcile net income (loss) to net cash used in operating activities:				2.050		- 110	
Depreciation and amortization	5,5	580		3,859		6,442	
Amortization of acquired intangible assets		_		8,111		6,214	
Impairment of intangible assets				151,794			
Loss (gain) on disposal of property and equipment		146		(1,867)		694	
Share-based compensation expense	31,2			40,526		30,905	
Gain on lease modification		169)		_		_	
Change in fair value of note hedge warrants	16,2			(58,425)		(21,049)	
Change in fair value of convertible note hedges	(19,2	255)		67,168		24,333	
Write-down of commercial supply and inventory to net realizable value and (settlement) loss on non-cancellable purchase commitments	(3,5	530)		219		1,313	
Write-down of excess non-cancellable ZURAMPIC and DUZALLO sample purchase commitments		—		390		309	
Gain on facility subleases		_				(1,579)	
Accretion of discount/premium on investment securities		_		(165)		(75)	
Non-cash interest expense	19,5	590		17,601		16,080	
Non-cash change in fair value of contingent consideration		_		(31,045)		(31,310)	
Loss on extinguishment of debt	30,9	<del>)</del> 77		_		2,009	
Changes in assets and liabilities:							
Accounts receivable and related party accounts receivable, net	(68,8	893)		1,207		(17,303)	
Prepaid expenses and other current assets	(1,0	046)		(3,727)		2,271	
Inventory, net		_		(806)		346	
Other assets	1	159		702		195	
Accounts payable, related party accounts payable and accrued expenses	(32,7	700)		2,678		(7,725)	
Accrued research and development costs	(4	483)		542		(2,120)	
Deferred revenue		875		_			
Operating lease right-of-use assets	14,1			_		_	
Operating lease liabilities	(12,0	J46)		_		_	
Deferred rent		_		916		(1,053)	
Net cash used in continuing operating activities		639)		(82,690)		(108,040)	
Net cash provided by discontinued operating activities	11,3	364		11,808		7,287	
Net cash provided by (used in) operating activities	10,7	725		(70,882)		(100,753)	
Cash flows from investing activities:							
Purchases of available-for-sale securities		_		(3,241)		(191,354)	
Sales and maturities of available-for-sale securities		_		99,165		346,890	
Purchases of property and equipment	(7,	189)		(351)		(2,803)	
Proceeds from sale of property and equipment		268		1,563		135	
Net cash (used in) provided by continuing investing activities	(6,9	921)		97,136		152,868	
Net cash used in discontinued investing activities	(4,2	223)		(8,270)		(1,408	
Net cash (used in) provided by investing activities	(11,1	144)		88,866		151,460	
Cash flows from financing activities:							
Proceeds from issuance of convertible senior notes	400,0	000		_		_	
Purchase of capped calls	(25,1	159)		_		_	
Proceeds from partial termination of convertible note hedges and note hedge warrants	3,1	174		_		_	
Costs associated with issuance of convertible senior notes	(9,0	048)		_		_	
Proceeds from exercise of stock options and employee stock purchase plan	13,5	595		32,061		26,370	
Payments on capital lease obligations		_		(1,824)		(3,234)	
Payments for partial repurchase of 2022 Convertible Notes	(227,3	338)		_		_	
Payments on 2026 Notes	(156,4	409)		_		_	
Principal payments on PhaRMA notes		_		_		(134,258)	
Costs associated with issuance of 2026 Notes		_		_		(235)	
Proceeds from issuance of 2026 Notes, net of discount to lender				_		146,250	
		_		(165)		(15,058)	
Payments on contingent purchase price consideration							
Payments on contingent purchase price consideration  Net cash (used in) provided by continuing financing activities	(1.1	185)		30,072		19.835	
Payments on contingent purchase price consideration  Net cash (used in) provided by continuing financing activities  Net cash (used in) provided by discontinued financing activities	(1,1	185)		30,072		19,835	

Net increase (decrease) in cash, cash equivalents and restricted cash	(1,604)	48,056	70,542
Cash, cash equivalents and restricted cash, beginning of period	 180,848	 132,792	 62,250
Cash, cash equivalents and restricted cash, end of period	\$ 179,244	\$ 180,848	\$ 132,792
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets			
Cash and cash equivalents	\$ 177,023	\$ 173,172	\$ 125,736
Restricted cash	 2,221	 7,676	 7,056
Total cash, cash equivalents, and restricted cash	\$ 179,244	\$ 180,848	\$ 132,792
Supplemental cash flow disclosure:			
Cash paid for interest	\$ 17,584	\$ 18,235	\$ 20,388
Non-cash investing and financing activities			
Purchases under capital leases	\$ _	\$ 664	\$ 1,151
Extinguishment of capital leases	\$ _	\$ 2,687	\$ 149
Recognition of asset retirement obligation	\$ 486	\$ _	\$ _
Fixed asset purchases in accounts payable and accrued expenses	\$ 1,282	\$ 439	\$ 1,136

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

#### Ironwood Pharmaceuticals, Inc.

#### **Notes to Consolidated Financial Statements**

#### 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. On April 1, 2019, the Company completed its tax-free spin-off of its soluble guanylate cyclase ("sGC") business into a separate publicly traded company, Cyclerion Therapeutics, Inc. ("Cyclerion").

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, Allergan plc (together with its affiliates) ("Allergan"), began commercializing LINZESS in the U.S. in December 2012. Under the Company's collaboration with Allergan for North America, total net sales of LINZESS in the U.S., as recorded by Allergan, are reduced by commercial costs incurred by each party, and the resulting amount is shared equally between the Company and Allergan. Allergan also has an exclusive license from the Company to develop and commercialize linaclotide in all countries other than China (including Hong Kong and Macau), Japan and the countries and territories of North America (the "Allergan License Territory"). On a country-by-country and product-by-product basis in the Allergan License Territory, Allergan pays the Company a royalty as a percentage of net sales of products containing linaclotide as an active ingredient. In addition, Allergan has exclusive rights to commercialize linaclotide in Canada as CONSTELLA and in Mexico as LINZESS.

Astellas Pharma Inc. ("Astellas"), the Company's partner in Japan, has an exclusive license to develop and commercialize linaclotide in Japan. In March 2017, Astellas began commercializing LINZESS for the treatment of adults with IBS-C in Japan, and in September 2018, Astellas began commercializing LINZESS for the treatment of adults with chronic constipation in Japan. On August 1, 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 6).

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 January 2019, the Chinese National Medical Products Administration approved the marketing application for LINZESS for adults with IBS-C in China. As of September 16, 2019, AstraZeneca has the exclusive right to develop, manufacture, and commercialize products containing linaclotide in the AstraZeneca License Territory (Note 6). AstraZeneca launched LINZESS in China in November 2019.

The Company and Allergan 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 and Allergan are advancing 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 2019, the Company and Allergan announced the initiation of a Phase II clinical trial evaluating the safety and efficacy of MD-7246 in adult patients with IBS with diarrhea ("IBS-D").

The Company is advancing 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.

Additionally, the Company periodically enters into co-promotion agreements to bolster its salesforce productivity. For example, in April 2019, the Company entered into an agreement with Allergan to continue to perform sales detailing activities for VIBERZI® (eluxadoline) from April 1, 2019 through December 31, 2019. 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.

These and other agreements are more fully described in Note 6, *Collaboration, License, Co-Promotion and Other Commercial Agreements*, to these consolidated financial statements.

On April 1, 2019, Ironwood completed the separation of its sGC business, and certain other assets and liabilities, into Cyclerion (the "Separation"). 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 3).

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 23<sup>rd</sup> floor of 100 Summer Street, Boston, Massachusetts (the "Summer Street Property"). The Summer Street Property became the Company's new headquarters in October 2019, replacing its prior headquarters at 301 Binney Street (Note 9).

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.

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 (the "2026 Notes") (Note 12). The Company 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, the Company 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. These transactions are more fully described in Note 12, *Notes Payable*, to these consolidated financial statements.

The Company was incorporated in Delaware on January 5, 1998 as Microbia, Inc. On April 7, 2008, the Company changed its name to Ironwood Pharmaceuticals, Inc. To date, the Company has dedicated a majority of its activities to the research, development and commercialization of linaclotide, as well as to the research and development of its other product candidates. Prior to the year ended December 31, 2019, the Company incurred net losses in each year since its inception in 1998. For the year ended December 31, 2019, the Company recorded net income of approximately \$21.5 million. As of December 31, 2019, the Company had an accumulated deficit of approximately \$1.6 billion.

# 2. Summary of Significant Accounting Policies

## **Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of Ironwood and its wholly-owned subsidiaries, as of December 31, 2019, 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.

# **Segment Information**

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company currently operates in one reportable business segment—human therapeutics.

#### Reclassifications and Revisions to Prior Period Financial Statements

Certain prior period financial statement items have been reclassified to conform to current period presentation. The Company has presented its sGC business as discontinued operations in its consolidated financial statements for all periods presented. The historical financial statements and footnotes have been recast accordingly.

## **Discontinued Operations**

During the three months ended June 30, 2019, the Company determined that its sGC business met the criteria for classification as a discontinued operation in accordance with Accounting Standards Codification ("ASC") Subtopic 205-20, *Discontinued Operations* ("ASC 205-20"). Accordingly, the accompanying consolidated financial statements for all periods presented have been recast to present the assets and liabilities associated with the sGC business as held for disposition and the expenses directly associated with the sGC business as discontinued operations. For additional information related to discontinued operations, refer to Note 3, *Cyclerion Separation*, to these consolidated financial statements.

## **Use of Estimates**

The preparation of 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 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 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 its acquired intangible assets and goodwill; valuation procedures for right-of-use assets and operating lease liabilities; valuation procedures for the issuance and repurchase of convertible notes; valuation of assets and liabilities held for disposition and losses related to discontinued operations; fair value of derivatives; balance sheet classification of notes payable and convertible notes; income taxes, including the valuation allowance for deferred tax assets; research and development expenses; 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.

# **Cash and Cash Equivalents**

The Company considers all highly liquid investment instruments with a remaining maturity when purchased of three months or less to be cash equivalents. Investments qualifying as cash equivalents primarily consist of money market funds, U.S. government-sponsored securities, and repurchase agreements. The carrying amount of cash equivalents approximates fair value. The amount of cash equivalents included in cash and cash equivalents was approximately \$177.0 million and approximately \$173.1 million at December 31, 2019 and 2018, respectively.

## **Restricted Cash**

The Company is contingently liable under unused letters of credit with a bank, related to the Company's facility lease and vehicle lease agreements, in the amount of approximately \$2.2 million and approximately \$7.7 million as of December 31, 2019 and 2018, respectively. The Company records as restricted cash the collateral used to secure these letters of credit. During the year ended December 31, 2019, approximately \$6.4 million of the Company's restricted cash

related to the termination of its former headquarters lease in Cambridge, Massachusetts was released. The amount of restricted cash in current assets and non-current assets was approximately \$1.2 million and \$1.0 million at December 31, 2019, respectively.

## **Inventory**

Inventory is stated at the lower of cost or net realizable value with cost determined under the first-in, first-out basis in accordance with ASC 330, *Inventory*, including Accounting Standards Update ("ASU") No. 2015-11, *Inventory* (*Topic 330*): Simplifying the Measurement of Inventory.

The Company evaluates inventory levels quarterly and any inventory that has a cost basis in excess of its expected net realizable value, inventory that becomes obsolete, inventory in excess of expected sales requirements, inventory that fails to meet commercial sale specifications or is otherwise impaired is written down with a corresponding charge to the statement of operations in the period that the impairment is first identified. The Company also assesses, on a quarterly basis, whether it has any excess non-cancelable purchase commitments resulting from its minimum supply agreements with its suppliers. The Company relies on data from several sources to estimate the net realizable value of inventory and non-cancelable purchase commitments, including partner forecasts of projected inventory purchases that are received quarterly, the Company's internal forecasts and related process, historical sales by geographic region, and the status of and progress toward commercialization of linaclotide in partnered territories.

The Company capitalizes inventories manufactured in preparation for initiating sales of a product candidate when the related product candidate is considered to have a high likelihood of regulatory approval and the related costs are expected to be recoverable through sales of the inventories. In determining whether or not to capitalize such inventories, the Company evaluates, among other factors, information regarding the product candidate's safety and efficacy, the status of regulatory submissions and communications with regulatory authorities and the outlook for commercial sales, including the existence of current or anticipated competitive drugs and the availability of reimbursement. In addition, the Company evaluates risks associated with manufacturing the product candidate, including the ability of the Company's third-party suppliers to complete the validation batches, and the remaining shelf life of the inventories.

Costs associated with developmental products prior to satisfying the inventory capitalization criteria are charged to research and development expense as incurred.

## **Concentrations of Suppliers**

The Company relies on third-party manufacturers and its collaboration partners to manufacture linaclotide API, linaclotide finished drug product, and finished goods.

Currently, the Company uses three third-party facilities actively producing linaclotide API and finished drug product. The Company also has an agreement with another independent third party to serve as a redundant linaclotide API manufacturing capacity to support its partnered territories. Beginning in 2020, each of the Company's 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.

If any of the Company's suppliers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time the Company's production could be delayed. Such delays could have a material adverse effect on the Company's business, financial position and results of operations.

# **Accounts Receivable and Related Valuation Account**

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. The Company's receivables relate primarily to amounts reimbursed under its collaboration, license and co-promotion agreements, as well as historical amounts due from product sales to wholesalers. The Company believes that credit risks associated with

these partners and wholesalers are not significant. To date, the Company has not had any significant write-offs of bad debt, and the Company did not have an allowance for doubtful accounts as of December 31, 2019 or 2018.

#### **Concentrations of Credit Risk**

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents, restricted cash, and accounts receivable. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company has adopted an investment policy which limits the amounts the Company may invest in certain types of investments, and requires all investments held by the Company to be at least AA- rated, thereby reducing credit risk exposure.

Accounts receivable, including related party accounts receivable, primarily consist of amounts due under the linaclotide collaboration agreement with Allergan for North America and linaclotide license agreement with Astellas for Japan (Note 6). The Company does not obtain collateral for its accounts receivable. Accounts receivable or payable to or from Allergan and Cyclerion are presented as related party accounts receivable and related party accounts payable, respectively, on the consolidated balance sheets.

The percentages of revenue recognized from significant customers of the Company in the years ended December 31, 2019, 2018 and 2017 as well as the account receivable balances, net of any payables due, at December 31, 2019 and 2018 are included in the following table:

	Accou	ınts			
	Receiv	able		Revenue	
	Decemb	er 31,	Year End	led Decemb	er 31,
	2019	2018	2019	2018	2017
Collaborative Partner:					
Allergan (North America and Europe)	90 %	72 %	78 %	77 %	88 %
Astellas (Japan)	8 %	26 %	13 %	20 %	10 %

For the years ended December 31, 2019, 2018 and 2017, no additional customers accounted for more than 10% of the Company's revenue.

#### **Property and Equipment**

Property and equipment, including leasehold improvements, are recorded at cost, and are depreciated when placed into service using the straight-line method based on their estimated useful lives as follows:

	<b>Estimated Useful Life</b>
Asset Description	(In Years)
Manufacturing equipment	10
Laboratory equipment	5
Computer and office equipment	3
Furniture and fixtures	7
Software	3

Included in property and equipment are certain costs of software obtained for internal use. Costs incurred during the preliminary project stage are expensed as incurred, while costs incurred during the application development stage are capitalized and amortized over the estimated useful life of the software. The Company also capitalizes costs related to specific upgrades and enhancements when it is probable the expenditures will result in additional functionality. Maintenance and training costs related to software obtained for internal use are expensed as incurred.

Leasehold improvements are amortized over the shorter of the estimated useful life of the asset or the lease term. Under ASC Topic 840, *Leases* ("ASC 840"), capital lease assets were amortized over the lease term.

Costs for capital assets not yet placed into service have been capitalized as construction in process, and will be depreciated in accordance with the above guidelines once placed into service. Maintenance and repair costs are expensed as incurred.

# **Finite Lived Intangible Assets**

The Company records the fair value of purchased intangible assets with finite useful lives as of the transaction date of a business combination. Purchased intangible assets with finite useful lives are amortized to their estimated residual values over their estimated useful lives. The value of the Company's finite-lived intangible assets was based on the future expected net cash flows related to ZURAMPIC and DUZALLO (the "Lesinurad Products"), which included significant assumptions around future net sales and the respective investment to support these products. During the year ended December 31, 2018, the Company recorded an impairment charge of approximately \$151.8 million to fully write-off its ZURAMPIC and DUZALLO intangible assets.

## Goodwill

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounting for business combinations. Goodwill is not amortized, but is reviewed for impairment. The Company tests its goodwill for impairment annually as of October 1<sup>st</sup>, or more frequently if events or changes in circumstances indicate that would more likely than not reduce the fair value of the reporting unit below its carrying value. Impairment may result from, among other things, deterioration in the performance of the acquired asset, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, a write-down of the carrying value and an impairment charge to operating expenses in the period the determination is made is recorded. In evaluating the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. There were no impairments of goodwill for the years ended December 31, 2019, 2018, or 2017.

## **Impairment of Long-Lived Assets**

The Company regularly reviews the carrying amount of its long-lived assets to determine whether indicators of impairment may exist, which warrant adjustments to carrying values or estimated useful lives. If indications of impairment exist, projected future undiscounted cash flows associated with the asset are compared to the carrying amount to determine whether the asset's value is recoverable. If the carrying value of the asset exceeds such projected undiscounted cash flows, the asset will be written down to its estimated fair value. There were no significant impairments of long-lived assets for the years ended December 31, 2019, 2018, or 2017.

## **Income Taxes**

The Company provides for income taxes under the liability method. Deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements in accordance with the provisions of ASC Topic 740, *Income Taxes*, by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company evaluates uncertain tax positions on a quarterly basis and adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any changes to these estimates, based on the actual results obtained and/or a change in assumptions, could impact the Company's income tax provision in future periods. Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as a provision for income tax in the Company's consolidated statement of operations.

## **Financing Costs**

Financing costs include costs directly attributable to the Company's offerings of its equity securities and its debt financings. Costs attributable to equity offerings are charged as a reduction to stockholders' equity against the proceeds of the offering once the offering is completed. Costs attributable to debt financings are deferred and amortized to interest expense over the term of the debt using the effective interest method. Portions of the financing costs incurred in connection with the 2022 Convertible Notes, 2024 Convertible Notes and 2026 Convertible Notes were deemed to relate to the equity components and were recorded as a reduction to additional paid in capital. In accordance with ASC 835, *Interest*, the Company presents debt issuance costs on the balance sheet as a direct deduction from the associated debt liability. The convertible senior notes are more fully described in Note 12, *Notes Payable*, to these consolidated financial statements.

#### Leases

Effective January 1, 2019, the Company adopted ASC Topic 842, *Leases* ("ASC 842"), using the optional transition method. The adoption of ASC 842 represents a change in accounting principle that aims to increase transparency and comparability among organizations by requiring the recognition of right-of-use assets and lease liabilities on the balance sheet for both operating and finance leases. In addition, the standard requires enhanced disclosures that meet the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. The reported results for the year ended December 31, 2019 reflect the application of ASC 842 guidance, while the reported results for prior periods were prepared in conjunction with ASC 840. Because there were no material changes to the values of capital leases as a result of adoption of ASC 842, the Company concluded that no cumulative-effect adjustment to the accumulated deficit as of January 1, 2019 was necessary.

The recognition of right-of-use assets and lease liabilities related to the Company's operating leases under ASC 842 has had a material impact on the Company's consolidated financial statements.

As part of the ASC 842 adoption, the Company elected certain practical expedients outlined in the guidance. These practical expedients include:

- Accounting policy election to use the short-term lease exception by asset class; and
- Election of the practical expedient package during transition, which includes:
  - o An entity need not reassess whether any expired or existing contracts are or contain leases.
  - O An entity need not reassess the classification for any expired or existing leases. As a result, all leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases under ASC 842, and all leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases under ASC 842.
  - o An entity need not reassess initial direct costs for any existing leases.

Subsequent to the Company's adoption of ASC 842, the Company elected the post-transition practical expedient, by class of underlying asset, to account for lease components and non-lease components together as a single component for the asset class of operating lease right-of-use real estate assets.

The Company's lease portfolio for year ended December 31, 2019 includes: leases for its prior and current headquarters locations, a data center colocation lease, vehicle leases for its salesforce representatives, and leases for computer and office equipment. The Company determines if an arrangement is a lease at the inception of the contract. The asset component of the Company's operating leases is recorded as operating lease right-of-use assets, and the liability component is recorded as current portion of operating lease liabilities and operating lease liabilities, net of current portion in the Company's consolidated balance sheets. As of December 31, 2019, the Company did not record any finance leases.

Right-of-use assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term at the lease inception date. Existing leases in the Company's lease portfolio as of the adoption date were valued as of January 1, 2019. The Company uses an incremental borrowing rate based on the information available at lease inception in determining the present value of lease payments, if an implicit rate of return is not provided with the lease contract. Operating lease right-of-use assets are adjusted for incentives expected to be received.

Right-of-use assets and operating lease liabilities are remeasured upon certain modifications to leases using the present value of remaining lease payments and estimated incremental borrowing rate upon lease modification.

Lease cost is recognized on a straight-line basis over the lease term, and includes amounts related to short-term leases. The Company recognizes variable lease payments as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance, and other operating costs that are passed on from the lessor in proportion to the space leased by the Company.

#### **Derivative Assets and Liabilities**

In June 2015, in connection with the issuance of the 2022 Convertible Notes, the Company entered into convertible note hedge transactions (the "Convertible Note Hedges"). Concurrently with entering into the Convertible Note Hedges, the Company also entered into certain warrant transactions in which it sold note hedge warrants (the "Note Hedge Warrants") to the Convertible Note Hedge counterparties to acquire shares of the Company's Class A Common Stock, subject to customary anti-dilution adjustments (Note 12). In connection with the partial repurchase of the 2022 Convertible Notes in August 2019, the Company terminated its Convertible Note Hedges and Note Hedge Warrants proportionately. These instruments are derivative financial instruments under ASC Topic 815, *Derivatives and Hedging* ("ASC 815").

These derivatives are recorded as assets or liabilities at fair value each reporting date and the fair value is determined using the Black-Scholes option-pricing model. The changes in fair value are recorded as a component of other (expense) income in the consolidated statements of operations. Significant inputs used to determine the fair value include the price per share of the Company's Class A Common Stock on the date of valuation, expected term of the derivative instruments, strike prices of the derivative instruments, risk-free interest rate, 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 in future periods.

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 cover the same number of shares of Class A Common Stock that initially underlie the 2024 Convertible Notes and the 2026 Convertible Notes (subject to anti-dilution and certain other adjustments). 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.

## **Revenue Recognition**

Effective January 1, 2018, the Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (*Topic 606*) and related amendments ("ASU 2014-09") using the modified retrospective transition method. The adoption of ASU 2014-09 represented a change in accounting principle that aimed to more closely align revenue recognition with the delivery of the Company's products or services and provided financial statement readers with enhanced disclosures. ASU 2014-09 also included Subtopic 340-40, *Other Assets and Deferred Costs—Contracts with Customers*, which required the deferral of incremental costs of obtaining a contract with a customer. In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration which the Company expects to receive in exchange for the good or service. Upon adoption of ASC 606, the Company concluded that no cumulative-effect adjustment to the accumulated deficit as of January 1, 2018 was necessary. There were no remaining or ongoing deliverables or unrecognized consideration as of December 31, 2017 that required an adjustment to the accumulated deficit. The adoption of ASC 606 had no impact on the Company's consolidated statement of operations, balance sheets, or statement of cash flows. The reported results for the years ended December 31, 2019 and 2018 reflect the application of ASC 606 guidance, while the reported results for the year ended December 31, 2017 were prepared in accordance with ASC 605, *Revenue Recognition* ("ASC 605").

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

• Expensing as incurred incremental costs of obtaining a contract, such as sales commissions, if the

amortization period of the asset would be less than one year;

- Recognizing revenue in the amount that the Company has the right to invoice, when consideration
  from the customer corresponds directly with the value to the customer of the Company's performance
  completed to date; and
- For contracts that were modified before the beginning of the earliest reporting period presented in accordance with the pending content that links to this paragraph, an entity need not retrospectively restate the contract for those contract modifications in accordance with paragraphs ASC 606-10-25-12 through 25-13. Instead, an entity shall reflect the aggregate effect of all modifications that occur before the beginning of the earliest period presented in accordance with the pending content that links to this paragraph when: (a) Identifying the satisfied and unsatisfied performance obligations, (b) Determining the transaction price, and (c) Allocating the transaction price to the satisfied and unsatisfied performance obligations.

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

The Company's revenues are generated primarily through collaborative arrangements and license agreements related to the research and development and commercialization of linaclotide, as well as co-promotion arrangements in the U.S. The terms of the collaborative research and development, license, co-promotion and other agreements contain multiple performance obligations which may include (i) licenses, (ii) research and development activities, including participation on joint steering committees, (iii) the manufacture of finished drug product, API, or development materials for a partner, which are reimbursed at a contractually determined rate, and (iv) education or co-promotion activities by the Company's clinical sales specialists. Non-refundable payments to the Company under these agreements may include (i) up-front license fees, (ii) payments for research and development activities, (iii) payments for the manufacture of finished drug product, API, or development materials, (iv) payments based upon the achievement of certain milestones, (v) payments for sales detailing, promotional support services and medical education initiatives, and (vi) royalties on product sales. The Company receives its share of the net profits or bears its share of the net losses from the sale of linaclotide in the U.S. through its collaboration agreement with Allergan for North America. Prior to the execution of the amended and restated collaboration agreement with AstraZeneca (the "Amended AstraZeneca Agreement") on September 16, 2019, the Company received its share of the net profits and bore its share of the net losses from the sale of linaclotide in the China (including Hong Kong and Macau), through its collaboration with AstraZeneca. The Company has adopted a policy to recognize revenue net of tax withholdings, as applicable.

#### Revenue recognition under ASC 606

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

## Collaboration, License, Co-Promotion and Other Commercial Agreements

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

evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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

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

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

### Net Profit or Net Loss Sharing

In accordance with ASC 808 Topic, *Collaborative Arrangements* ("ASC 808"), the Company considered the nature and contractual terms of the arrangement and the nature of the Company's business operations to determine the classification of payments under the Company's collaboration agreements. While ASC 808 provides guidance on classification, the standard is silent on matters of separation, initial measurement, and recognition. Therefore, the Company, consistent with its accounting policies prior to the adoption of ASC 606, applies the separation, initial measurement, and recognition principles of ASC 606 to its collaboration agreements. The Company adopted ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, during the three months ended December 31, 2018 and confirmed that, consistent with its initial conclusions, the Company will continue to analogize to ASC 606 for further guidance on areas such as separation, initial measurement, and recognition for its existing collaborative arrangements where applicable.

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

In accordance with ASC 606-10-55, *Principal Agent Considerations*, the Company records revenue transactions as net product revenue in its consolidated statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor, retaining inventory risk, and control over pricing. Given that the Company is not the primary obligor and does not have the inventory risks in the collaboration agreement with Allergan for North America, it records its share of the net profits or net losses from the sales of LINZESS in the U.S. on a net

basis and presents the settlement payments to and from Allergan as collaboration expense or collaborative arrangements revenue, as applicable. The Company and Allergan settle the cost sharing quarterly, such that the Company's statements of operations reflects 50% of the pre-tax net profit or loss generated from sales of LINZESS in the U.S.

#### Product revenue, net

Product revenue consisted of sales of the Lesinurad Products, in the U.S. until the termination of the exclusive license to develop, manufacture, and commercialize in the U.S. products containing lesinurad as an active ingredient (the "Lesinurad License") in January 2019. The Company sold the Lesinurad Products principally to a limited number of national wholesalers and selected regional wholesalers (the "Distributors"). The Distributors resold the Lesinurad Products to retail pharmacies and healthcare providers, who then sold to patients.

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

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

Product revenue was recorded net of the trade discounts, allowances, rebates, chargebacks, discounts, product returns, and other incentives. Certain of these adjustments were recorded as an accounts receivable reserve, while certain of these adjustments were recorded as accrued expenses.

# Other

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

The Company recognizes revenue on linaclotide finished drug product, API and development materials when control has transferred to the partner, which generally occurs upon shipment for sales of API and finished drug product, after the material has passed all quality testing required for collaborator acceptance. As it relates to development materials and API produced for Astellas, the Company is reimbursed at a contracted rate. Such reimbursements are considered as part of revenue generated pursuant to the Astellas license agreement and are presented as collaborative arrangements revenue. Any linaclotide finished drug product, API and development materials currently produced for Allergan for the U.S. are recognized in accordance with the cost-sharing provisions of the collaboration agreement with Allergan for North America. Prior to the execution of the Amended AstraZeneca Agreement in September 2019, any linaclotide finished drug product, API and development materials produced for AstraZeneca for China (including Hong Kong and Macau) were recognized in accordance with the cost-sharing provisions of the AstraZeneca collaboration agreement. Beginning in 2020, the Company will no longer be responsible for the supply of linaclotide finished drug product or API to its partners.

The Company's deferred revenue balance consists of advance billings and payments received from customers in excess of revenue recognized.

# Agreements Entered into Prior to January 1, 2011

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

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

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

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

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

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

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

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

# Up-Front License Fees prior to January 1, 2018

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

# Milestones prior to January 1, 2018

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

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

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

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

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

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

# Royalties on Product Sales prior to January 1, 2018

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

#### Product Revenue, Net prior to January 1, 2018

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

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

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

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

# Other

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

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

#### Cost of Revenues

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

# **Research and Development Costs**

The Company generally expenses research and development costs to operations as incurred. The Company capitalizes nonrefundable advance payments made by the Company for research and development activities and defers expense recognition until the related goods are received or the related services are performed.

Research and development expenses are comprised of costs incurred in performing research and development activities, including salary, benefits, share-based compensation, and other employee-related expenses; laboratory supplies and other direct expenses; facilities expenses; overhead expenses; third-party contractual costs relating to nonclinical studies and clinical trial activities and related contract manufacturing expenses, development of manufacturing processes and regulatory registration of third-party manufacturing facilities; licensing fees for the Company's product candidates; and other outside expenses.

The Company has certain collaboration agreements pursuant to which it shares or has shared research and development expenses related to linaclotide. The Company records expenses incurred under such linaclotide collaboration arrangements as research and development expense. Prior to the execution of the Amended AstraZeneca Agreement in September 2019, under the Company's collaboration agreement with AstraZeneca for China (including Hong Kong and Macau), the Company was reimbursed for certain research and development expenses and it netted these reimbursements against its research and development expenses as incurred. Under the Company's collaboration agreement with Allergan for North America, the Company is reimbursed for certain research and development expenses and nets these reimbursements against its research and development expenses as incurred. Amounts owed to Allergan or AstraZeneca under the Company's respective collaboration agreements were recorded as incremental research and development expense. Nonrefundable advance payments for research and development activities are capitalized and expensed over the related service period or as goods are received. In connection with the execution of the Amended AstraZeneca Agreement, AstraZeneca is fully responsible for all research and development costs incurred related to the development, manufacture, and commercialization of linaclotide in China (including Hong Kong and Macau).

## **Restructuring Expenses**

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

#### Selling, General and Administrative Expenses

The Company expenses selling, general and administrative costs to operations as incurred. Selling, general and administrative expenses consist primarily of compensation, benefits and other employee-related expenses for personnel in the Company's administrative, finance, legal, information technology, business development, commercial, sales, marketing, communications and human resource functions. Other costs include the legal costs of pursuing patent protection of the Company's intellectual property, general and administrative related facility costs, insurance costs and professional fees for accounting, tax, consulting, legal and other services.

Prior to the execution of the Amended AstraZeneca Agreement, the Company was reimbursed for certain selling, general and administrative expenses and the Company netted these reimbursements against the Company's selling, general and administrative expenses as incurred. In connection with the Amended AstraZeneca Agreement,

effective in September 2019, AstraZeneca will be fully responsible for all costs related to the development, manufacture, and commercialization of linaclotide in China (including Hong Kong and Macau). The Company includes Allergan's selling, general and administrative cost-sharing payments in the calculation of the net profits and net losses from the sale of LINZESS in the U.S. and presents the net payment to or from Allergan as collaboration expense or collaborative arrangements revenue, respectively.

# **Share-Based Compensation Expense**

The Company grants awards under its share-based compensation programs, including stock awards, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), stock options, and shares issued under the Company's employee stock purchase plan ("ESPP"). Share-based compensation is recognized as expense in the consolidated statements of operations based on the grant date fair value over the requisite service period, net of estimated forfeitures. The Company estimates the fair value of the stock option and ESPP shares using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility and expected term, among others. The fair value of stock awards, RSAs, and RSUs is based on the market value of the Company's Class A Common Stock on the date of grant. For awards that vest based on service conditions, the Company uses a straight-line method to allocate compensation expense to reporting periods. For awards that contain performance conditions, the Company determines the appropriate amount to expense based on the anticipated achievement of performance targets, which requires judgement, including forecasting the achievement of future specified targets. The Company makes certain assumptions in order to value and record expense associated with awards made to employees and non-employees under our share-based compensation arrangements. Changes in these assumptions may lead to variability with respect to the amount of expense the Company recognizes in connection with share-based payments.

The Company estimates forfeitures at the time of grant and revises those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures over the requisite service period using historical forfeiture activity and records share-based compensation expense only for those awards that are expected to vest.

Compensation expense related to modified awards is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite remaining service period, as appropriate.

The Company records the expense for stock option grants subject to performance-based milestone vesting using the accelerated attribution method over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

Compensation expense for discounted purchases under the ESPP is measured using the Black-Scholes model to compute the fair value of the lookback provision plus the purchase discount and is recognized as compensation expense over the offering period.

While the assumptions used to calculate and account for share-based compensation awards represent management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment. As a result, if revisions are made to the Company's underlying assumptions and estimates, the Company's share-based compensation expense could vary significantly from period to period.

#### **Patent Costs**

The Company incurred and recorded as operating expense legal and other fees related to patents of approximately \$7.8 million, approximately \$5.0 million, and approximately \$3.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. These costs were charged to selling, general and administrative expenses as incurred.

## **Contingent Consideration**

In accordance with ASC Topic 805, *Business Combinations*, the Company recognizes assets acquired and liabilities assumed in business combinations, as well as contingent liabilities and non-controlling interests in the acquiree based on the fair value estimates as of the date of acquisition. The consideration for the Company's business acquisitions includes future payments that are contingent upon the occurrence of a particular event or events. Contingent consideration at December 31, 2018 related to future royalty and milestone payments based on the estimated future sales of the Lesinurad Products. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated as of each reporting date. Changes in the fair value of contingent consideration obligations, other than changes due to payments, are recognized as a (gain) loss on fair value remeasurement of contingent consideration in the consolidated statements of operations. Adjustments are recorded when there are changes in significant assumptions, including net sales projections, probability weighted net cash outflow projections, the discount rate, passage of time, and the yield curve equivalent to the Company's credit risk, which is based on the estimated cost of debt for market participants (Note 7).

## Net Income (Loss) Per Share

The Company calculates basic net income (loss) per common share and diluted net income (loss) per common share by dividing the net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the diluted number of shares outstanding during the period. Except where the result would be antidilutive to net income (loss), diluted net income (loss) per common share is computed assuming the conversion of the 2022 Convertible Notes, the 2024 Convertible Notes and the 2026 Convertible Notes, the exercise of outstanding common stock options and the vesting of RSUs and RSAs (using the treasury stock method), as well as their related income tax effects.

As of December 31, 2018, there were no longer any Class B common shares outstanding as all Class B common shares converted on a one-to-one basis to Class A common shares. Historically, the Company allocated undistributed earnings between the classes of common stock on a one-to-one basis when computing net income (loss) per share. As a result, historically, basic and diluted net income (loss) per Class A and Class B shares were equivalent.

# **Comprehensive Income (Loss)**

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances from non-owner sources and consists of net income (loss) and changes in unrealized gains and losses on available-for-sale debt securities in the periods presented in the Company's consolidated statements of comprehensive income (loss).

### **Subsequent Events**

The Company considers events or transactions that have occurred after the balance sheet date of December 31, 2019, but prior to the filing of the financial statements with the Securities and Exchange Commission ("SEC") to provide additional evidence relative to certain estimates or to identify matters that require additional recognition or disclosure. Subsequent events have been evaluated through the filing of the financial statements accompanying this Annual Report on Form 10-K.

# **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 year ended December 31, 2019 that had a material effect on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718)*: *Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early

adoption is permitted but not earlier than an entity's adoption date of Topic 606. The Company adopted this standard during the three months ended March 31, 2019. The adoption of ASU 2018-07 did not have a material impact on the Company's financial position and results of operations.

In July 2018, the FASB issued ASU 2018-09, *Codification Improvements* ("ASU 2018-09"). The amendments in ASU 2018-09 affect a wide variety of Topics in the FASB codification and apply to all reporting entities within the scope of the affected accounting guidance. The Company has evaluated ASU 2018-09 in its entirety and determined that the amendments related to Topic 718-740, *Compensation—Stock Compensation—Income Taxes*, are the only provisions that currently apply to the Company. The amendments in ASU 2018-09 related to Topic 718-740, *Compensation—Stock Compensation—Income Taxes*, clarify that an entity should recognize excess tax benefits related to stock compensation transactions in the period in which the amount of the deduction is determined. The amendments in ASU 2018-09 related to Topic 718-740 are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company adopted this standard during the three months ended March 31, 2019. The adoption of this standard did not have a material impact on the Company's financial position and results of operations.

The Company adopted ASC 842 using the optional transition method outlined in ASU 2018-11 as of January 1, 2019. The adoption of ASC 842 resulted in the recognition of operating lease right-of-use assets of approximately \$88.3 million and corresponding lease liabilities of approximately \$94.9 million.

In July 2019, the FASB issued ASU No. 2019-07, *Disclosure Update and Simplification and Investment Company Reporting Modernization* ("ASU 2019-07"). The update is intended to simplify disclosure requirements to reflect the amendments of various SEC disclosure requirements that the SEC determined were redundant, duplicative, overlapping, outdated or superseded and is effective upon issuance. The adoption of ASU 2019-07 did not have a material impact on the Company's financial position, results of operations, or financial statement disclosures.

In June 2016, the FASB issued 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 2019-10"), and ASU No. 2019-11, Codification Improvements to Topic 326, Financial Instruments—Credit Losses ("ASU 2019-11") 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, ASU 2019-04, ASU 2019-05, ASU 2019-10, and ASU 2019-11 are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-13 and related amendments to 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 is permitted. The Company does not expect the adoption of ASU 2017-04 to 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 is currently evaluating the potential impact that the adoption of ASU 2018-13 may have on the Company's financial position and results of operations.

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 additional 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 new internal-use software guidance to determine which implementation costs to capitalize as assets or expense as incurred. The new 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 is currently evaluating the potential impact that the adoption of ASU 2018-15 may have 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 is currently evaluating the potential impact that the adoption of ASU 2018-17 may have 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 consolidated financial statements upon adoption.

# 3. Cyclerion Separation

On April 1, 2019, Ironwood completed the separation of its sGC business, and certain other assets and liabilities, into 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, as described in Note 1, *Nature of Business*, 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, 20		
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 three months ended September 30, 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. No incremental stock-based compensation expense related to the Separation-related adjustments was recognized during the year ended December 31, 2019 (Note 15).

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

Pursuant to the transition service agreements, the Company is obligated to provide and is entitled to receive certain transition services related to corporate functions, such as finance, procurement, facilities and development. Services provided by the Company to Cyclerion will 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 will continue for an initial term of one year from the date of the Separation, unless earlier terminated or extended according to the terms of such transition services agreement. Services received and performed are paid at a mutually agreed upon rate. Amounts received for services provided to Cyclerion are recorded as other income and amounts paid for services provided by Cyclerion are recorded as selling, general and administrative expense and research and development expense, as applicable. During the year ended December 31, 2019, the Company recorded approximately \$0.3 million as other income for services provided to Cyclerion. During the year ended December 31, 2019, the Company recorded an insignificant amount in both selling,

general and administrative expense and research and development expense for services provided by Cyclerion, respectively.

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 \$4.5 million in research and development expenses under the development agreement during the year ended December 31, 2019.

# **Discontinued Operations**

Upon Separation, the Company determined its sGC business qualified for discontinued operations accounting treatment in accordance with ASC 205-20. The following is a summary of expenses of Cyclerion for years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year Ended December 31,			
	2019	2018	2017	
Costs and expenses:				
Research and development	21,792	65,443	60,083	
Selling, general and administrative	15,646	21,615	1,939	
Restructuring expenses		1,164		
Net loss from discontinued operations	\$ 37,438	\$ 88,222	\$ 62,022	

There were no assets and liabilities related to discontinued operations as of December 31, 2019, as all balances were transferred to Cyclerion upon Separation. The following is a summary of assets and liabilities of discontinued operations as of December 31, 2018 (in thousands):

Assets:	
Prepaid expenses and other current assets	\$ 847
Property and equipment, net	9,618
Other assets	 25
	\$ 10,490
Liabilities:	 
Accounts payable	\$ 3,232
Accrued research and development costs	5,256
Accrued expenses and other current liabilities	 7,251
	\$ 15,739

#### 4. Net Income (Loss) Per Share

The following table sets forth the computation of basic and diluted net income (loss) per common share (in thousands, except per share amounts), which is computed by dividing net (income) loss by the weighted average number of common shares outstanding during the period:

	Year Ended December 31,			
	2019	2018	2017	
Numerator:		·		
Net income (loss)	\$ 21,505	\$(282,368)	\$(116,937)	
Denominator:				
Weighted average number of common shares outstanding used in net income				
(loss) per share — basic and diluted	156,023	152,634	148,993	
Net income (loss) per share — basic and diluted	\$ 0.14	\$ (1.85)	\$ (0.78)	

In June 2015, in connection with the issuance of approximately \$335.7 million in aggregate principal amount of the 2022 Convertible Notes (Note 12), the Company entered into the Convertible Note Hedges. The Convertible Note Hedges are generally expected to reduce the potential dilution to the Company's Class A common stockholders upon a conversion of the 2022 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 with the Convertible Note Hedge counterparties to acquire shares of the Company's Class A Common Stock, subject to customary anti-dilution adjustments (Note 12). 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 antidilutive.

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.

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

	Year Ended December 31,			
	2019	2018	2017	
Options to purchase Class A Common Stock	17,194	20,457	21,086	
Shares subject to repurchase	182	65	62	
Restricted stock units	3,207	3,058	2,277	
Note Hedge Warrants	8,318	20,250	20,250	
2022 Convertible Notes	8,318	20,250	20,250	
2024 Convertible Notes	14,934		_	
2026 Convertible Notes	14,934	_	_	
	67,087	64,080	63,925	

#### 5. Goodwill and Intangible Assets

The Company closed a transaction with AstraZeneca (the "Lesinurad Transaction") on June 2, 2016 (the "Acquisition Date") pursuant to which the Company received an exclusive license to develop, manufacture and commercialize the Lesinurad Products in the U.S. On August 2, 2018, the Company delivered to AstraZeneca a notice of termination of the lesinurad license agreement, which termination was made with respect to all products under the lesinurad license agreement.

The value of the developed technology – ZURAMPIC and developed technology – DUZALLO intangible assets as of the Acquisition Date was approximately \$22.0 million and approximately \$145.1 million, respectively. As of July 31, 2018, the accumulated amortization for developed technology – ZURAMPIC and developed technology – DUZALLO intangible assets was approximately \$3.6 million and approximately \$11.7 million, respectively.

During the year ended December 31, 2018, the Company completed its initiative to evaluate the optimal mix of investments for the lesinurad franchise for uncontrolled gout using a comprehensive marketing mix in select test markets (with paired controls). Data from the test markets did not meet expectations. As a result, during the year ended December 31, 2018, the Company reduced its projected revenue and net cash flow assumptions associated with the value of its developed technology – ZURAMPIC and developed technology – DUZALLO intangible assets. Accordingly, the Company evaluated its developed technology – ZURAMPIC and developed technology – DUZALLO intangible assets for impairment and recorded an approximately \$151.8 million impairment charge during the year ended December 31, 2018. The impairment assessment performed utilized the revised projected revenue and net cash flows assumed through the termination of the lesinurad license agreement, resulting in an impairment of the full carrying value of the intangible assets. The impairment charge was recorded as impairment of intangible assets in the Company's consolidated statement of operations.

The Company tests its goodwill for impairment annually as of October 1<sup>st</sup>, or more frequently if events or changes in circumstances indicate an impairment may have occurred (Note 2). As of December 31, 2019, there was no impairment of goodwill.

#### 6. Collaboration, License, Co-Promotion and Other Commercial Agreements

For the year ended December 31, 2019, the Company had linaclotide collaboration agreements with Allergan for North America and AstraZeneca for China (including Hong Kong and Macau), as well as linaclotide license agreements with Astellas for Japan and with Allergan for the Allergan License Territory. The Company also had agreements with Allergan to co-promote VIBERZI in the U.S. and 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

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

	Year	Year Ended December 31,			
Collaborative Arrangements Revenue	2019	2018	2017		
Linaclotide Collaboration Agreements:					
Allergan (North America)	\$ 327,591	\$266,177	\$260,210		
Allergan (Europe and other)	1,718	1,146	617		
AstraZeneca (China, including Hong Kong and Macau)	32,628	_	208		
Astellas (Japan)	10,147	_	_		
Co-Promotion and Other Agreements:					
Exact Sciences (COLOGUARD) (1)	_	_	2,544		
Allergan (VIBERZI)	3,723	4,290	1,535		
Alnylam (GIVLAARI)	2,000	_	_		
Other	1,845	1,226	419		
Total collaborative arrangements revenue	\$ 379,652	\$272,839	\$265,533		
Sale of API					
Linaclotide License Agreements:					
Astellas (Japan)	\$ 45,788	\$ 69,599	\$ 29,682		
AstraZeneca (China, including Hong Kong and Macau)	2,973	_	_		
Other (2)		756			
Total sale of API	\$ 48,761	\$ 70,355	\$ 29,682		

<sup>(1)</sup> In August 2016, the Company terminated the Co-Promotion Agreement for COLOGUARD with Exact Sciences Corp. Under the terms of the agreement, the Company continued to receive royalty payments through July 2017.

(2) During the year ended December 31, 2018, the Company recorded approximately \$0.8 million in revenue related to the sale of API to Allergan, separate from its existing revenue agreements.

Accounts receivable, net included approximately \$43.9 million and approximately \$21.0 million related to collaborative arrangements revenue and sale of API, collectively, as of December 31, 2019 and 2018, respectively. Related party accounts receivable, net included approximately \$110.1 million and approximately \$63.0 million related to collaborative arrangements revenue, net of approximately \$4.1 million and approximately \$3.1 million related to related party accounts payable as of December 31, 2019 and 2018, respectively. As of December 31, 2019, deferred revenue was approximately \$0.9 million related to the disease education and promotional agreement with Alnylam.

As of December 31, 2019 and 2018, there were no impairment indicators for the accounts receivable recorded.

## **Linaclotide Agreements**

# Collaboration Agreement for North America with Allergan

In September 2007, the Company entered into a collaboration agreement with Allergan to develop and commercialize linaclotide for the treatment of IBS-C, CIC, and other GI conditions in North America. Under the terms of this collaboration agreement, the Company received a non-refundable, upfront licensing fee and shares equally with Allergan all development costs as well as net profits or losses from the development and sale of linaclotide in the U.S. The Company receives royalties in the mid-teens' percent based on net sales in Canada and Mexico. Allergan is solely responsible for the further development, regulatory approval and commercialization of linaclotide in those countries and funding any costs. The collaboration agreement for North America also includes contingent milestone payments, as well as a contingent equity investment, based on the achievement of specific development and commercial milestones. At December 31, 2019, \$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 years ended December 31, 2019, 2018 and 2017, the Company incurred approximately \$37.6 million, approximately \$39.2 million, and approximately \$28.5 million 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 offset approximately \$7.2 million and approximately \$9.0 million in research and development costs during the years ended December 31, 2019 and 2018, respectively, to reflect the obligations of each party under the collaboration to bear half of the development costs incurred. The Company recognized approximately \$0.6 million in incremental research and development costs during the year ended December 31, 2017, to reflect the obligations of each party under the collaboration to bear half of the development costs incurred.

The Company and Allergan began commercializing LINZESS in the U.S. in December 2012. The Company receives 50% of the net profits and bears 50% of the net losses from the commercial sale of LINZESS in the U.S. Net profits or net losses consist of net sales of LINZESS to third-party customers and sublicense income in the U.S. less the cost of goods sold as well as selling, general and administrative expenses. LINZESS net sales are calculated and recorded by Allergan and may include gross sales net of discounts, rebates, allowances, sales taxes, freight and insurance charges, and other applicable deductions. If either party provided fewer calls on physicians in a particular year than it was contractually required to provide, such party's share of the net profits would be adjusted as set forth in the collaboration agreement for North America. During the year ended December 31, 2017, the adjustment to the share of the net profits was eliminated in connection with the co-promotion activities under the Company's agreement with Allergan for VIBERZI. Additionally, these adjustments to the share of the net profits have been eliminated, in full, in 2018 and all subsequent years under the terms of the Company's commercial agreement with Allergan entered into in January 2017 under which the Company promoted Allergan's CANASA® product and promoted its DELZICOL® products as described below in Commercial Agreement with Allergan. The Company has completed its obligations under the terms of the commercial agreement with Allergan.

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

From time to time, in accordance with the terms of the collaboration with Allergan for North America, the Company engages an independent certified public accounting firm to review the accuracy of the financial reporting from Allergan to the Company. In connection with such a review during the three months ended September 30, 2018, Allergan reported to the Company an approximately \$59.3 million negative adjustment to LINZESS net sales. The

adjustment related to the cumulative difference between certain previously estimated LINZESS gross-to-net sales reserves and allowances made by Allergan during the years ended December 31, 2015, 2016 and 2017, and subsequent actual payments made. This adjustment was primarily associated with estimated governmental and contractual rebates, as reported by Allergan. Upon receiving this information from Allergan, the Company recorded a change in accounting estimate to reduce collaborative arrangements revenue by approximately \$29.7 million during the three months ended September 30, 2018 related to the Company's share of this adjustment. In addition, during the three months ended December 31, 2018, Allergan reported to the Company a true-up of approximately \$0.2 million related to the previously reported adjustment for the cumulative difference between certain previously estimated LINZESS gross-to-net sales reserves and allowances.

The Company recognized collaborative arrangements revenue from the Allergan collaboration agreement for North America during the years ended December 31, 2019, 2018 and 2017 as follows (in thousands):

	Year Ended December 31,			
	2019	2018	2017	
Collaborative arrangements revenue related to sales of LINZESS in the U.S.	\$ 325,429	\$ 264,243	\$ 256,238	
Royalty revenue	2,162	1,934	2,295	
Other (1)			1,677	
Total collaborative arrangements revenue	\$ 327,591	\$ 266,177	\$ 260,210	

(1) Includes net profit share adjustments of approximately \$1.7 million recorded during the year ended December 31, 2017 related to a change in estimated selling expenses previously recorded.

The collaborative arrangements revenue recognized in the years ended December 31, 2019, 2018 and 2017 primarily represents the Company's share of the net profits and net losses on the sale of LINZESS in the U.S.

The following table presents the amounts recorded by the Company for commercial efforts related to LINZESS in the U.S. in the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Collaborative arrangements revenue related to sales of LINZESS in the U.S. (1)(2)	\$ 325,429	\$264,243	\$256,238
Selling, general and administrative costs incurred by the Company <sup>(1)</sup>	(38,123)	(42,435)	(41,252)
The Company's share of net profit	\$ 287,306	\$221,808	\$214,986

- (1) Includes only collaborative arrangements revenue or selling, general and administrative costs attributable to the cost-sharing arrangement with Allergan. Excludes approximately \$2.4 million, approximately \$2.2 million, and approximately \$0.9 million for the years ended December 31, 2019, 2018 and 2017, respectively, related to patent prosecution and patent litigation costs recognized in connection with the collaboration agreement with Allergan.
- (2) Certain of the unfavorable adjustments to the Company's share of the LINZESS net profits were reduced or eliminated in connection with the co-promotion activities under the Company's agreement with Allergan to co-promote VIBERZI in the U.S., as described below in *Agreement with Allergan for VIBERZI*.

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 \$2.2 million, approximately \$1.9 million, and approximately \$2.3 million of combined royalty revenues from Canada and Mexico during the years ended December 31, 2019, 2018 and 2017, respectively.

License Agreement with Allergan (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. Additionally, the Company was required to participate on a joint development committee during linaclotide's development period and is required to participate in a joint commercialization committee while linaclotide is commercially available. In October 2015, Almirall transferred its exclusive license to develop and commercialize linaclotide in Europe to Allergan.

Additionally, in October 2015, the Company and Allergan separately entered into an amendment to the European License Agreement relating to the development and commercialization of linaclotide in Europe. Pursuant to the terms of the amendment, (i) 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 midsingle digit percent and escalate to the upper-teens percent by calendar year 2019, and (iii) Allergan assumed responsibility for the manufacturing of linaclotide API for Europe from the Company, as well as the associated costs. The Company concluded that the 2015 amendment to the European License Agreement was not a modification to the linaclotide collaboration agreement with Allergan for North America.

In January 2017, concurrently with entering into the commercial agreement as described below in *Commercial Agreement with Allergan*, the Company and Allergan entered into an amendment to the European License Agreement (the "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, Allergan is obligated to pay the Company a royalty as a percentage of net sales of products containing linaclotide as an active ingredient in the uppersingle digits for five years following the first commercial sale of a linaclotide product in a country, and in the low-double digits thereafter. The royalty rate for products in the expanded territory will decrease, on a country-by-country basis, to the lower-single digits, or cease entirely, following the occurrence of certain events. Allergan is obligated to assume certain purchase commitments for quantities of linaclotide API under the Company's agreements with third-party API suppliers. The 2017 Amendment did not modify any of the milestones or royalty terms related to Europe.

Prior to the adoption of ASC 606, the Company concluded that the 2017 Amendment was a material modification to the European License Agreement; however, this modification did not have a material impact on the Company's consolidated financial statements as there was no deferred revenue associated with the Amended European License Agreement. The Company also concluded that the 2017 Amendment was not a material modification to the linaclotide collaboration agreement with Allergan for North America. The Company's conclusions on deliverables under ASC 605-25 are described below in *Commercial Agreement with Allergan*.

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

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

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

The Company recognized approximately \$1.7 million, approximately \$1.1 million and approximately \$0.6 million of royalty revenue from the Amended European License Agreement during the years ended December 31, 2019, 2018 and 2017, respectively.

## License Agreement for Japan with Astellas

In November 2009, the Company entered into a license agreement with Astellas, as amended, to develop and commercialize linaclotide for the treatment of IBS-C, CIC and other GI conditions in Japan (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, which was recognized as collaborative arrangements revenue on a straight-line basis over the Company's estimate of the period over which linaclotide was to be developed under the 2009 License Agreement with Astellas in accordance with ASC 605. The development period was completed in December 2016 upon approval of LINZESS by the Japanese Ministry of Health, Labor and Welfare, at which point all previously deferred revenue under the agreement was recognized.

The 2009 License Agreement with Astellas also includes three development milestone payments that totaled up to \$45.0 million, all of which were achieved and recognized as revenue through December 31, 2016 in accordance with ASC 605.

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

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

During the years ended December 31, 2019, 2018, and 2017, the Company recognized approximately \$27.5 million, approximately \$69.6 million, and approximately \$29.7 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 is considered a modification to the 2009 License Agreement with Astellas and is 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. Astellas committed to purchase certain quantities of linaclotide API from the Company in 2019.

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 will, in lieu of the royalty payment terms set forth in the 2009 License Agreement with Astellas, 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 will reimburse the Company for the Company's performance of adverse event reporting services at a fixed monthly rate until such services are terminated.

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 knowhow:
- 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 \$10.0 million in collaborative arrangements revenue during the year ended December 31, 2019 related to the upfront fee associated with the execution of the Amended Astellas License Agreement. The Company recognized approximately \$18.3 million from the sale of API to Astellas under the Amended License Agreement during the year ended December 31, 2019. The Company recognized an insignificant amount of collaborative arrangements revenue related to adverse event reporting services for the year ended December 31, 2019.

# 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.

The parties agreed to an Initial Development Plan ("IDP"), which included the planned development of linaclotide in China, including the lead responsibility for each activity and the related internal and external costs. The IDP indicated that AstraZeneca was responsible for a multinational Phase III clinical trial (the "Phase III Trial"), the Company was responsible for nonclinical development and supplying clinical trial material and both parties were responsible for the regulatory submission process. The IDP indicated that the party specifically designated as being responsible for a particular development activity under the IDP should implement and conduct such activities. The activities were governed by a Joint Development Committee ("JDC"), with equal representation from each party. The JDC was responsible for approving, by unanimous consent, the joint development plan and development budget, as well as approving protocols for clinical studies, reviewing and commenting on regulatory submissions, and providing an exchange of data and information.

There were no refund provisions in the AstraZeneca Collaboration Agreement.

Under the terms of the AstraZeneca Collaboration Agreement, the Company received a \$25.0 million non-refundable up-front payment upon execution. The Company was also eligible for \$125.0 million in additional commercial milestone payments contingent on the achievement of certain sales targets. The parties also shared in the net

profits and losses associated with the development and commercialization of linaclotide in the AstraZeneca License Territory, with AstraZeneca receiving 55% of the net profits or incurring 55% of the net losses until a certain specified commercial milestone was achieved, at which time profits and losses would be shared equally thereafter.

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

- an exclusive license to develop and commercialize linaclotide in the AstraZeneca License Territory (the "License Deliverable") (the deliverable was completed upon execution and all associated revenue was recognized as of December 31, 2016);
- research, development and regulatory services pursuant to the IDP, as modified from time to time (the "R&D Services");
- JDC services;
- obligation to supply clinical trial material; and
- co-promotion services for NEXIUM (the "Co-Promotion Deliverable") (the deliverable was completed and all associated revenue was recognized as of December 31, 2013).

Under ASC 605, the License Deliverable was nontransferable and had certain sublicense restrictions. The Company determined that the License Deliverable had standalone value as a result of AstraZeneca's internal product development and commercialization capabilities, which would enable it to use the License Deliverable for its intended purposes without the involvement of the Company. The remaining deliverables were deemed to have standalone value based on their nature and all deliverables met the criteria to be accounted for as separate units of accounting under ASC 605-25.

The Company performed R&D services and JDC services and supplied clinical trial materials during the estimated development period. All consideration allocated to such services was being recognized as a reduction of research and development costs, using the proportional performance method, by which the amounts were recognized in proportion to the costs incurred in accordance with ASC 605.

In August 2014, the Company and AstraZeneca, through the JDC, modified the IDP and development budget to include approximately \$14.0 million in additional activities over the remaining development period, to be shared by the Company and AstraZeneca under the terms of the AstraZeneca Collaboration Agreement.

The total amount of the non-contingent consideration allocable to the AstraZeneca Collaboration Agreement was approximately \$34.0 million ("Arrangement Consideration"), which included the \$25.0 million non-refundable upfront payment and approximately \$9.0 million representing 55% of the costs for clinical trial material supply services and research, development and regulatory activities allocated to the Company in the IDP or as approved by the JDC in subsequent periods.

The Company allocated the Arrangement Consideration to the non-contingent deliverables based on management's best estimated selling price ("BESP") of each deliverable using the relative selling price method, as the Company did not have vendor-specific objective evidence or third-party evidence of selling price for such deliverables. Of the total Arrangement Consideration, approximately \$29.7 million was allocated to the License Deliverable, approximately \$1.8 million to the R&D Services, approximately \$0.1 million to the JDC services, approximately \$0.3 million to the clinical trial material supply services, and approximately \$2.1 million to the Co-Promotion Deliverable in the relative selling price model.

Because the Company shared development costs with AstraZeneca, payments from AstraZeneca with respect to both research and development and selling, general and administrative costs incurred by the Company prior to the commercialization of linaclotide in the AstraZeneca License Territory were recorded as a reduction in expense, in accordance with the Company's policy, which was consistent with the nature of the cost reimbursement. Development costs incurred by the Company that pertain to the joint development plan and subsequent amendments to the joint

development plan, as approved by the JDC, were recorded as research and development expense as incurred. Payments to AstraZeneca were recorded as incremental research and development expense. As a result of the cost-sharing arrangements under the collaboration, the Company recognized approximately \$0.3 million in incremental research and development costs during the year ended December 31, 2017.

In March 2017, the Company began providing supply of linaclotide finished drug product and certain commercialization-related services pursuant to the AstraZeneca Collaboration Agreement. During the year ended December 31, 2017, the Company recognized approximately \$0.2 million as collaborative arrangements revenue related to linaclotide finished drug product, as this deliverable was no longer contingent.

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

At the ASC 606 adoption date, the Company had fully satisfied its obligation to transfer the license and NEXIUM co-promotion services to AstraZeneca. The following remaining performance obligations were ongoing as of the adoption date:

- R&D Services
- JDC services:
- obligation to supply clinical trial material; and
- JCC services.

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

Under ASC 606, amounts of consideration allocated to the license and NEXIUM co-promotion services would have been recognized in full prior to adoption as these performance obligations were satisfied in October 2012 and December 2013, respectively. Consideration allocated to the R&D Services was recognized as such services were provided over the performance period using an output method based on full-time employee labor hours and external expenses incurred. Consideration allocated to the JDC services was recognized ratably over the development period using a time-based, straight-line attribution model. Revenue from the supply of clinical trial material was recognized as the clinical trial material was delivered to the customer. During the year ended December 31, 2019, the Company incurred no costs related to R&D services and JDC services. During the year ended December 31, 2018, the Company offset approximately \$1.2 million related to R&D Services and JDC services.

Additionally, the parties shared in the net profits and losses associated with the development and commercialization of linaclotide in the AstraZeneca License Territory, with AstraZeneca receiving 55% of the net profits or incurring 55% of the net losses until a certain specified commercial milestone was achieved; from that point, profits and losses would have been shared equally thereafter. Any cost reimbursements received from AstraZeneca during the commercialization period were 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. During the years ended December 31, 2019 and 2018, the Company incurred approximately \$1.2 million and approximately \$0.9 million, respectively, related to pre-launch commercial services and supply chain services.

In September 2019, the Company and AstraZeneca entered into 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").

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 will supply linaclotide API, finished drug product and finished goods for the Licensed Territory through no later than March 31, 2020 at predetermined rates.

The Company evaluated the Amended AstraZeneca Agreement in accordance with ASC 606 and determined that it would be treated as a separate contract because it adds a distinct good or service at an amount that reflects standalone selling price. The following performance obligations under the Amended AstraZeneca Agreement were identified:

- delivery of the 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 during the year ended December 31, 2019 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 will be recognized over the performance period using an output method as linaclotide API, finished drug product and finished goods are shipped to AstraZeneca.

During the year ended December 31, 2019, the Company recognized approximately \$32.6 million in collaborative arrangements revenue related to the Amended AstraZeneca License, of which approximately \$32.4 million related to the delivery of the AstraZeneca License and approximately \$0.2 million related to the AstraZeneca TSA services. During the year ended December 31, 2019, the Company recognized approximately \$3.0 million of sale of API on its consolidated statement of operations relating to the supply of linaclotide finished drug product and finished goods under the AstraZeneca CSA.

#### **Co-Promotion and Other Agreements**

Agreement with Allergan for VIBERZI

In August 2015, the Company and Allergan entered into an agreement for the co-promotion in the U.S. of VIBERZI, Allergan's treatment for adults suffering from IBS-D (the "VIBERZI Co-Promotion Agreement"). Under the

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

Under the terms of the VIBERZI Co-Promotion Agreement, the Company's promotional efforts were compensated based on the volume of calls delivered by the Company's sales force, with the terms of the agreement reducing or eliminating certain of the unfavorable adjustments to the Company's share of net profits stipulated by the linaclotide collaboration agreement with Allergan for North America, provided that the Company provided a minimum number of VIBERZI calls on physicians. The Company provided the minimum number of VIBERZI calls on physicians pursuant to the VIBERZI Co-Promotion Agreement, and was compensated with the elimination of certain of the unfavorable adjustments to the Company's share of net profits stipulated by the linaclotide collaboration agreement with Allergan for North America for the year ending December 31, 2017.

During the year ended December 31, 2017, the Company recognized approximately \$1.5 million in revenue related to the VIBERZI Co-Promotion Agreement for the performance of medical education services.

In December 2017, the Company and Allergan entered into an amendment to the commercial agreement with Allergan (the "VIBERZI Amendment"), as described below, to include the VIBERZI promotional activities through December 31, 2018. Under the terms of the VIBERZI Amendment, the Company's clinical sales specialists continued detailing VIBERZI in the second position to the same health care practitioners to whom they detailed LINZESS in the first position and provided certain medical education services. The Company evaluated the VIBERZI Amendment in accordance with ASC 606 and determined that it would be treated as a separate contract because it adds a distinct good or service at an amount that reflects standalone selling price. The following performance obligations under the VIBERZI Amendment were identified:

- sales detailing of VIBERZI in either first or second position; and
- medical education services.

During the three months ended December 31, 2018, the Company determined that the sales-based milestone was no longer constrained and recognized approximately \$1.3 million as collaborative arrangements revenue. During the year ended December 31, 2018, the Company recognized approximately \$3.0 million of collaborative arrangements revenue related to VIBERZI for medical education events. In December 2018 and in March 2019, the Company extended the VIBERZI Amendment through April 2019.

In April 2019, the Company entered into a new agreement with Allergan to continue to perform sales detailing activities for VIBERZI, from April 1, 2019 through December 31, 2019 (the "VIBERZI Promotion Agreement"). Under the terms of the VIBERZI Promotion Agreement, the Company's clinical sales specialists detailed VIBERZI in the second position to the same health care practitioners to whom they detailed LINZESS in the first position. In accordance with ASC 606, the VIBERZI Promotion Agreement is accounted for as a separate contract as it contains distinct services at an amount that reflects standalone selling price, incremental to past agreements. Under the VIBERZI Promotion Agreement the Company identified the performance of VIBERZI second position sales details as the sole performance obligation under the agreement. The Company had the potential to achieve a milestone payment of up to \$4.2 million based on the number of VIBERZI prescription extended units filled over the term of the agreement. The Company had the potential to be compensated up to a maximum amount of approximately \$4.1 million, based on the number of VIBERZI sales details performed. The Company and Allergan terminated the VIBERZI Promotion Agreement effective January 1, 2020.

The Company did not receive payment based on the number of VIBERZI prescription extended units filled because the milestone was not achieved during the year ended December 31, 2019. During the year ended December 31, 2019, the Company recognized approximately \$3.7 million of collaborative arrangements revenue related to VIBERZI sales details. The compensation related to the VIBERZI sales details was recognized over the term of the agreement using an output method based on estimated amounts for which the Company had the right to invoice based on the number of sales details performed during the associated period.

#### Co-Promotion Agreement with Exact Sciences Corp. for COLOGUARD®

In March 2015, the Company and Exact Sciences Corp. ("Exact Sciences") entered into an agreement to copromote Exact Sciences' COLOGUARD, the first and only U.S. FDA-approved noninvasive stool DNA screening test for colorectal cancer (the "Exact Sciences Co-Promotion Agreement"). The Exact Sciences Co-Promotion Agreement was terminated by the parties in August 2016. Under the terms of the non-exclusive Exact Sciences Co-Promotion Agreement, the Company's sales team promoted and educated health care practitioners regarding COLOGUARD through July 2016. Exact Sciences maintained responsibility for all other aspects of the commercialization of COLOGUARD outside of the co-promotion. Under the terms of the Exact Sciences Co-Promotion Agreement, the Company was compensated primarily via royalties earned on the net sales of COLOGUARD generated from the healthcare practitioners on whom the Company called with such royalties payable through July 2017. There were no refund provisions in the Exact Sciences Co-Promotion Agreement.

During the year ended December 31, 2017, the Company recognized approximately \$2.5 million as collaborative arrangements revenue related to this arrangement in accordance with ASC 605-25.

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

#### 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, a therapeutic for the potential treatment of AHP (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 will perform disease awareness activities and sales detailing activities of 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 year ended December 31, 2019, the Company recognized \$2.0 million in collaborative arrangements revenue related to the service fees. As of December 31, 2019, the Company had a deferred revenue balance of approximately \$0.9 million related to the Givosiran Education and Promotion Activities performed in accordance with the Alnylam Agreement. The Company did not recognize any royalty revenue related to the Alnylam Agreement.

## 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 December 31, 2019. Pursuant to the terms of another license agreement, the Company recognized approximately \$0.5 million in collaborative arrangements revenue during the year ended December 31, 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 a 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 the year ended December 31, 2019. The Company recorded approximately \$5.0 million in research and development expenses associated with the Company's other

collaboration and license agreements during the year ended December 31, 2018. The Company did not record any research and development expense associated with the Company's other collaboration and license agreements during the year ended December 31, 2017.

#### 7. 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 December 31, 2019 and 2018 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					te Using
			_	noted Prices in	0	ificant Other		ignificant
	De	cember 31.		ive Markets for lentical Assets	(	Observable Inputs		observable Inputs
	ъ.	2019		(Level 1)		(Level 2)		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		<u> </u>		<u> </u>		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

		Fair Value Measurements at Reporting Date Using					
		Quoted Prices in	Significant Other	Significant			
		Active Markets for	Observable	Unobservable			
	December 31,	Identical Assets	Inputs	Inputs			
	2018	(Level 1)	(Level 2)	(Level 3)			
Assets:							
Cash and cash equivalents:							
Money market funds	\$ 142,218	\$ 142,218	\$ —	\$ —			
Repurchase agreements	30,875	30,875		_			
Convertible Note Hedges	41,020			41,020			
Total assets measured at fair value	\$ 214,113	\$ 173,093	\$ —	\$ 41,020			
Liabilities:							
Note Hedge Warrants	\$ 33,763	\$ —	\$ —	\$ 33,763			
Contingent Consideration	51			51			
Total liabilities measured at fair value	\$ 33,814	\$	\$	\$ 33,814			
Money market funds Repurchase agreements Convertible Note Hedges Total assets measured at fair value  Liabilities: Note Hedge Warrants Contingent Consideration	30,875 41,020 \$ 214,113 \$ 33,763 51	\$ 173,093 \$	\$ —	\$ 41,02 \$ 41,02 \$ 33,76 5			

There were no transfers between fair value measurement levels during each of the years ended December 31, 2019 or 2018.

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, the current portion of capital lease obligations, deferred rent, deferred revenue and operating lease obligations at December 31, 2019 and 2018 are carried at amounts that approximate fair value due to their short-term maturities.

#### **Convertible Note Hedges and Note Hedge Warrants**

The Company's Convertible Note Hedges and the Note Hedge Warrants are recorded as derivative assets and liabilities, 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 December 31, 2019 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 rate, 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 December 31, 2019 and 2018:

	Year Ended		Year Ended					
		Decemb	er 3	1,	December 31,			
		201	9		2018			
	Co	nvertible	No	te Hedge	Co	nvertible	No	ote Hedge
	Not	te Hedges	V	arrants	Not	te Hedges	V	Varrants
Risk-free interest rate (1)		1.6 %		1.6 9	%	2.5 %		2.5 %
Expected term		2.5		3.0		3.5		4.1
Stock price (2)	\$	13.31	\$	13.31	\$	10.36	\$	10.36
Strike price (3)	\$	14.51	\$	18.82	\$	16.58	\$	21.50
Common stock volatility (4)		49.1 %		46.5 %	%	43.8 %		43.6 %
Dividend yield (5)		— %		9	%	— %		— %

<sup>(1)</sup> Based on U.S. Treasury yield curve, with terms commensurate with the terms of the Convertible Note Hedges and the Note Hedge Warrants.

<sup>(2)</sup> The closing price of the Company's Class A Common Stock on the last trading days of the years ended December 31, 2019 and 2018, respectively.

<sup>(3)</sup> As per the respective agreements for the Convertible Note Hedges and Note Hedge Warrants. The strike prices for the Convertible Note Hedges and Note Hedge Warrants were adjusted in conjunction with the conversion rate adjustment in April 2019 (Note 12).

- (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 consolidated statements of operations. Gains and losses for these derivative financial instruments are presented separately in the Company's 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, 2017 through December 31, 2019 (in thousands):

	C	Convertible	Note Hedge
	N	ote Hedges	Warrants
Balance at December 31, 2017	\$	108,188	\$ (92,188)
Change in fair value, recorded as a component of gain (loss) on derivatives		(67,168)	58,425
Balance at December 31, 2018	\$	41,020	\$ (33,763)
Cash settlement (received) paid upon early termination of derivatives		(28,909)	25,735
Change in fair value, recorded as a component of gain (loss) on derivatives		19,255	(16,232)
Balance at December 31, 2019	\$	31,366	\$ (24,260)

In August 2019, the Company repurchased \$215.0 million aggregate principal amount of the 2022 Convertible Notes, which triggered a partial termination of the outstanding Convertible Note Hedges and Note Hedge Warrants (Note 12). During the year ended December 31, 2019, the Company recorded a gain of approximately \$3.0 million on derivatives as a result of the partial termination of the Convertible Note Hedges and Note Hedge Warrants and the change in fair value of the remaining Convertible Note Hedges and Note Hedge Warrants during the year.

## **Contingent Consideration**

In connection with the Lesinurad Transaction, the Company recorded a liability of \$67.9 million as of the Acquisition Date for contingent payments due to AstraZeneca. This valuation was based on a Monte-Carlo simulation, which includes significant estimates related to probability weighted net cash outflow projections, primarily comprised of estimated future royalty and milestone payments to AstraZeneca, discounted using a yield curve equivalent to the Company's credit risk, which was the estimated cost of debt financing for market participants. During the three months ended September 30, 2018, the Company reduced its projected revenue assumptions associated with the sales of ZURAMPIC and DUZALLO and delivered to AstraZeneca a notice of termination of the lesinurad license agreement. The Company recognized a gain on fair value remeasurement of contingent consideration of approximately \$31.0 million during the year ended December 31, 2018. The contingent consideration was fully settled during the year ended December 31, 2019 and no liability remains as of December 31, 2019.

The following table reflects the change in the Company's Level 3 contingent consideration payable from December 31, 2017 through December 31, 2019 (in thousands):

	C	ontingent
	Co	nsideration
Fair Value at December 31, 2017	\$	31,258
Changes in fair value		(31,045)
Payments/transfers to accrued expenses and other current liabilities		(162)
Fair Value at December 31, 2018		51
Payments		(51)
Fair value at December 31, 2019	\$	

## **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 issuance 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 12). 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 as of December 31, 2019 and 2018 was approximately \$141.3 million and approximately \$315.0 million, respectively. The estimated fair value of the 2024 Convertible Notes was approximately \$235.7 million as of December 31, 2019. The estimated fair value of the 2026 Convertible Notes was approximately \$240.1 million as of December 31, 2019.

## **Capped Calls**

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 12). 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 815 to be classified in stockholders' deficit and are not subsequently remeasured as long as the conditions for equity classification continue to be met (Note 12).

#### 8.375% Notes Due 2026

In September 2016, the Company closed a direct private placement pursuant to which the Company issued \$150.0 million in aggregate principal amount of the 2026 Notes in January 2017. The outstanding principal balance of the 2026 Notes was redeemed in September 2019 (Note 12). The estimated fair value of the 2026 Notes was approximately \$148.2 million as of December 31, 2018. This valuation was calculated using a discounted cash flow estimate of expected interest and principal payments and was determined using Level 3 inputs, including significant estimates related to expected LINZESS sales and a discount rate equivalent to market participant interest rates.

## Nonrecurring fair value measurements – Intangible Assets

On August 2, 2018, the Company delivered to AstraZeneca a notice of termination of the lesinurad license agreement. During the three months ended September 30, 2018, the Company recorded an approximately \$151.8 million impairment charge related to its acquired intangible assets. The impairment assessment performed utilized the revised projected revenue and net cash flows assumed through the termination of the lesinurad license agreement, resulting in an impairment of the full carrying value of the intangible assets (Note 5).

## 8. Inventory

Inventory consisted of the following (in thousands):

	Decem	ber 31,
	2019	2018
Raw Materials	\$ 65	\$ —
Work in Progress	392	_
Finished Goods	\$ 191	\$ —
	\$ 648	\$ —

The Company's inventory represents linaclotide API, finished drug product, and finished goods. The Company evaluates inventory levels at each quarterly reporting date and any inventory that has a cost basis in excess of its expected net realizable value, inventory that becomes obsolete, inventory in excess of expected sales requirements, inventory that fails to meet commercial sale specifications or is otherwise impaired is written down with a corresponding charge to the statement of operations in the period that the impairment is first identified. No impairment of linaclotide API inventory was recorded during the years ended December 31, 2019 or 2018.

The Company has entered into multiple commercial supply agreements for the purchase of linaclotide API. Two of the Company's linaclotide API supply agreements for supplying API to its collaboration and license partners outside of North America historically contained minimum purchase commitments.

The determination of the net realizable value of inventory and non-cancelable purchase commitments is based on demand forecasts from the Company's partners, which are received quarterly, and the Company's internal forecast for projected demand in subsequent years. During the year ended December 31, 2015, the Company wrote down approximately \$10.1 million related to excess non-cancelable purchase commitments for linaclotide API. During the three months ended September 30, 2018, the Company assigned to Allergan certain of these linaclotide excess non-cancelable purchase commitments that the Company had previously accrued for. Accordingly, the Company relieved the previous accrual of approximately \$2.5 million, which was recorded as write-down of commercial supply and inventory to net realizable value and (settlement) loss on non-cancelable purchase commitments on the Company's consolidated statement of operations. As of December 31, 2018, the accrual for excess linaclotide purchase commitments was recorded as approximately \$2.5 million in accrued expenses and approximately \$2.5 million in other liabilities, in the Company's consolidated balance sheet.

In connection with the Amended AstraZeneca Agreement, certain of the Company's previously written-down linaclotide excess purchase commitments were assumed by AstraZeneca and resulted in a settlement of approximately \$2.5 million. Additionally, certain previously written-down linaclotide purchase commitments were satisfied through API purchases at pricing terms favorable to the pricing estimates at the time of the write-down, resulting in a gain of approximately \$0.7 million upon purchase. Accordingly, the Company recorded a settlement of approximately \$3.5 million as write-down of commercial supply and inventory to net realizable value and (settlement) loss on non-cancelable purchase commitments related to certain of the aforementioned reversals during the year ended December 31, 2019. As of December 31, 2019, the Company had no remaining accruals for excess purchase commitments on its consolidated balance sheet.

The Company relied exclusively on AstraZeneca for the commercial manufacture and supply of ZURAMPIC and DUZALLO under the Lesinurad Commercial Supply Agreement (the "Lesinurad CSA") through the termination of the lesinurad license agreement. As part of the Company's net realizable value assessment of its inventory, the Company assesses whether it has any excess non-cancelable purchase commitments resulting from its minimum supply agreements with its suppliers.

During the lesinurad transition service agreement ("Lesinurad TSA") period, title for ZURAMPIC commercial supply and samples did not pass to the Company. Accordingly, the Company recorded purchases of ZURAMPIC commercial supply and samples from AstraZeneca as prepaid assets until they were sold or used. Purchases of DUZALLO commercial supply and samples were not within the scope of the Lesinurad TSA. As of October 1, 2017, in connection with the expiration of the Lesinurad TSA period, the Company was no longer operating under this agreement

for the warehousing and distribution of commercial supply and samples of ZURAMPIC. During the year ended December 31, 2017, the Company wrote down approximately \$0.3 million of lesinurad commercial supply purchase commitments as a result of revised demand forecasts and recorded in write-downs of commercial supply and inventory to net realizable value and (settlement) loss on non-cancelable inventory purchase commitments in the Company's consolidated statement of operations. Further, during the year ended December 31, 2017, the Company wrote-down approximately \$1.7 million of ZURAMPIC sample supply purchase commitments as a result of a reduction in near-term forecasted demand. These write-downs were recorded in selling, general and administrative expenses in the Company's consolidated statement of operations.

The Company wrote down approximately \$2.5 million related to lesinurad inventory and commercial supply purchase commitments during the year ended December 31, 2018, as a result of revised demand forecasts and the notice of termination of the Lesinurad License. The adjustment was recorded as write-down of commercial supply and inventory to net realizable value and loss on non-cancelable purchase commitments. Further, during the year ended December 31, 2018, the Company wrote-down approximately \$0.4 million of DUZALLO sample supply purchase commitments as a result of the notice of termination of the lesinurad license agreement. These write-downs were recorded in selling, general and administrative expenses in the Company's consolidated statement of operations.

#### 9. Leases

Effective January 1, 2019, the Company adopted ASC 842 using the optional transition method. The Company's lease portfolio for the year ended December 31, 2019 includes: leases for its prior and current headquarters locations, 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 year ended December 31, 2019 are as follows (in thousands):

	Year Ended
	 December 31,
	 2019
Operating lease cost during period, net <sup>(1)</sup>	\$ 16,452
Variable lease payments	1,526
Short-term lease cost	1,512
Total lease cost	\$ 19,490

<sup>(1)</sup> Operating lease cost is presented net of approximately \$0.3 million of sublease income for the year ended December 31, 2019. Sublease income related to a sublease agreement between Ironwood and Cyclerion executed upon Separation. The sublease agreement terminated in May 2019.

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

	Year Ended December 31,
	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 <sup>(1)</sup> (in thousands)	18,452
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	18,598
Weighted-average remaining lease term of operating leases (in years)	10.2
Weighted-average discount rate of operating leases	5.8 %

Future minimum lease payments under non-cancelable operating leases under ASC 842 as of December 31, 2019 are as follows (in thousands):

	O	perating Lease
	P	ayments
2020	\$	1,146
2021		3,128
2022		3,129
2023		3,065
2024		3,126
2025 and thereafter		18,044
Total future minimum lease payments		31,638
Less: present value adjustment		8,410
Operating lease liabilities at December 31, 2019		23,228
Less: current portion of operating lease liabilities		1,146
Operating lease liabilities, net of current portion	\$	22,082

At December 31, 2018, future minimum lease payments under non-cancelable leases under ASC 840 were as follows (in thousands):

	Operating Lease Payments
2019	\$ 18,736
2020	18,312
2021	18,863
2022	19,365
2023	19,818
2024 and thereafter	 22,118
Total future minimum lease payments	\$ 117,212

#### Summer Street Lease (current headquarters)

On June 11, 2019, the Company entered into the Summer Street Lease, a non-cancelable operating lease with MA-100 Summer Street Owner, L.L.C. (the "Summer Street Landlord") for 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 restricted cash on the Company's consolidated balance sheet as of December 31, 2019.

At lease inception, the Company recorded a right-of-use asset and a lease liability associated with the Summer Street Lease using an incremental borrowing rate of approximately 5.8%. 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.

The Company recorded an asset retirement obligation in connection with the estimated future costs related to the removal of certain leasehold improvements at the Summer Street Property upon termination of the lease. The balance of the Company's asset retirement obligation for the Summer Street Lease was approximately \$0.5 million as of December 31, 2019.

<sup>(1)</sup> Relates to right-of-use assets and operating lease liabilities for the Summer Street Lease.

Lease cost related to the Summer Street Lease recorded during the year ended December 31, 2019 was approximately \$1.5 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.

Prior to the modifications discussed below, the term of the Binney Street Lease was through January 31, 2025 for approximately 223,000 square feet of laboratory and office space. The Binney Street Lease included an option to extend the term of the lease for an additional five years at a market base rental rate, a 3% annual rent escalation, free rent periods, and a tenant improvement allowance. The rent expense for the Binney Street Lease, inclusive of the escalating rent payments and lease incentives, was to be recognized on a straight-line basis over the lease term through January 2025. Additionally, the Binney Street Lease required a letter of credit to secure the Company's obligations under the lease agreement of approximately \$6.4 million, which was collateralized by a certificate of deposit recorded as restricted cash and released during the year ended December 31, 2019.

As of January 1, 2019, in conjunction with the adoption of ASC 842, the Company recorded a right-of-use asset of approximately \$87.7 million and a lease liability of approximately \$94.3 million associated with the Binney Street Lease.

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 became 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, recorded as operating expenses on its 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 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 existing 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 year ended December 31, 2019 was approximately \$16.3 million, net of sublease income of approximately \$0.3 million. Under ASC 840, rent expense related to the Binney Street Lease recorded during the years ended December 31, 2018 and 2017 was approximately \$10.0 million and approximately \$7.6 million, respectively.

#### 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 contains various provisions, including 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 impaired. The Company

recorded a charge of approximately \$0.5 million to selling, general, and administrative expenses on its consolidated statement of operations as a result of the impairment during the three months ended March 31, 2019.

At December 31, 2019, the lease liability associated with the Data Center Lease was approximately \$0.4 million, and the right-of-use asset remained fully impaired.

Lease costs related to the Data Center Lease was approximately \$0.2 million for the year ended December 31, 2019. Under ASC 840, rent expenses related to the Data Center Lease were approximately \$0.2 million and an insignificant amount for the years ended December 31, 2018 and 2017, respectively.

## Vehicle fleet leases

During April 2018, the Company entered into a master services agreement containing 12-month leases (the "2018 Vehicle Leases") for certain 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 restricted cash on the Company's consolidated balance sheets.

Lease cost related to the 2018 Vehicle Leases was approximately \$1.5 million for the year ended December 31, 2019. Under ASC 840, lease cost related to the 2018 Vehicle Leases was approximately \$0.8 million for the year ended December 31, 2018.

Prior to the adoption of ASC 842, during 2018, the Company had certain ongoing vehicle leases for its field-based sales force and medical science liaisons (the "2015 Vehicle Leases"). These leases were classified as capital leases under ASC 840. The 2015 Vehicle Leases expired at varying times through December 2018. In connection with entering into the 2018 Vehicle Leases, all of the 2015 Vehicle Leases were terminated through December 31, 2018. At December 31, 2018, the Company had no remaining capital lease obligations related to the 2015 Vehicle Leases.

#### Other leases

Prior to the adoption of ASC 842, the Company entered into leases for certain computer and office equipment certain of which expired in 2018. These leases were classified as capital leases under ASC 840. At December 31, 2018, the Company had approximately \$0.2 million in capital lease obligations. At December 31, 2018, the weighted average interest rate on the outstanding capital lease obligations was approximately 3.4%. As of December 31, 2019, the Company has not recorded any finance leases within its portfolio in accordance with ASC 842.

## 10. Property and Equipment

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

	Decen	nber 31,
	2019	2018
Software	\$ 9,568	\$ 10,976
Leasehold improvements	7,318	12,472
Laboratory equipment	2,193	1,597
Furniture and fixtures	1,508	1,845
Computer and office equipment	1,293	2,737
Construction in process	631	115
Manufacturing equipment		3,748
	22,511	33,490
Less accumulated depreciation and amortization	(10,082)	(25,838)
	\$ 12,429	\$ 7,652

As of December 31, 2018, certain of the Company's manufacturing equipment was located in the United Kingdom at one of the Company's contract manufacturers. During the year ended December 31, 2019, the Company

ceased use of its manufacturing equipment that was previously located in the United Kingdom at one of its contract manufacturers in connection with the restructuring of certain of its agreements with its partners outside of the U.S.

As of December 31, 2018, the Company had approximately \$0.2 million of assets under capital leases and recorded an insignificant amount of accumulated amortization. Depreciation expense of property and equipment for the year ended December 31, 2019 was approximately \$5.6 million.

Depreciation and amortization expense of property and equipment, including amounts recorded under capital leases under ASC 840, was approximately \$3.9 million, and approximately \$6.4 million for the years ended December 31, 2018 and 2017, respectively.

## 11. Accrued Expenses and Other Current Liabilities

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

	_	December 31,		
		2019		2018
Salaries	\$	2,973	\$	3,054
Accrued vacation		2,540		3,493
Accrued incentive compensation		11,760		13,867
Other employee benefits		1,260		1,883
Professional fees		1,421		1,735
Accrued interest		301		873
Restructuring liabilities		179		2,885
Other		10,031		10,211
	\$	30,465	\$	38,001

As of December 31, 2019, other accrued expenses of approximately \$10.0 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.

As of December 31, 2018, other accrued expenses of approximately \$10.2 million included approximately \$2.5 million related to linaclotide excess purchase commitments and, approximately \$1.4 million related to excess non-cancelable Lesinurad Products commercial supply and sample purchase commitments.

## 12. Notes Payable

## 8.375% Notes due 2026

On September 23, 2016, the Company closed a direct private placement, pursuant to which the Company issued \$150.0 million in aggregate principal amount of the 2026 Notes on January 5, 2017 (the "Funding Date"). The Company received net proceeds of approximately \$11.2 million from the 2026 Notes, which were used to redeem the outstanding principal balance of the 11% PhaRMA Notes due 2024 (the "PhaRMA Notes") on the Funding Date. The Company capitalized approximately \$0.5 million of debt issuance costs, which were netted against the carrying value of the 2026 Notes. Proceeds from the issuance of the 2024 Convertible Notes and the 2026 Convertible Notes were used, in part, to redeem the outstanding principal balance of the 2026 Notes in September 2019. The Company 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. The redemption of the 2026 Notes resulted in a loss on extinguishment of debt of approximately \$7.6 million related to the prepayment premium and write-off of the unamortized debt issuance costs and unamortized debt discount.

The 2026 Notes had an annual interest rate of 8.375%, with interest payable March 15, June 15, September 15 and December 15 of each year (each an "8.375% Payment Date"), which began June 15, 2017. Principal of the 2026 Notes was payable on the 8.375% Payment Dates beginning March 15, 2019 through the redemption of the 2026 Notes. From March 15, 2019, the Company made quarterly payments on the 2026 Notes equal to the greater of (i) 7.5% of net sales of linaclotide in the U.S. for the preceding quarter (the "8.375% Synthetic Royalty Amount") and (ii) accrued and

unpaid interest on the 2026 Notes (the "8.375% Required Interest Amount"). Principal on the 2026 Notes was due to be repaid in an amount equal to the 8.375% Synthetic Royalty Amount minus the 8.375% Required Interest Amount, when this was a positive number, until the principal had been paid in full.

## **Convertible Senior Notes**

#### 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 of the Company's sGC business, 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 will bear cash interest at the annual rate of 0.75% and the 2026 Convertible Notes will 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 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 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.

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 December 31, 2019 and 2018 consisted of the following (in thousands):

		oer 31,	
		2019	2018
Liability component:			
Principal:			
2022 Convertible Notes	\$	120,699	\$ 335,699
2024 Convertible Notes		200,000	
2026 Convertible Notes		200,000	_
Less: unamortized debt discount		(104,700)	(65,094)
Less: unamortized debt issuance costs		(8,005)	(5,004)
Net carrying amount	\$	407,994	\$ 265,601
Equity component:			
2022 Convertible Notes		19,807	114,199
2024 Convertible Notes		41,152	_
2026 Convertible Notes		51,350	_
Total equity component	\$	112,309	\$ 114,199

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 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. The effective interest rate on the liability components of the 2022 Convertible Notes for the period from the date of issuance through June 30, 2019 was 9.34%. From the date of the partial repurchase of the 2022 Convertible Notes in August 2019 through December 31, 2019, the effective interest rate on the liability component of the 2022 Convertible Notes was 7.50%.

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 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 December 31, 2019 was 4.73%.and 4.69%, respectively.

The following table sets forth total interest expense recognized related to convertible senior notes during the years ended December 31, 2019, 2018, and 2017, (in thousands):

		Year Ended		
		December 31,		
	2019 2018 2017			2017
Contractual interest expense	\$	7,361	\$ 7,553	\$ 7,553
Amortization of debt issuance costs		1,190	971	806
Amortization of debt discount		17,683	15,437	14,145
Total interest expense	\$	26,234	\$ 23,961	\$ 22,504

Future minimum payments under the convertible senior notes as of December 31, 2019, are as follows (in thousands):

2020	\$	7,216
2021		7,216
2022		126,556
2023		4,500
2024		203,750
2025 and Thereafter		204,500
Total future minimum payments under the convertible senior notes		553,738
Less: amounts representing interest		(33,039)
Less: unamortized debt discount	(	104,700)
Less: unamortized debt issuance costs		(8,005)
Convertible senior notes balance	\$	407,994

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 2022 Convertible Notes and the Note Hedge Warrants do not have any rights with respect to the Convertible Note Hedges. The Company paid approximately \$91.9 million for the Convertible Note Hedges and recorded this amount as a long-term asset on its

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 related to net termination payments from the counterparties of the Convertible Note Hedges and Note Hedge Warrants. During the year ended December 31, 2019, the Company recorded approximately \$3.0 million in gain on derivatives as a result of the partial termination of the Convertible Note Hedges and Note Hedge Warrants and change in fair value during the period.

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. 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. 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.

# 13. Commitments and Contingencies

## **Commercial Supply Commitments**

The Company has multiple supply agreements for the purchase of linaclotide finished drug product and API. Two of the Company's API supply agreements for supplying API to its collaboration partners outside of North America have historically contained minimum purchase commitments. During the year ended December 31, 2019, the Company amended its API supply agreements to transfer its minimum purchase commitments to its partners outside of North America beginning in 2020. Under its remaining agreements, the Company had no minimum purchase commitments as of December 31, 2019.

In addition, the Company and Allergan are jointly obligated to make minimum purchases of linaclotide API for the territories covered by the Company's collaboration with Allergan for North America. Currently, Allergan fulfills all such minimum purchase commitments.

## Commitments Related to the Collaboration and License Agreements

Under the collaboration agreement with Allergan for North America the Company shares all development and commercialization costs related to linaclotide in the U.S. with Allergan. The actual amounts that the Company pays its partner or that the partner pays to the Company will depend on numerous factors outside of the Company's control, including the success of certain clinical development efforts with respect to linaclotide, the content and timing of decisions made by the regulators, the reimbursement and competitive landscape around linaclotide and the Company's other product candidates, and other factors.

In addition, the Company has commitments to make potential future milestone payments to third parties under certain of its license and collaboration arrangements. These milestones primarily relate to the initiation and results of clinical trials, obtaining regulatory approval in various jurisdictions and the future commercial success of development programs, the outcome and timing of which are difficult to predict and subject to significant uncertainty. In addition to the milestones discussed above, the Company is obligated to pay royalties on future sales, which are contingent on generating levels of sales of future products that have not been achieved and may never be achieved.

These agreements are more fully described in Note 6, *Collaboration, License, Co-promotion and Other Commercial Agreements*, to these consolidated financial statements.

## Other Funding Commitments

As of December 31, 2019, the Company has several on-going studies in various clinical trial stages. The Company's most significant clinical trial expenditures are to contract research organizations. These contracts are generally cancellable, with notice, at the Company's option and do not have any significant cancellation penalties.

#### Guarantees

As permitted under Delaware law, the Company indemnifies its directors and certain of its officers for certain events or occurrences while such director or officer is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that is intended to limit its exposure and enable it to recover a portion of any future amounts paid.

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with business partners, contractors, landlords, clinical sites and customers. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities. These indemnification provisions generally survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of December 31, 2019 and 2018.

## Litigation

From time to time, the Company is involved in various legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. While the outcome of these other claims cannot be predicted with certainty, management does not believe that the outcome of any of these ongoing legal matters, individually and in aggregate, will have a material adverse effect on the Company's consolidated financial statements.

In connection with the settlements the Company entered into in 2018, the Company agreed to pay an aggregate of \$4.0 million in avoidance of litigation fees and expenses during the year ended December 31, 2018. For additional

information relating to such ANDAs and any resolution of related litigation, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K.

## 14. Stockholders' Equity

#### **Preferred Stock**

The Company's preferred stock may be issued from time to time in one or more series, with each such series to consist of such number of shares and to have such terms as adopted by the board of directors. Authority is given to the board of directors to determine and fix such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitation or restrictions thereof, including without limitation, dividend rights, conversion rights, redemption privileges and liquidation preferences.

#### **Common Stock**

Prior to December 31, 2018, the Company had designated two series of common stock, Series A common stock ("Class A Common Stock") and Series B common stock ("Class B Common Stock"). The holders of Class A Common Stock and Class B Common Stock voted together as a single class. Class A Common Stock is entitled to one vote per share. Class B Common Stock was also entitled to one vote per share with the following exceptions: (1) after the completion of an initial public offering of the Company's stock, the holders of the Class B Common Stock were entitled to ten votes per share if the matter was an adoption of an agreement of merger or consolidation, an adoption of a resolution with respect to the sale, lease, or exchange of the Company's assets or an adoption of dissolution or liquidation of the Company, and (2) Class B common stockholders were entitled to ten votes per share on any matter if any individual, entity, or group sought to obtain or had obtained beneficial ownership of 30% or more of the Company's outstanding shares of common stock. Class B Common Stock could be sold at any time and irrevocably converted to Class A Common Stock, on a one-for-one basis, upon sale or transfer. The Class B Common Stock was also entitled to a separate class vote for the issuance of additional shares of Class B Common Stock (except pursuant to dividends, splits or convertible securities), or any amendment, alteration or repeal of any provision of the Company's charter.

On December 31, 2018, all Class B Common Stock automatically converted into Class A Common Stock. The Company had reserved such number of shares of Class A Common Stock as there were outstanding shares of Class B Common Stock solely for the purpose of effecting the conversion of the Class B Common Stock. Upon conversion, 13,972,688 shares of Class B Common Stock were converted to Class A Common Stock. There are no outstanding shares of Class B Common Stock remaining after the conversion as of December 31, 2018.

The Company has reserved, out of its authorized but unissued shares of Class A Common Stock, sufficient shares to effect the conversion of the convertible senior notes and the Note Hedge Warrants pursuant to the terms thereof (Note 12).

The Company's shareholders are entitled to dividends if and when declared by the board of directors.

## 15. Employee Stock Benefit Plans

The Company has several share-based compensation plans under which stock options, RSAs, RSUs, 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):

	Year Ended December 31,		
	2019	2018	2017
Employee stock options	\$ 12,526	\$ 20,478	\$ 19,331
Restricted stock units	15,488	17,160	7,646
Restricted stock awards	2,095	2,330	2,441
Non-employee stock options	_		301
Employee stock purchase plan	1,115	1,097	1,172
Stock award	54	17	14
	\$ 31,278	\$ 41,082	\$ 30,905

The following table summarizes the expenses reflected in the consolidated statements of operations as follows for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Years 1	Years Ended December 31,			
	2019	2018	2017		
Research and development	\$ 6,343	\$11,500	\$ 9,853		
Selling, general and administrative	24,281	27,440	21,052		
Restructuring expenses	654_	2,142			
	\$ 31,278	\$41,082	\$30,905		

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

During the three months ended June 30, 2018, the Company initiated a reduction in its headquarter-based workforce by approximately 40 employees associated with the Separation. Certain share-based payment awards were modified in connection with the reduction in workforce. As a result of the modifications, the Company recorded share-based compensation expense of approximately \$1.4 million during the year ended December 31, 2018.

During the three months ended September 30, 2018, the Company reduced its workforce by approximately 100 employees, primarily consisting of field-based sales representatives, as a result of the termination of the exclusive Lesinurad License. Certain share-based payment awards were modified in connection with the reduction in workforce. As a result of the modifications, the Company recorded share-based compensation expense of approximately \$0.6 million to restructuring expenses during the year ended December 31, 2018.

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 share-based compensation expense of approximately \$0.7 million to restructuring expenses for the year ended December 31, 2019.

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. No share-based compensation expense was recognized in connection with these modifications. Additionally, modifications with respect to the Company's 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 approximately \$0.3 million of share-based compensation expense for the year ended December 31, 2019.

In connection with certain other modifications of share-based payment awards for the year ended December 31, 2019, the Company recognized approximately \$3.0 million in share-based compensation expense.

#### **Stock Benefit Plans**

As of December 31, 2019, the Company has the following active stock benefit plans pursuant to which awards are currently outstanding: the 2019 Equity Incentive Plan (the "2019 Equity Plan"), the Amended and Restated 2010 Employee Stock Purchase Plan (the "2010 Purchase Plan"), the Amended and Restated 2010 Employee, Director, and Consultant Equity Incentive Plan (the "2010 Equity Plan"), and the Amended and Restated 2005 Stock Incentive Plan (the "2005 Equity Plan"). At December 31, 2019, there were 15,867,625 shares available for future grant under the 2019 Equity Plan and the 2010 Purchase Plan.

## 2019 Equity Plan

During 2019, the Company's stockholders approved the 2019 Equity Plan under which stock options, RSAs, RSUs, and other stock-based awards may be granted to employees, officers, directors, or consultants of the Company. Under the 2019 Equity Plan, 10,000,000 shares of Class A Common Stock were initially reserved for issuance. Awards that are returned to the 2010 Equity Plan and 2005 Equity Plan as a result of their expiration, cancellation, termination or repurchase are automatically made available for issuance under the 2019 Equity Plan. Awards that expire, cancel, terminate, or are repurchased under the 2019 Equity Plan will no longer be available for future grant. As of December 31, 2019, 10,954,595 shares were available for future grant under the 2019 Equity Plan.

#### 2010 Purchase Plan

During 2010, the Company's stockholders approved the 2010 Purchase Plan, which gives eligible employees the right to purchase shares of common stock at the lower of 85% of the fair market value on the first or last day of an offering period. Each offering period is six months. There were 400,000 shares of common stock initially reserved for issuance pursuant to the 2010 Purchase Plan. The number of shares available for future grant under the 2010 Purchase Plan may be increased on the first day of each fiscal year by an amount equal to the lesser of: (i) 1,000,000 shares, (ii) 1% of the Class A shares of common stock outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares as is determined by the board of directors. At December 31, 2019, there were 4,913,030 shares available for future grant under the 2010 Purchase Plan.

## 2010 Equity Plan & 2005 Equity Plan

The 2010 Equity Plan and 2005 Equity Plan provided for the granting of stock options, RSAs, RSUs, and other share-based awards to employees, officers, directors, consultants, or advisors of the Company. At December 31, 2019, there were no shares available for future grant under the 2010 Equity Plan or 2005 Equity Plan.

## **Restricted Stock Awards**

In 2019, the Company granted an aggregate of 198,523 shares of Class A Common Stock to independent members of the board of directors under restricted stock agreements in accordance with the terms of the 2010 Equity Plan, and either the Company's director compensation plan, effective in January 2014, or the Company's non-employee director compensation policy, effective May 2019. These shares of restricted stock vest ratably over the period of service from the Company's 2019 annual meeting of stockholders through the Company's 2020 annual meeting of stockholders, provided the individual continues to serve on the Company's board of directors through each vest date.

In 2018, the Company granted an aggregate of 129,784 shares of Class A Common Stock to independent members of the board of directors under restricted stock agreements in accordance with the terms of the 2010 Equity Plan and the Company's director compensation plan, effective in January 2014. These shares of restricted stock vested ratably over the period of service from the Company's 2018 annual meeting of stockholders through the Company's 2019 annual meeting of stockholders, provided the individual continued to serve on the Company's board of directors through each vesting date.

In 2017, the Company granted an aggregate of 134,793 shares of Class A Common Stock to independent members of the board of directors under restricted stock agreements in accordance with the terms of the 2010 Equity

Plan and the Company's director compensation plan, effective in January 2014. These shares of restricted stock vested ratably over the period of service from the Company's 2017 annual meeting of stockholders through the Company's 2018 annual meeting of stockholders, provided the individual continued to serve on the Company's board of directors through each vest date.

A summary of restricted stock activity for the year ended December 31, 2019 is presented below:

	Number of Shares	A Gra	eighted- verage ant Date Value <sup>(1)</sup>
Unvested as of December 31, 2018	64.896	\$	18.58
Granted	198,523	\$	10.96
Vested	(65,547)	\$	17.18
Forfeited	(16,224)	\$	18.58
Unvested as of December 31, 2019	181,648	\$	10.76

<sup>(1)</sup> Prior period amounts have not been retrospectively adjusted to reflect the effect of the Separation on the Company's stock price.

#### **Restricted Stock Units**

RSUs granted under the Company's equity plans represent the right to receive one share of the Company's Class A Common Stock pursuant to the terms of the applicable award agreement. The RSUs generally vest 25% per year on the approximate anniversary of the date of grant until fully vested, provided the individual remains in continuous service with the Company through each vesting date. Shares of the Company's Class A Common Stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of all RSUs is based on the market value of the Company's Class A Common Stock on the date of grant. Compensation expense, including the effect of estimated forfeitures, is recognized over the applicable service period.

A summary of RSU activity for the year ended December 31, 2019 is as follows:

	Number of Shares	Av Gra	ighted- erage nt Date Value <sup>(1)</sup>
Unvested as of December 31, 2018	3,057,808	\$	15.53
Granted	3,097,661		12.11
Vested	(1,298,536)		15.38
Forfeited	(1,649,844)		13.84
Unvested as of December 31, 2019	3,207,089	\$	12.33

<sup>(1)</sup> Prior period amounts have not been retrospectively adjusted to reflect the effect of the Separation on the Company's stock price.

## **Stock Options**

Stock options granted under the Company's equity plans generally have a ten-year term and vest over a period of four years, provided the individual continues to serve at the Company through the vesting dates. Options granted under all equity plans are exercisable at a price per share not less than the fair market value of the underlying common stock on the date of grant. The estimated fair value of options, including the effect of estimated forfeitures, is recognized over the requisite service period, which is typically the vesting period of each option.

The weighted average assumptions used to estimate the fair value of the stock options using the Black-Scholes option-pricing model were as follows for the years ended December 31, 2019, 2018 and 2017:

	Y	Year Ended		
	De	December 31,		
	2019	2018	2017	
Expected volatility	46.3 %	43.7 %	45.8 %	
Expected term (in years)	6.1	6.0	6.0	
Risk-free interest rate	2.5 %	2.7 %	2.0 %	
Expected dividend yield	— %	— %	— %	

Expected volatility is based on the historic volatility of the Company's Class A Common Stock. The Company estimates the expected term using historical data. The risk-free interest rate used for each grant is based on a zero-coupon U.S. Treasury instrument with a remaining term similar to the expected term of the share-based award. 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 weighted-average grant date fair value per share of options granted during the years ended December 31, 2019, 2018 and 2017 was \$6.10, \$6.81, and \$7.62, respectively. Prior period amounts have not been adjusted to reflect the effect of the Separation on the Company's stock price.

The Company grants to certain employees performance-based options to purchase shares of common stock. These options are subject to performance-based milestone vesting. During the years ended December 31, 2019 and 2018, there were no shares that vested as a result of performance milestone achievements. The Company recorded no share-based compensation expense related to these performance-based options during each of the years ended December 31, 2019, 2018 and 2017.

The following table summarizes stock option activity under the Company's share-based compensation plans, including performance-based options:

	Shares of Common Stock Attributable to Options	Weighted- Average Exercise Price <sup>(1)</sup>	Weighted- Average Contractual Life (in years)	I	ggregate ntrinsic Value housands)
Outstanding at December 31, 2018	20,457,537	\$ 13.47	5.80	\$	4,147
Granted	5,743,167	\$ 11.71		\$	_
Exercised	(1,369,327)	\$ 8.33	_	\$	_
Cancelled	(7,637,138)	\$ 12.32	_	\$	_
Outstanding at December 31, 2019	17,194,239	\$ 12.13	5.11	\$	25,226
Vested or expected to vest at December 31, 2019	16,729,428	\$ 12.13	5.01	\$	24,590
Exercisable at December 31, 2019	14,030,936	\$ 12.07	4.33	\$	21,423

<sup>(1)</sup> Prior period amounts have not been retrospectively adjusted to reflect the effect of the Separation on the exercise price of the Company's stock options.

The total intrinsic value of options exercised during the years ended December 31, 2019, 2018 and 2017 was approximately \$5.1 million, approximately \$20.1 million, and approximately \$16.0 million, respectively. The intrinsic value was calculated as the difference between the fair value of the Company's common stock and the exercise price of the option issued.

The following table sets forth the Company's unrecognized share-based compensation expense, net of estimated forfeitures, as of December 31, 2019, by type of award and the weighted-average period over which that expense is expected to be recognized:

	Unrecognized Expense, Net of Estimated Forfeitures	Weighted-Average Remaining Recognition Period
	(in thousands)	(in years)
Type of award:		
Stock options with time-based vesting	\$ 13,849	2.63
Restricted stock awards	758	0.41
Restricted stock units	24,469	2.45
Stock options with time-based and performance-based vesting (1)	147	_

<sup>(1)</sup> The weighted-average remaining recognition period cannot be determined for performance-based or time-accelerated options due to the nature of such awards, as detailed above.

The total unrecognized share-based compensation cost will be adjusted for future changes in estimated forfeitures.

## 16. Income Taxes

In general, the Company has not recorded a provision for federal or state income taxes as it has had cumulative net operating losses since inception.

On December 22, 2017, the Tax Cuts and Jobs Act was enacted. This law substantially amended the Internal Revenue Code, including reducing the U.S. corporate tax rates. Upon enactment, the Company's deferred tax asset and related valuation allowance decreased by approximately \$153.9 million. As the deferred tax asset is offset in full by valuation allowance, this enacted legislation had no impact on the Company's financial position or results of operations. The Company completed its accounting for the tax effects of the Tax Cuts and Job Act as of December 31, 2018 and did not record any material adjustments to its original estimate.

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Income tax benefit using U.S. federal statutory rate	\$ 4,517	\$ (59,297)	\$ (39,759)
Effect of U.S. tax reform			153,894
Permanent differences	65	218	34
State income taxes, net of federal benefit	(1,902)	(17,121)	(6,117)
Disallowed Separation related costs	4,658	_	_
Executive compensation - Section 162(m)	662	8	
Meals and entertainment	495	995	1,346
Non-deductible share-based compensation	(1,202)	(494)	9
Excess tax benefits	3,324	(1,223)	(2,626)
Fair market valuation of Note Hedge Warrants and Convertible Note Hedges	(290)	2,367	1,289
Tax credits	(4,374)	(7,863)	(12,290)
Expiring net operating losses and tax credits	3,764	250	276
Effect of change in state tax rate on deferred tax assets and deferred tax			
liabilities	(2,563)	1,476	(232)
Change in the valuation allowance	(7,154)	80,684	(95,824)
	\$ —	\$ —	\$ —

Components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	Year Ended December 31,		
	2019	2018	
Deferred tax assets:			
Net operating loss carryforwards	\$ 265,494	\$ 259,450	
Tax credit carryforwards	59,892	60,115	
Capitalized research and development	9,952	12,113	
Contingent consideration	_	14	
Share-based compensation	24,401	23,242	
Basis difference on North America collaboration agreement	48,594	36,423	
Accruals and reserves	6,415	10,867	
Basis difference on 2022 Convertible Notes	4,322	7,220	
Interest expense	22,020	5,104	
Intangibles	_	25,928	
Operating lease liability	6,421	_	
Other	5,295	18,867	
Total deferred tax assets	452,806	459,343	
Deferred tax liabilities:			
Basis Difference on 2024 Convertible Notes	(7,381)	_	
Basis Difference on 2026 Convertible Notes	(10,276)		
Operating lease right-of-use assets	(4,905)	_	
Total deferred tax liabilities	(22,562)		
Net deferred tax asset	430,244	459,343	
Valuation allowance	(430,244)	(459,343)	
Net deferred tax asset	\$ —	\$	

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has considered the Company's history of operating losses prior to the year ended December 31, 2019 and concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company will not realize the benefit of its deferred tax assets. Accordingly, the deferred tax assets have been fully reserved at December 31, 2019 and 2018. Management reevaluates the positive and negative evidence on a quarterly basis.

The valuation allowance decreased approximately \$29.1 million during the year ended December 31, 2019 primarily due to a decrease of the intangible deferred tax asset due to the recognition of a tax loss during the year ended December 31, 2019 related to the termination of the lesinural license agreement and establishment of a deferred tax liability for a basis difference in the 2024 Convertible Notes and 2026 Convertible Notes, partially offset by an increase in the deferred tax asset for temporarily disallowed interest expense.

The valuation allowance increased approximately \$80.7 million during the year ended December 31, 2018 primarily due to the 2018 net operating loss and increase in tax credit carryforwards; the establishment of a deferred tax asset for temporarily disallowed interest expense; an increase in the basis difference on the collaboration agreement for North America with Allergan; and an increase in intangible deferred tax assets as a result of the impairment of the lesinurad franchise, partially offset by adjustments to the contingent consideration obligation.

Subject to the limitations described below, at each of December 31, 2019 and 2018, the Company had federal net operating loss carryforwards of approximately \$1.2 billion to offset future federal taxable income, which expiration began in 2019 and will continue through 2037. The 2019 and 2018 net operating loss of \$32.7 million and \$89.1 million, respectively, have an indefinite life. As of December 31, 2019 and 2018, the Company had state net operating loss carryforwards of approximately \$1.0 billion and approximately \$877.1 million, respectively, to offset future state taxable income, which will begin to expire in 2020 and will continue to expire through 2039. The Company also had tax credit carryforwards of approximately \$64.6 million and approximately \$63.3 million as of December 31, 2019 and 2018, respectively, to offset future federal and state income taxes, which expire at various times through 2039.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception which may result in a change in control as defined by IRC Section 382, or could result in a change in control in the future.

The following table summarizes the changes in the Company's unrecognized income tax benefits for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Yea	Year Ended December 31,								
	2019	2018	2017							
Balance at the beginning of the period	\$ 38,551	\$ 24,078	\$ 26,393							
Increases based on tax positions related to the current period	51,699	38,551	24,078							
Increases for tax positions related to prior periods	1,400	_	_							
Decreases for tax positions in prior periods	(38,551)	(24,078)	(26,393)							
Balance at the end of the period	\$ 53,099	\$ 38,551	\$ 24,078							

The Company had gross unrecognized tax benefits of approximately \$53.1 million, approximately \$38.6 million, and approximately \$24.1 million as of December 31, 2019, 2018 and 2017, respectively. Of the approximately \$53.1 million of total unrecognized tax benefits at December 31, 2019, none of the unrecognized tax positions would, if recognized, affect the Company's effective tax rate, due to a valuation allowance against deferred tax assets and only impacts the Company's deferred tax accounting.

The Company will recognize interest and penalties, if any, related to uncertain tax positions in income tax expense. As of December 31, 2019, no interest or penalties have been accrued.

The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities is open for tax years ended December 31, 2019, 2018, and 2017. There are currently no federal or state income tax audits in progress.

#### 17. Defined Contribution Plan

The Ironwood Pharmaceuticals, Inc. 401(k) Savings Plan is a defined contribution plan in the form of a qualified 401(k) plan in which substantially all employees are eligible to participate upon employment. Subject to certain IRS limits, eligible employees may elect to contribute from 1% to 100% of their compensation. Company contributions to the plan are at the sole discretion of the Company's board of directors. Currently, the Company provides a matching contribution of 75% of the employee's contributions, up to \$6,000 annually. During the years ended December 31, 2019, 2018 and 2017, the Company recorded approximately \$2.2 million, approximately \$3.2 million, and approximately \$3.5 million of expense related to its 401(k) company match, respectively.

#### 18. Related Party Transactions

Under the collaboration agreement, the Company and Allergan equally support the development and commercialization of linaclotide (Note 6). Amounts due to and due from Allergan are reflected as related party accounts payable and related party accounts receivable, respectively. These balances are reported net of any balances due to or from the related party. As of December 31, 2019 and 2018, the Company had approximately \$106.0 million and approximately \$60.0 million, respectively, in related party accounts receivable, net of related party accounts payable, associated with Allergan.

The Company has and currently obtains health insurance services for its employees from an insurance provider whose President and Chief Executive Officer became a member of the Company's Board of Directors in April 2016. The Company paid approximately \$7.4 million, approximately \$11.9 million, and approximately \$12.1 million in

insurance premiums to this insurance provider during the years ended December 31, 2019, 2018, and 2017, respectively. At both December 31, 2019 and 2018, the Company had no accounts payable due to this related party.

In connection with the Separation, the Company executed certain contracts with Cyclerion whose President became a member of the Company's Board of Directors in April 2019 (Note 3). 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.

#### 19. Workforce Reduction

On January 30, 2018, the Company commenced an initiative to evaluate the optimal mix of investments for the lesinurad franchise. As part of this effort, the Company reduced its field-based workforce by approximately 60 employees, primarily consisting of field-based sales representatives that promoted DUZALLO or ZURAMPIC in the first position. During the three months ended March 31, 2018, the Company substantially completed the implementation of this reduction in field-based workforce and, in accordance with ASC 420, recorded approximately \$2.4 million of costs in its consolidated statement of operations as restructuring expenses.

On June 27, 2018, the Company determined the initial organizational designs of the two new businesses, including employees' roles and responsibilities, in connection with the Separation. As part of this process, the Company initiated a reduction in its headquarter-based workforce by approximately 40 employees and substantially completed the reduction in its workforce during the year ended December 31, 2019. During the years ended December 31, 2019 and 2018, the Company recorded an insignificant amount of adjustments and approximately \$4.0 million in connection with the reduction in workforce in accordance with ASC 420, respectively. These costs are reflected in the consolidated statement of operations as restructuring expenses.

On August 16, 2018, the Company initiated a reduction in its workforce by approximately 100 employees, primarily consisting of field-based sales representatives in connection with the termination of the Lesinurad License and substantially completed the reduction in its workforce and recorded associated costs during the year ended December 31, 2019. During the year ended December 31, 2019, the Company recorded an insignificant amount of adjustments to restructuring costs related to this workforce reduction. During the year ended December 31, 2018, the Company recorded approximately \$8.3 million of costs, including approximately \$5.4 million of severance, benefits and related costs and approximately \$2.9 million of contract-related costs, including the write-down of certain prepaid assets and deposits, in accordance with ASC 420 in connection with the reduction in workforce. These costs are reflected in the consolidated statement of operations as restructuring expenses.

On February 7, 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. During the year ended December 31, 2019, the Company recorded approximately \$3.7 million of costs that are reflected in the consolidated statement of operations as restructuring expenses.

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the year ended December 31, 2019 (in thousands):

	Amounts Accrued at December 31, 2018 Charges			Am	ount Paid	Adju	Amounts Accrued at December 31, 2019			
Employee severance, benefits and										
related costs										
June 2018 Reduction	\$	696	\$	16	\$	(689)	\$	(23)	\$	_
August 2018 Reduction		1,756		_		(1,708)		(48)		_
February 2019 Reduction				3,182		(2,968)		(139)		75
Total	\$	2,452	\$	3,198	\$	(5,365)	\$	(210)	\$	75
Contract related costs										
August 2018 Reduction	\$	433	\$		\$	(287)	\$	(42)	\$	104
Total	\$	433	\$		\$	(287)	\$	(42)	\$	104

The following table summarizes the accrued liabilities activity recorded in connection with the reduction in workforce for the year ended December 31, 2018 (in thousands):

	Amou Accrue December	Charges Amount Paid					stments	Accr	ounts ued at er 31, 2018	
Employee severance, benefits and								' <u> </u>		
related costs										
January 2018 Reduction	\$		\$	2,228	\$	(2,215)	\$	(13)	\$	_
June 2018 Reduction		_		2,881		(2,074)		(111)		696
August 2018 Reduction				5,383		(3,522)		(105)		1,756
Total	\$		\$	10,492	\$	(7,811)	\$	(229)	\$	2,452
								,		
Contract related costs										
August 2018 Reduction	\$		\$	1,265	\$	(614)	\$	(218)	\$	433
Total	\$	_	\$	1,265	\$	(614)	\$	(218)	\$	433

During the years ended December 31, 2019 and 2018, the Company recorded approximately \$3.6 million and approximately \$14.7 million in restructuring expenses, respectively.

## 20. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for the years ended December 31, 2019 and 2018. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	First		Second	Third	Fourth		Total
		Quarter	Quarter	 Quarter		Quarter	 Year
2019							
Total revenues (1)	\$	68,730	\$ 102,215	\$ 131,167	\$	126,301	\$ 428,413
Total cost and expenses (2)		85,663	80,638	65,280		76,709	308,290
Other expense, net (3)		(4,912)	(9,294)	(45,239)		(1,735)	(61,180)
Net (loss) income from continuing operations	(	(21,846)	12,283	20,648		47,858	58,943
Net loss from discontinued operations <sup>(4)</sup>	(	(37,438)	_	_		_	(37,438)
Net (loss) income	(	(59,284)	12,283	20,648		47,858	21,505
Net (loss) income per share from continuing							
operations—basic	\$	(0.14)	\$ 0.08	\$ 0.13	\$	0.31	\$ 0.38
Net (loss) income per share from continuing							
operations—diluted		(0.14)	0.08	0.13		0.30	0.38
Net loss per share from discontinued							
operations—basic and diluted		(0.24)	_	_		_	(0.24)
Net (loss) income per sharebasic		(0.38)	0.08	0.13		0.31	0.14
Net (loss) income per share—diluted <sup>(5)</sup>		(0.38)	0.08	0.13		0.30	0.14

	Fir Qua		-	econd uarter		Third Quarter	_	Fourth Juarter		Total Year
		(in thousands, except per share data)								_
2018										
Total revenues (6)	\$ 69	,155	\$ 8	81,106	\$	65,686	\$ 1	30,692	\$	346,639
Total cost and expenses (7)	88	,438	Ģ	95,783		212,257	1	00,831		497,309
Other expense, net (8)	(7,	,276)		(9,460)		(5,252)	(	21,488)		(43,476)
Net (loss) income from continuing operations	(26,	,559)	(2	24,137)	(	(151,823)		8,373	(	(194,146)
Net loss from discontinued operations <sup>(4)</sup>	(16,	,585)	(2	25,243)		(22,528)	(	23,866)		(88,222)
Net loss	(43,	,144)	(4	49,380)	(	174,351)	(	15,493)	(	(282,368)
Net (loss) income per share from continuing										
operations—basic and diluted	(	0.18)		(0.16)		(0.99)		0.05		(1.27)
Net loss per share from discontinued operations—										
basic and diluted	(	0.11)		(0.17)		(0.15)		(0.15)		(0.58)
Net loss per sharebasic and diluted	\$ (	0.29)	\$	(0.32)	\$	(1.14)	\$	(0.10)	\$	(1.85)

<sup>(1)</sup> Total revenues includes approximately \$48.8 million of revenue from sales of linaclotide API to our linaclotide partners, primarily driven by the commercialization of linaclotide in Japan for the year ended December 31, 2019, as well as approximately \$32.4 million related to the non-contingent payments from the Amended AstraZeneca Agreement and a \$10.0 million upfront fee from the Amended Astellas License Agreement, both executed during the third quarter of 2019.

- (2) Total costs and expenses includes approximately \$3.6. million in restructuring expenses for the year ended December 31, 2019, as well as approximately \$3.2 million related to the gain on lease modification in April 2019.
- (3) Other expense, net includes approximately \$31.0 million in loss on extinguishment of debt related to the partial repurchase of the 2022 Convertible Notes and the redemption of the 2026 Notes, and approximately \$3.0 million gain on fair value remeasurement of derivatives for the year ended December 31, 2019.
- (4) During the year ended December 31, 2019, the Company completed the Separation. Certain amounts related to Cyclerion have been reclassified as discontinued operations for the years ended December 31, 2019 and 2018.
- (5) Diluted earnings per share is equivalent to basic earnings per share for the year ended December 31, 2019.
- (6) Total revenue includes approximately \$70.4 million of revenue from sales of linaclotide API to our linaclotide partners, primarily driven by the commercialization of linaclotide in Japan for the year ended December 31, 2018.
- (7) Total costs and expenses includes approximately \$14.7 million in restructuring expenses for the year ended December 31, 2018, as well as approximately \$151.8 million related to the impairment of intangible assets and approximately \$31.0 million related to a gain on remeasurement of contingent consideration incurred during the third quarter of 2018 in connection with the exit of the Lesinurad License.
- (8) Other expense, net includes approximately \$8.7 million loss on fair value remeasurement of derivatives for the year ended December 31, 2018.

## 21. Subsequent Events

In January 2020, the Company and Allergan entered into settlement agreements with Sandoz Inc. ("Sandoz") and Teva Pharmaceuticals, USA ("Teva") resolving patent litigation brought in response to Sandoz's and Teva's abbreviated new drug applications seeking approval to market generic versions of LINZESS prior to the expiration of the Company and Allergan's applicable patents. For additional information relating to the resolution of such litigation, see Item 3, *Legal Proceedings*, elsewhere in this Annual Report on Form 10-K.