

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from: _____ to _____

Commission File Number: 001-13111

ASSERTIO THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

94-3229046

(I.R.S. Employer
Identification No.)

100 South Saunders Road, Suite 300, Lake Forest, Illinois

(Address of Principal Executive Offices)

60045

(Zip Code)

Registrant's telephone number, including area code: **(224) 419-7106**

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

Title of each class:

Name of each exchange on which registered:

Common Stock, \$0.0001 par value

The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

The aggregate market value of the shares of common stock held by non-affiliates of the registrant, computed by reference to the closing price as reported on the Nasdaq Stock Market as of June 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$423.2 million.

The number of shares outstanding of the registrant's common stock, \$0.0001 par value, as of March 1, 2019 was 64,263,988.

Documents Incorporated by Reference

Part III of this Annual Report on Form 10-K incorporates by reference portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders, which Proxy Statement will be filed with the United States Securities and Exchange Commission within 120 days after the end of the registrant's 2018 fiscal year.

ASSERTIO THERAPEUTICS, INC.
FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018
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NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Annual Report on Form 10-K that are not statements of historical fact are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “will,” “may” and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

- the commercial success and market acceptance of our products and product candidate, long-acting cosyntropin;
- the success of Collegium Pharmaceutical, Inc. (Collegium) in commercializing NUCYNTA® ER and NUCYNTA®;
- the reversal or any successful appeal of the court’s favorable ruling in our patent infringement litigation against the filers of Abbreviated New Drug Applications (each, an ANDA) to market generic versions of NUCYNTA ER and NUCYNTA in the United States (U.S.);
- any additional patent infringement or other litigation, investigation or proceeding that may be instituted related to us or any of our products, product candidates or products we may acquire;
- our ability to generate sufficient cash flow from our business to make payments on our indebtedness and our compliance with the terms and conditions of the agreements governing our indebtedness;
- our and our collaborative partners’ compliance or non-compliance with legal and regulatory requirements related to the development or promotion of pharmaceutical products in the U.S.;
- our plans to acquire, in-license or co-promote other products;
- the results of our research and development efforts including clinical studies relating to our product candidates, including long-acting cosyntropin;
- approval of regulatory filings, including filings for long-acting cosyntropin;
- our ability to raise additional capital, if necessary;
- our ability to successfully develop and execute our sales and marketing strategies;
- variations in revenues obtained from commercialization and collaborative agreements, including contingent milestone payments, royalties, license fees and other contract revenues, including non-recurring revenues, and the accounting treatment with respect thereto;
- our collaborative partners’ compliance or non-compliance with obligations under our collaboration agreements;
- the outcome of both our opioid-related investigations, our opioid-related litigation brought by state and local governmental entities and private parties, and our insurance litigation, and the costs and expenses associated therewith;
- the regulatory strategy for long-acting cosyntropin and both our and our collaborative partner’s ability to successfully develop and execute such strategy; and

- our ability to attract and retain key executive leadership following our restructuring and office relocation.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in “**ITEM 1A. RISK FACTORS**” and elsewhere in this Annual Report on Form 10-K. Forward looking statements are made as of the date of this report. Except as required by law, we assume no obligation to update any forward-looking statement, or to revise any forward-looking statement to reflect events or developments occurring after the date of this Annual Report on Form 10-K, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

PART I

ITEM 1. BUSINESS

Our Company

Assertio Therapeutics, Inc. (Assertio or the Company) is a specialty pharmaceutical company focused on neurology, orphan and specialty medicines. Our current specialty pharmaceutical business includes the following three products which we market in the United States (U.S.):

- Gralise® (gabapentin), a once daily product for the management of postherpetic neuralgia (PHN), that we launched in October 2011.
- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, that we acquired in December 2013.
- Zipsor® (diclofenac potassium liquid filled capsules), a non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain, that we acquired in June 2012.

We also have the exclusive rights to market long-acting cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the U.S. Food and Drug Administration (FDA) for our 505(b)(2) New Drug Application (NDA) for our novel injectable formulation of long-acting cosyntropin. We, together with our development partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

We maintain a Commercialization Agreement with Collegium Pharmaceutical, Inc. (Collegium) pursuant to which we granted Collegium the right to commercialize the NUCYNTA® franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We receive a royalty on all NUCYNTA revenues based on certain net sales thresholds.

Corporate Information

The address of our Internet website is <http://www.assertiotx.com>. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Assertio was formerly known as Depomed, Inc. and was originally incorporated in California in August 1995. On August 14, 2018 (Effective Time), we reincorporated from California to Delaware and changed our name to Assertio Therapeutics, Inc. In connection with this name change, our common stock began trading under the ticker symbol “ASRT.” The use of the terms “Company,” “we,” “our” and “us” in this filing refers to Depomed any time prior to the Effective Time and to Assertio any time after the Effective Time.

Our Strategy

Our business strategy is based on three pillars: Maintain, Grow and Build. We intend to “*Maintain*” our NUCYNTA franchise of pain products through our Commercialization Agreement with Collegium. We intend to “*Grow*” our neurology, orphan and specialty medicine business through organic and inorganic growth. We intend to “*Build*” a portfolio of high-value products positioned to address the needs of patients, physicians and payers.

Our Business Operations

As of December 31, 2018, our revenues were generated primarily from the following products.

Products

Gralise (Gabapentin)

Gralise is our proprietary, once-daily formulation of gabapentin indicated for management of PHN, a persistent pain condition caused by nerve damage during a shingles, or herpes zoster, viral infection. We made Gralise commercially available in October 2011, following its U.S. Food and Drug Administration (FDA) approval in January 2011. The FDA has granted Orphan Drug exclusivity for PHN.

CAMBIA (Diclofenac Potassium for Oral Solution)

CAMBIA is a non-steroidal anti-inflammatory drug (NSAID) indicated for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older. We acquired CAMBIA in December 2013 from Nautilus Neurosciences, Inc. (Nautilus). We began shipping and recognizing product sales on CAMBIA in December 2013.

Zipsor (Diclofenac Potassium Liquid-Filled Capsules)

Zipsor is an NSAID indicated for relief of mild to moderate acute pain in adults. Zipsor uses proprietary ProSorb® delivery technology to deliver a finely dispersed, rapidly absorbed formulation of diclofenac. We acquired Zipsor in June 2012 from Xanodyne Pharmaceuticals, Inc. (Xanodyne). We began shipping and recognizing product sales on Zipsor in June 2012.

NUCYNTA ER (Tapentadol Extended Release Tablets) and NUCYNTA IR (NUCYNTA) (Tapentadol)

NUCYNTA ER is an extended release version of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults, and for which alternate treatment options are inadequate. NUCYNTA is an immediate release version of tapentadol that is indicated for the management of moderate to severe acute pain in adults. We acquired the U.S. rights to NUCYNTA ER and NUCYNTA from Janssen Pharmaceuticals, Inc. (Janssen Pharma) and began shipping and recognizing product sales on NUCYNTA ER and NUCYNTA in April 2015. We began commercial promotion of NUCYNTA ER and NUCYNTA in June 2015.

In December 2017, we entered into a Commercialization Agreement with Collegium, which we amended in November 2018. Pursuant to the Commercialization Agreement, we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, with a minimum royalty of \$132.0 million for the year ended December 31, 2018. Beginning in 2019, we will receive royalties based on certain annual NUCYNTA net sales thresholds for future years. Both we and Collegium may terminate the Commercialization Agreement under certain circumstances; however, Collegium may not terminate the agreement prior to the end of 2021. Additionally, we retained certain rights to co-promote NUCYNTA products, subject to providing advanced notice to Collegium. See “Item 8. Financial Statements and Supplementary Data—Note 4. Revenue” for additional information regarding the terms of the Commercialization Agreement.

The following table shows sales for each of the above-described products over each of the past three fiscal years.

<u>(Dollars in Millions)</u> <u>Products</u>	<u>2018</u>	<u>2017</u>	<u>2016</u>
Gralise	\$ 58.1	\$ 77.0	\$ 88.4
CAMBIA	\$ 35.8	\$ 31.6	\$ 31.3
Zipsor	\$ 16.4	\$ 16.7	\$ 27.5
NUCYNTA ER and NUCYNTA			
Product Sales(1)	\$ 18.9	\$239.5	\$281.3
Commercialization Agreement(2)	\$155.7	\$ 0	\$ 0
Lazanda(3)	\$ 0.8	\$ 15.0	\$ 26.5

- (1) NUCYNTA ER and NUCYNTA product sales for 2018 reflect our sales of NUCYNTA between January 1 and January 8, 2018. See “Item 8. Financial Statements and Supplementary Data—Note 4. Revenue” for additional information.
- (2) NUCYNTA ER and NUCYNTA royalties from Collegium reflect royalties earned and inventory sold pursuant to the Commercialization Agreement after January 8, 2018. See “Item 8. Financial Statements and Supplementary Data—Note 4. Revenue” for additional information.
- (3) In November 2017, we entered into agreements with Slán Medicinal Holdings Limited and certain of its affiliates (Slán) pursuant to which Slán acquired our rights to Lazanda. Lazanda nasal spray is an intranasal fentanyl drug used to manage breakthrough pain in adults (18 years of age and older) who are already routinely taking other opioid pain medicines around-the-clock for cancer pain. We acquired Lazanda in July 2013 from Archimedes Pharma US Inc. and its affiliated companies.

Product Candidates

Long-Acting Cosyntropin. In November 2017, we entered into definitive agreements with Slán Medicinal Holdings Limited and certain of its affiliates (Slán) pursuant to which we acquired Slán’s rights to market the specialty drug long-acting cosyntropin (synthetic ACTH) in the U.S. and Canada. In February 2019, notification of acceptance for filing was received from the FDA for our 505(b)(2) NDA for our novel injectable formulation of long-acting cosyntropin. We, together with our partner, West, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

Collaboration and License Agreement with Ironwood Pharmaceuticals, Inc. (Ironwood)

In July 2011, we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for IW 3718, an Ironwood product candidate under evaluation for refractory GERD. During the second quarter of 2018, we received a \$5.0 million milestone payment related to the dosing of the first patient in a Phase 3 trial. We will receive additional contingent milestone payments upon the occurrence of certain development milestones and royalties on net sales of the product, if approved.

PDL BioPharma, Inc. (PDL) Royalty Purchase and Sale Agreement

In October 2013, pursuant to the terms and conditions of a Royalty Purchase and Sale Agreement with PDL (Royalty Purchase Agreement), we sold to PDL our right to receive royalty, milestone and other specified payments arising on and after October 2013 under each of the following license

agreements relating to our Acuform technology in the Type 2 diabetes therapeutic area: (i) the License and Services Agreement, effective as of March 4, 2011, with Boehringer Ingelheim International GMBH (BI) relating to potential future development milestones and sales of BI's investigational fixed-dose combinations of drugs and extended-release metformin worldwide; (ii) the License Agreement, effective as of August 5, 2010, with Janssen Pharmaceutica N.V. (Janssen) relating to potential future development milestones and sales of Janssen's investigational fixed-dose combination of Invokana[®] (canagliflozin) and extended-release metformin worldwide; (iii) the Non-Exclusive License, Covenant Not to Sue and Right of Reference Agreement, effective as of July 21, 2009, with Merck & Co., Inc. relating to sales of Janumet XR[®] (sitagliptin and metformin HCL extended-release) worldwide; (iv) the Commercialization Agreement, effective as of August 22, 2011, with Santarus, Inc. relating to sales of Glumetza[®] (metformin HCL extended-release tablets) in the United States; (v) the Amended License Agreement, effective as of January 9, 2007, with LG Life Sciences Ltd. relating to sales of extended-release metformin in Korea; and (vi) the Amended and Restated License Agreement (Extended Release Metformin Formulations—Canada), dated as of December 13, 2005, with Biovail Laboratories International SRL relating to sales of extended-release metformin in Canada. Under the Royalty Purchase Agreement, PDL was entitled to receive all payments due under such license agreements until PDL received \$481 million, after which all net payments received were to be shared evenly between us and PDL. In August 2018, we amended the Royalty Purchase Agreement and sold our remaining interest in such payments to PDL for \$20.0 million.

Segment and Customer Information

We maintain one operating segment and have operations solely in the United States. To date, substantially all of our revenues from product sales are related to sales in the United States.

The three large, national wholesale distributors represent the vast majority of our product sales and represented the percentages of product shipments and consolidated revenue for the years ended December 31, 2018, 2017 and 2016 set forth below. Further, as described above, we entered into a Commercialization Agreement with Collegium pursuant to which we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States, effective January 9, 2018. We receive a royalty on all NUCYNTA revenues based on certain net sales thresholds, which royalties represented the following percentage of consolidated revenue for the years ended December 31, 2018, 2017 and 2016.

	Consolidated Revenue			Accounts Receivable related to product shipments		
	2018	2017	2016	2018	2017	2016
McKesson Corporation	14%	36%	36%	28%	41%	39%
AmerisourceBergen Corporation	13%	27%	27%	28%	27%	33%
Cardinal Health	11%	26%	25%	32%	23%	20%
Collegium	55%	—%	—%	—%	—%	—%
All others	7%	11%	12%	12%	9%	8%
Total	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

Marketing and Sales

We have developed capabilities in various aspects relating to the commercialization of our marketed products, including sales, marketing, manufacturing, quality assurance, wholesale distribution, managed market contracting, government price reporting, medical affairs, compliance, and regulatory. Members of our commercial organization are also engaged in the commercial and marketing assessments of other potential product candidates.

Our neurology sales organization includes approximately 90 full time sales representatives, approximately half of whom are our employees and the balance of whom are employees of a contract sales organization. Our neurology sales force primarily calls on neurologists, pain specialists and primary care physicians, and their affiliated physician assistants and nurse practitioners, throughout most of the United States. Our marketing organization is comprised of professionals who have developed a variety of marketing techniques and programs to promote our products, including promotional materials, industry publications, advertising and other media.

Seasonality

Our product revenues for Gralise, CAMBIA and Zipsor have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year. This variation is influenced by both wholesaler buying patterns and the reset of annual limits on deductibles and out-of-pocket costs of many health insurance plans and government programs at the beginning of each calendar year. For additional information, please also refer to “Item 1A, Risk Factors—*Our product revenues have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year, which may cause our stock price to decline.*”

Manufacturing

Our facility is used for office purposes. No commercial manufacturing takes place at our facility.

We are responsible for the supply and distribution of our marketed products. We have manufacturing and supply agreements with sole commercial suppliers for each of our marketed products, as follows: for Gralise, with Patheon Puerto Rico Inc. (Patheon); for CAMBIA, with MiPharm, S.p.A. (MiPharm); for Zipsor, with Catalent Ontario Limited (Catalent); for NUCYTNA ER, with an affiliate of Janssen Pharma; and for NUCYNTA, with Halo Pharmaceutical, Inc. (Halo).

We have one qualified supplier for the active pharmaceutical ingredient in each of our marketed products. We have supply agreements with the suppliers of the active pharmaceutical ingredients in each of our marketed products. We also obtain polyethylene oxide, one of the excipients common to Gralise and products under development by our partners. We currently have no long term supply arrangement with respect to polyethylene oxide.

For additional information regarding our manufacturing, please also refer to “Item 1A, Risk Factors—*We depend on third parties that are single source suppliers to manufacture our products. If these suppliers are unable to manufacture and supply our products, or if there is insufficient availability of our products or the raw materials necessary to manufacture our products, our business will suffer.*”

Intellectual Property

Our Trademarks

Assertio™, Depomed®, NUCYNTA®, Gralise®, CAMBIA®, Zipsor® and Acuform® are trademarks of Assertio. All other trademarks and trade names referenced in this Annual Report on Form 10 K are the property of their respective owners.

Our Patents and Proprietary Rights

The material issued in the U.S. patents we own or have in-licensed, and the marketed products they cover, are as follows:

<u>Product</u>	<u>U.S. Patent Nos. (Exp. Dates)</u>
NUCYNTA [®] ER	8,536,130 (September 22, 2028)(1)(2)
	7,994,364 (June 27, 2025)(1)(2)
	RE39593 (August 5, 2022)(1)(2)
NUCYNTA [®]	7,994,364 (June 27, 2025)(1)
	RE39593 (August 5, 2022)(1)
Gralise [®]	7,438,927 (February 26, 2024)
	7,731,989 (October 25, 2022)
	8,192,756 (October 25, 2022)
	8,252,332 (October 25, 2022)
	8,333,992 (October 25, 2022)
	6,723,340 (October 25, 2021)
Zipsor [®]	6,488,962 (June 20, 2020)
	7,662,858 (February 24, 2029)
	7,884,095 (February 24, 2029)
	7,939,518 (February 24, 2029)
	8,110,606 (February 24, 2029)
	8,623,920 (February 24, 2029)
CAMBIA [®]	6,287,594 (January 15, 2019)
	9,561,200 (February 24, 2029)
	7,759,394 (June 16, 2026)(1)
	8,097,651 (June 16, 2026)(1)
	8,927,604 (June 16, 2026)(1)
	9,827,197 (June 16, 2026)

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- (1) Subject to six-month pediatric patent term extension beyond scheduled expiration date.
 - (2) Patent rights are exclusively in-licensed by us.

Our success will depend in part on our ability to obtain and maintain patent protection for our products and technologies. Our policy is to seek to protect our proprietary rights, by among other methods, filing patent applications in the U.S. and foreign jurisdictions to cover certain aspects of our technology. In addition to those patents noted on the above table, we have one patent application pending in the U.S. Our pending patent application may lack priority over other applications or may not result in the issuance of a patent. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or

circumvented, which could limit our ability to stop competitors from marketing related products or may not provide us with competitive advantages against competing products. We also rely on trade secrets and proprietary know how, which are difficult to protect. We seek to protect such information, in part, through entering into confidentiality agreements with employees, consultants, collaborative partners and others before such persons or entities have access to our proprietary trade secrets and know how. These confidentiality agreements may not be effective in certain cases. In addition, our trade secrets may otherwise become known or be independently developed by competitors. For further information regarding risks associated with the protection of our intellectual property rights, please also refer to “Item 1A, “Risk Factors—*We may be unable to protect our intellectual property and may be liable for infringing the intellectual property of others.*” For information regarding currently pending litigation related to intellectual property matters, please also refer to “Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies.”

Competition

General. We believe that we compete favorably in our markets on the basis of the safety and efficacy of our products. However, competition in pharmaceutical products is intense, and we expect competition to increase. There may be other companies developing products competitive with ours of which we are unaware. Many of our principal competitors have greater financial, sales, marketing, personnel and research and development resources than we do. Competing products developed in the future may prove superior to our products, either generally or in particular market segments. These developments could make our products noncompetitive or obsolete.

Gralise. Gabapentin is currently sold by Pfizer Inc. (Pfizer) as Neurontin® and by several generic manufacturers for adjunctive therapy for partial onset seizures and for the management of PHN (postherpetic neuralgia). In addition, Pfizer’s product Lyrica® (pregabalin) has been approved for marketing in the United States for the management of PHN, neuropathic pain associated with DPN (diabetic peripheral neuropathy), neuropathic pain associated with spinal cord injury, fibromyalgia, and adjunctive therapy in partial onset seizures. In January 2018, Pfizer began to sell Lyrica® CR a controlled release formulation of Lyrica® for neuropathic pain associated with DPN and for PHN. Gralise competes against these products and other neuropathic pain treatments, such as anti-depressants, anti-convulsants, local anesthetics used as regional nerve blockers, anti-arrhythmics and opioids. Arbor Pharmaceutical, LLC’s Horizant™ (gabapentin enacarbil extended-release tablets) product, a prodrug of gabapentin, is also marketed for the management of PHN in the U.S. as well as for Restless Leg Syndrome.

CAMBIA. Diclofenac, the active pharmaceutical ingredient in CAMBIA, is a NSAID approved in the United States for the acute treatment of migraine in adults. CAMBIA competes with a number of triptans which are used to treat acute migraine and certain other headaches. Currently, eight triptans are available generically and sold in the United States (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan). Branded competitors include Zomig® Nasal Spray, Onzetra®, Xsail®, Sumavel®, Zembrace™ SymTouch™ and Treximet®, which is a fixed dose combination product containing sumatriptan and naproxen. There are other products prescribed for or under development for the treatment or prevention of migraines that are now or may become competitive with CAMBIA, including calcitonin gene-related peptide (CGRP) inhibitor products.

Zipsor. Diclofenac, the active pharmaceutical ingredient in Zipsor, is a NSAID that is approved in the United States for relief of mild to moderate acute pain. Both branded and generic versions of diclofenac are marketed in the United States. Zipsor competes against other drugs that are widely used to treat mild to moderate acute pain. In addition, a number of other companies are developing NSAIDs in a variety of dosage forms for the treatment of mild to moderate pain and related indications. Other drugs are in clinical development to treat acute pain.

NUCYNTA ER (tapentadol extended release tablets). NUCYNTA ER competes against other long-acting opioid medications. Those include, among others: OxyContin® (oxycodone hydrochloride extended-release tablets); Butrans® (buprenorphine); Belbuca™ (buprenorphine buccal film); Hysingla® ER (hydrocodone bitartrate); Xtampza® ER (oxycodone); Zohydro® ER (hydrocodone bitartrate); Embeda® (morphine sulfate and naltrexone hcl); Arymo® ER (morphine sulfate); MorphaBond™ ER (morphine sulfate); and numerous generically available long-acting opioids. New products continue to be developed and approved, such as Pfizer's Troxyca, Teva's Vantrela and Daiichi-Sankyo's RoxyBond.

NUCYNTA (tapentadol). NUCYNTA (*tapentadol*) competes primarily against other short-acting opioids. There are numerous such medicines, including, among others: Oxaydo® (oxycodone hcl); generic oxycodone hcl; generic oxycodone acetaminophen; generic oxymorphone; generic hydrocodone acetaminophen; generic hydromorphone; generic morphine; generic tramadol hcl and generic tramadol acetaminophen. New short-acting opioids continue to be developed and approved.

Government Regulation

Product Development

Numerous governmental authorities in the U.S. and other countries regulate our research and development activities and those of our collaborative partners. Governmental approval is required of all potential pharmaceutical products prior to the commercial use of those products. The regulatory process takes several years and requires substantial funds.

In the U.S., the FDA rigorously regulates pharmaceutical products. If a company fails to comply with applicable requirements, the FDA or the courts may impose sanctions. These sanctions may include civil penalties, criminal prosecution of the company or its officers and employees, injunctions, product seizure or detention, product recalls, and total or partial suspension of production. The FDA may withdraw approved applications or refuse to approve pending new drug applications, premarket approval applications, or supplements to approved applications.

We may be required to conduct preclinical testing on laboratory animals of new pharmaceutical products prior to commencement of clinical studies involving human beings. These studies evaluate the potential efficacy and safety of the product. If preclinical testing is required, we must submit the results of the studies to the FDA as part of an Investigational New Drug Application, which must become effective before beginning clinical testing in humans.

Some of the products we have developed have been submitted for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetics Act (FDCA), which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For instance, the NDA for Gralise relies on the FDA's prior approval of Neurontin® (gabapentin), the immediate release formulation of gabapentin initially approved by the FDA.

Typically, human clinical evaluation involves a time-consuming and costly three-phase process:

- In Phase 1, we conduct clinical trials with a small number of subjects to determine a drug's early safety profile and its pharmacokinetic pattern.
- In Phase 2, we conduct limited clinical trials with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and further evidence of safety.

- In Phase 3, we conduct large-scale, multi-center, comparative trials with patients afflicted with a target disease in order to provide enough data to statistically evaluate the efficacy and safety of the product candidate, as required by the FDA.

The FDA closely monitors the progress of each phase of clinical testing. The FDA may, at its discretion, re-evaluate, alter, suspend or terminate testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to patients. The FDA may also require additional clinical trials after approvals, which are known as Phase 4 trials.

The results of preclinical and clinical testing are submitted to the FDA in the form of an NDA, for approval prior to commercialization. An NDA requires that our products are compliant with current good manufacturing practices (cGMP). Failure to achieve or maintain cGMP standards for our products would adversely impact their marketability.

In responding to an NDA, the FDA may grant marketing approval, request additional information or deny the application.

Foreign regulatory approval of a product must also be obtained prior to marketing the product internationally. Foreign approval procedures vary from country to country. The time required for approval may delay or prevent marketing in certain countries. In certain instances we or our collaborative partners may seek approval to market and sell certain products outside of the United States before submitting an application for United States approval to the FDA. The clinical testing requirements and the time required to obtain foreign regulatory approvals may differ from that required for FDA approval. Although there is now a centralized European Union (EU) approval mechanism in place, each EU country may nonetheless impose its own procedures and requirements. Many of these procedures and requirements are time-consuming and expensive. Some EU countries require price approval as part of the regulatory process. These constraints can cause substantial delays in obtaining required approval from both the FDA and foreign regulatory authorities after the relevant applications are filed, and approval in any single country may not meaningfully indicate that another country will approve the product.

Reimbursement

Sales of pharmaceutical products in the U.S. depend in significant part on the extent of coverage and reimbursement from government programs, including Medicare and Medicaid, as well as other third party payers. Third party payers are undertaking significant efforts to control the cost of pharmaceutical products, including by implementing cost containment measures to control, restrict access to, or influence the purchase of drugs, and other health care products and services.

Government programs may regulate reimbursement, pricing, and coverage of products in order to control costs or to affect levels of use of certain products. Private health insurance plans may exclude or restrict coverage of some products, such as by using payer formularies under which only selected drugs are covered, variable co-payments that make drugs that are not preferred by the payer more expensive for patients, and by employing utilization management controls, such as requirements for prior authorization or prior failure on another type of treatment.

Fraud and Abuse

Pharmaceutical companies that participate in federal healthcare programs are subject to various U.S. federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback and false claims laws. Violations of U.S. federal and state fraud and abuse laws may be punishable by criminal or civil sanctions, including fines, civil monetary penalties and exclusion from federal healthcare programs (including Medicare and Medicaid).

Federal statutes that apply to us include the federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration in exchange for or to generate business, including the purchase or prescription of a drug, that is reimbursable by a federal healthcare program such as Medicare and Medicaid, and the Federal False Claims Act (FCA), which generally prohibits knowingly and willingly presenting, or causing to be presented, for payment to the federal government any false, fraudulent or medically unnecessary claims for reimbursed drugs or services. Government enforcement agencies and private whistleblowers have asserted liability under the FCA for claims submitted involving inadequate care, kickbacks, improper promotion of off-label uses and misreporting of drug prices to federal agencies.

Similar state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payers, including private insurers. These state laws may be broader in scope than their federal analogues, such as state false claims laws that apply where a claim is submitted to any third-party payer, regardless of whether the payer is a private health insurer or a government healthcare program, and state laws that require pharmaceutical companies to certify compliance with the pharmaceutical industry's voluntary compliance guidelines.

Federal and state authorities have increased enforcement of fraud and abuse laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the law and bringing suits on behalf of the government under the FCA and under state and local laws. These laws are broad in scope and there may not be regulations, guidance, or court decisions that definitively interpret these laws and apply them to particular industry practices. In addition, these laws and their interpretations are subject to change.

Prescription Limitations

Many states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of immediate release form of opiates (such as NUCYNTA), mandate the use by prescribers of prescription drug databases and mandate prescriber education. These and other state and local laws applicable to the pharmaceutical industry may affect our business and operations as well as those of our commercialization and development partners.

Controlled Substances

Tapentadol (Federal and State). The U.S. Drug Enforcement Administration (DEA) is the federal agency responsible for domestic enforcement of the Controlled Substances Act of 1970 (CSA). The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have high potential for abuse, no currently accepted medical use in the United States and lack accepted safety for use under medical supervision, and may not be marketed or sold in the United States. Except for research and industrial purposes, a pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Tapentadol, the active ingredient in NUCYNTA and NUCYNTA ER, is listed by the DEA as a Schedule II substance under the CSA. Consequently, its manufacture, shipment, storage, sale and use are subject to a high degree of regulation.

Registration with the DEA is required for any facility that manufactures, distributes, dispenses, imports or exports a controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and

manufacturing, and each registration will specify which schedules of controlled substances are authorized to be handled under that registration.

The availability and production of all Schedule II substances, including tapentadol, is limited by the DEA through a quota system that includes a national aggregate quota, production quotas for individual manufacturers and procurement quotas that authorize the procurement of specific quantities of Schedule II controlled substances for use in drug product manufacturing. The DEA annually establishes an aggregate quota for total tapentadol production in the U.S. based on the DEA's estimate of the quantity needed to meet commercial and scientific need. The aggregate quota of tapentadol that the DEA allows to be produced in the U.S. is allocated among applicable individual drug manufacturers, which must submit applications at least annually to the DEA for individual production quotas. In turn, the manufacturers of NUCYNTA and NUCYNTA ER, which are third party contract manufacturers, have to obtain a procurement quota to source tapentadol for the production of NUCYNTA and NUCYNTA ER.

The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas for these activities. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. The DEA may also require drug manufactures to submit applications for individual production quota on a rolling basis.

Individual states also regulate controlled substances, and we, as well as our third party active pharmaceutical ingredient suppliers and manufacturers, are subject to such regulation by several states with respect to the manufacture and distribution of these products.

Gabapentin (State). There has been recent regulatory attention focused on gabapentin as a result of a perceived risk of the compound being used as a potentiator for opioid abuse. Although gabapentin is neither an opioid nor classified as a controlled substance by the DEA, as a result of the perceived risks relating to opioid abuse, several states (Tennessee, West Virginia, Kentucky and Michigan) have scheduled gabapentin as a Schedule V substance. As a result, we, as well as our third party active pharmaceutical ingredient suppliers and manufacturers, are subject to regulation by these states with respect to the manufacture and distribution of Gralise (gabapentin).

Other U.S. Healthcare Laws

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) contains provisions that have or could potentially impact our business, including (a) an increase in the minimum Medicaid rebate to states participating in the Medicaid program on branded prescription drugs; (b) the extension of the Medicaid rebate to managed care organizations that dispense drugs to Medicaid beneficiaries; and (c) the expansion of the 340B Public Health Service Act drug pricing program (340B Program), which provides outpatient drugs at reduced rates, to include certain children's hospitals, free standing cancer hospitals, critical access hospitals and rural referral centers.

Additionally, the federal Physician Payments Sunshine Act (the Sunshine Act) provisions, enacted in 2010 as part of ACA, require pharmaceutical manufacturers, among others, to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures and impose penalties for failures to disclose. Many of these laws and regulations contain ambiguous requirements. As a result of the ambiguity in certain of these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Our operations and business are subject to a number of other laws and regulations, including those relating to the workplace, privacy, laboratory practices and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances as well as controlled substances. In addition, state laws may also govern the privacy and security of health information in some circumstances and may contain different or broader privacy protections than the federal provisions.

For additional information and risks regarding the above described government regulations, please also refer to “Item 1A, Risk Factors.”

Employees

As of December 31, 2018, we had 116 full-time employees. None of our employees are represented by a collective bargaining agreement, nor have we experienced any work stoppage. We believe that our relations with our retained employees are good.

ITEM 1A. RISK FACTORS

In addition to other information in this report, the following factors should be considered carefully in evaluating an investment in our securities. If any of the risks or uncertainties described in this Form 10-K actually occurs, our business, results of operations or financial condition would be materially and adversely affected. The risks and uncertainties described below have been grouped under general risk categories, one or more of which categories may be applicable to the risk factor described. The risks and uncertainties described in this Form 10-K are not the only ones facing us. Additional risks and uncertainties of which we are unaware or that we currently deem immaterial may also become important factors that may harm our business, results of operations and financial condition.

Risks Related to Commercial, Regulatory and Other Business Matters

We rely on Collegium Pharmaceutical Inc. to commercialize NUCYNTA and NUCYNTA ER and their failure to successfully commercialize these products could have a material adverse effect on our business, financial condition and results of operations.

In December 2017, we entered into a commercialization agreement with Collegium pursuant to which Collegium assumed, effective as of January 9, 2018, responsibility for the sales and marketing of NUCYNTA and NUCYNTA ER. Collegium will pay us royalties based on net sales of NUCYNTA and NUCYNTA ER. Although we have retained certain rights to promote NUCYNTA and NUCYNTA ER to physicians that Collegium does not call on, we do not have any immediate plans to exercise such rights. As a result, the commercial success of NUCYNTA and NUCYNTA ER will depend almost entirely on Collegium’s commercialization efforts.

As a company, Collegium has a limited history of selling and marketing pharmaceutical products. Collegium’s ability to successfully commercialize and generate revenues from NUCYNTA and NUCYNTA ER, our largest selling product, depends on a number of factors, including, but not limited to, Collegium’s ability to:

- develop and execute its sales and marketing strategies for NUCYNTA and NUCYNTA ER;
- achieve, maintain and grow market acceptance of, and demand for, NUCYNTA and NUCYNTA ER;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third- party payers;

- maintain and manage the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize NUCYNTA and NUCYNTA ER;
- obtain adequate supply of NUCYNTA and NUCYNTA ER; and
- comply with applicable legal and regulatory requirements.

Additional factors that may affect the success of our commercialization arrangement with Collegium include the following:

- Collegium may prioritize the commercialization of their other products, including Xtampza, over NUCYNTA and NUCYNTA ER;
- Collegium may pursue higher-priority programs, or change the focus of its marketing programs;
- Collegium may acquire or develop alternative products;
- Collegium may in the future choose to devote fewer resources to NUCYNTA and NUCYNTA ER;
- changes in laws and regulations applicable to, and scrutiny of, the pharmaceutical industry, including the opioid market;
- market acceptance of NUCYNTA and NUCYNTA ER may fail to increase or may decrease;
- the outcome of the appeal of the court's ruling in our litigation against the Abbreviated New Drug Application (ANDA) filers seeking to prevent such ANDA filers from marketing a generic version of NUCYNTA and NUCYNTA ER in the U.S.;
- Collegium may experience financial difficulties;
- Collegium may fail to comply with its obligations under our commercialization and related agreements; or
- Collegium's involvement in governmental investigations and inquires or lawsuits and the disposition of such proceedings.

Any of the preceding factors could affect Collegium's commitment to, and ability to perform, its obligations under the commercialization agreement, which, in turn could adversely affect the commercial success of NUCYNTA and NUCYNTA ER. Any failure by Collegium to successfully commercialize NUCYNTA and NUCYNTA ER could have a material adverse effect on our business, financial condition and results of operations.

If our commercialization agreement with Collegium terminates, we may not succeed in commercializing NUCYNTA and NUCYNTA ER on our own or through an alternative commercialization partner.

Our agreement with Collegium grants each party specified termination rights. If the agreement is terminated, we may either perform commercialization activities relating to NUCYNTA and NUCYNTA ER on our own or identify and collaborate with another commercialization partner. Both alternatives would result in us incurring greater expenses and could cause a disruption in the commercialization of the products while we expand our commercial operations or seek an alternative commercialization partner, which disruption could lead to a loss of market share and decreased demand for the products. If we elect to increase our expenditures to fund commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements. If we elect to seek another commercialization partner, we may be unsuccessful in identifying a satisfactory partner or, if we do

successfully identify a partner, we may be unable to negotiate a new commercialization agreement on acceptable terms, or at all.

If we do not successfully commercialize Gralise, CAMBIA, and Zipsor, our business, financial condition and results of operations will be materially and adversely affected.

In October 2011, we began commercial sales of Gralise. In June 2012, we acquired Zipsor and began commercial promotion of Zipsor in July 2012. In December 2013, we acquired CAMBIA and began commercial promotion of CAMBIA in February 2014. In addition to the risks discussed elsewhere in this section, our ability to successfully commercialize and generate revenues from Gralise, CAMBIA and Zipsor, depends on a number of factors, including, but not limited to, our ability to:

- develop and execute our sales and marketing strategies for our products;
- achieve, maintain and grow market acceptance of, and demand for, our products;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third party payers;
- maintain, manage or scale the necessary sales, marketing, manufacturing, managed markets, and other capabilities and infrastructure that are required to successfully integrate and commercialize our products;
- obtain adequate supply of our products;
- maintain and extend intellectual property protection for our products; and
- comply with applicable legal and regulatory requirements.

If we are unable to successfully achieve or perform these functions, we will not be able to maintain or increase our product revenues and our business, financial condition and results of operations will be materially and adversely affected.

We depend on one qualified supplier for the active pharmaceutical ingredient in each of our products, and we depend on third parties that are single source suppliers to manufacture our products. If there is insufficient availability of our products or the active pharmaceutical ingredients and other raw materials necessary to manufacture our products, or if our suppliers are unable to manufacture and supply our products, our business will suffer.

We have one qualified supplier for the active pharmaceutical ingredient in each of NUCYNTA ER, NUCYNTA, CAMBIA, Zipsor and Gralise. An affiliate of Janssen Pharma is currently the sole supplier of NUCYNTA ER pursuant to a manufacturing supply agreement we entered into with such entity in April 2015. Halo Pharmaceutical, Inc. (Halo) is the sole supplier of NUCYNTA pursuant to a manufacturing supply agreement we entered into with Halo in June 2017. Patheon Puerto Rico Inc. (Patheon) is our sole supplier for Gralise pursuant to a manufacturing and supply agreement we entered into with Patheon in September 2011. Catalent Ontario Limited (Catalent) is our sole supplier for Zipsor pursuant to a manufacturing agreement we entered into with Catalent effective June 30, 2018. MiPharm, S.p.A is our sole supplier for CAMBIA pursuant to a manufacturing and supply agreement that we assumed in connection with our acquisition of CAMBIA in December 2013. We do not have, and we do not intend to establish in the foreseeable future, internal commercial scale manufacturing capabilities. Rather, we intend to use the facilities of third parties to manufacture products for commercialization and clinical trials. Our dependence on third parties for the manufacture of our products and our product candidates may adversely affect our ability to obtain such products on a timely or competitive basis, if at all. Any stock out, or failure to obtain sufficient supplies of NUCYNTA or NUCYNTA ER, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture NUCYNTA or NUCYNTA ER, would adversely affect

Collegium's ability to commercialize such products, which would adversely affect our results of operations and financial condition. Any stock out, quality concern or failure to obtain sufficient supplies of Gralise, CAMBIA, or Zipsor, or the necessary active pharmaceutical ingredients, excipients or components from our suppliers would adversely affect our business, results of operations and financial condition.

Hurricanes Irma and Maria caused significant devastation and damage throughout Puerto Rico in 2017, including widespread flooding and power loss. As a result, we experienced delays in the manufacture, packaging and delivery of certain dosage strengths of NUCYNTA ER in fourth quarter of 2017 and the first quarter of 2018. We and Collegium may experience further outages in the future. Any delay in the manufacture, packaging or delivery of NUCYNTA and NUCYNTA ER, whether due to the manufacturing facility at which NUCYNTA and NUCYNTA ER are produced not being fully operational for an extended period of time or otherwise, could adversely affect the ability of Collegium to commercialize such products, which could adversely affect our results of operations and financial condition.

The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third party manufacturers and our suppliers are subject to numerous regulations, including current FDA regulations governing manufacturing processes, stability testing, record keeping, product serialization and quality standards. Similar regulations are in effect in other countries. Our third party manufacturers and suppliers are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any third party manufacturer or supplier fails to perform as required or fails to comply with the regulations of the FDA and other applicable governmental authorities, our ability to deliver adequate supplies of our products to our customers on a timely basis, or to continue our clinical trials could be adversely affected. The manufacturing processes of our third party manufacturers and suppliers may also be found to violate the proprietary rights of others. To the extent these risks materialize and adversely affect such third party manufacturers' performance obligations to us, and we are unable to contract for a sufficient supply of required products on acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers or suppliers, our business, results of operation and financial condition could be adversely affected.

Our commercialization, collaborative and other arrangements may give rise to disputes over commercial terms, contract interpretation and ownership or protection of our intellectual property and may adversely affect the commercial success of our products.

We currently have a commercialization agreement with Collegium. We currently have collaboration or license arrangements with a number of companies, including Grünenthal, Janssen Pharma, Ironwood and Slán. In addition, we have in the past and may in the future enter into other commercialization or collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. We may not execute definitive agreements formalizing these arrangements.

Commercialization and collaborative relationships are generally complex and may give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes can delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of such arrangements may also limit or preclude us from developing products or technologies developed pursuant to such collaborations. Additionally, the commercialization or collaborative partners under these arrangements might breach the terms of their respective agreements or fail to maintain, protect or prevent infringement of the licensed patents

or our other intellectual property rights by third parties. Moreover, negotiating commercialization and collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs. Any failure by our commercialization or collaborative partners to abide by the terms of their respective agreements with us, including their failure to accurately calculate, report or pay any royalties payable to us or a third party, may adversely affect our results of operations.

We may be unable to enter into future commercialization or collaborative arrangements on acceptable terms, and we may be unable to maintain our current commercialization arrangement with Collegium on acceptable terms, either of which could harm our ability to develop and commercialize our current and potential future products and technologies. Other factors relating to collaborations that may adversely affect the commercial success of our products include:

- any parallel development by a commercialization or collaborative partner of competitive technologies or products;
- arrangements with commercialization or collaborative partners that limit or preclude us from developing products or technologies;
- premature termination of a commercialization or collaboration agreement or the inability to renegotiate existing agreements on favorable terms; or
- failure by a commercialization or collaborative partner to devote sufficient resources to the development and commercial sales of products using our current and potential future products and technologies.

Our commercialization or collaborative arrangements do not necessarily restrict our commercialization or collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future commercialization or collaborative partners may pursue existing or other development-stage products or alternative technologies in preference to those being commercialized or developed in collaboration with us.

In addition, contract disputes with customers or other third parties may arise from time to time. Our commercialization or collaborative partners, or customers or other third parties, may also terminate their relationships with us or otherwise decide not to proceed with development, commercialization or purchase of our products.

We and our commercial partner may be unable to compete successfully in the pharmaceutical industry.

Competition in the pharmaceutical industry is intense and we expect competition to increase. Competing products currently under development or developed in the future may prove superior to our products and may achieve greater commercial acceptance. Most of our principal competitors have substantially greater financial, sales, marketing, personnel and research and development resources than we or Collegium do.

Branded gabapentin is currently sold by Pfizer as Neurontin for adjunctive therapy for partial onset epileptic seizures and for the management of PHN. Pfizer's basic U.S. patents relating to Neurontin have expired, and numerous companies have received approval to market generic versions of the immediate release product. In addition to receiving approval for marketing to treat neuropathic pain associated with DPN, Lyrica (pregabalin) has also been approved for marketing in the U.S. for the treatment of post herpetic pain, fibromyalgia, adjunctive therapy for partial onset epileptic seizures, and nerve pain associated with spinal cord injury and has captured a significant portion of the market. Moreover, generic versions of Lyrica (pregabalin) are expected to be available as early as 2019. In January 2018, Pfizer began to sell Lyrica CR (pregabalin extended-release tablets), a once-daily

treatment for the management of DPN and PHN. Arbor Pharmaceuticals, LLC's Horizant (gabapentin enacarbil extended-release tablets) is approved for the management of PHN and Restless Leg Syndrome. There are other products prescribed for or under development for PHN which are now or may become competitive with Galise.

An alternate formulation of diclofenac is the active ingredient in CAMBIA that is approved in the U.S. for the acute treatment of migraines in adults. CAMBIA competes with a number of triptans that are used to treat migraines and certain other headaches. Currently, eight triptans are available generically and sold in the United States (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and zolmitriptan). Branded competitors include Zomig Nasal Spray, Onzetra, Xsail, Sumavel, Zembrace SymTouch and Treximet, which is a fixed-dose combination product containing sumatriptan and naproxen. There are other products prescribed for or under development for the treatment or prevention of migraines that are now or may become competitive with CAMBIA, including CGRP inhibitor products.

Diclofenac, the active pharmaceutical ingredient in Zipsor, is an NSAID that is approved in the U.S. for the treatment of mild to moderate pain in adults, including the symptoms of arthritis. Both branded and generic versions of diclofenac are marketed in the U.S. Zipsor competes against other drugs that are widely used to treat mild to moderate pain in the acute setting. In addition, a number of other companies are developing NSAIDs in a variety of dosage forms for the treatment of mild to moderate pain and related indications. Other drugs are in clinical development to treat acute pain.

Tapentadol, the active pharmaceutical ingredient in NUCYNTA and NUCYNTA ER, is a proprietary opioid analgesic that is marketed in the U.S. by our commercialization partner Collegium. NUCYNTA and NUCYNTA ER compete with a number of branded and generic products that are widely used to treat moderate to severe pain, including neuropathic pain associated with DPN, and acute pain, respectively. These products include OxyContin® (oxycodone hydrochloride extended-release tablets), which is owned by Purdue and is approved for marketing in the U.S. for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. OxyContin® has achieved significant levels of market acceptance. Unlike NUCYNTA ER, a number of long-acting opioids have product labelling related to their abuse deterrent properties, which may put NUCYNTA ER at a competitive disadvantage. There are also a number of branded and generic short and long acting opioids, including oxycodone, oxymorphone, fentanyl patch, morphine, buprenorphine patch, tramadol, hydrocodone and hydromorphone, which have received approval and are marketed in the U.S. for the treatment of moderate to severe pain, including chronic and acute pain. More opioid development and launches of both generics and brands are expected to continue. For example, Butrans (promoted by Purdue) has been facing generic entrants since June 2017. In addition, Pfizer's new opioid Troxyca ER was approved in 2016, but has not yet launched. Teva's Vantrela ER was approved in 2017, but has not yet launched. Inspirion received approval for MorphaBond™ ER (morphine sulfate) and RoxyBond (oxycodone HCL). MorphaBond launched in the fourth quarter of 2017 and RoxyBond had a marketing start date of January 2018. Lyrica (pregabalin), which is marketed by Pfizer, is approved for marketing in the U.S. for the treatment of neuropathic pain associated with DPN. In January 2018, Pfizer began to sell Lyrica CR (pregabalin extended-release tablets), a once-daily treatment for the management of DPN and PHN. Branded and generic versions of duloxetine and lidocaine have also been approved for marketing in the U.S. for the treatment of neuropathic pain associated with DPN. There are a number of other products and treatments prescribed for, or under development for, the management of chronic and acute pain, including neuropathic pain associated with DPN, which are now or may become competitive with NUCYNTA and NUCYNTA ER. Further, in light of the FDA's efforts to spur the development of non-opioid medications for chronic pain, we expect that additional other competitive products and treatments may be developed and commercialized.

If we or our commercialization partner are unable to negotiate acceptable pricing or obtain adequate reimbursement for our products from third party payers, our business will suffer.

Sales of our products depend significantly on the availability of acceptable pricing and adequate reimbursement from third party payers such as:

- government health administration authorities;
- private health insurers;
- health maintenance organizations;
- managed care organizations;
- pharmacy benefit management companies; and
- other healthcare-related organizations.

If reimbursement is not available for our products or product candidates, demand for our products may be limited. Further, any delay in receiving approval for reimbursement from third-party payers could have an adverse effect on our future revenues.

Third party payers frequently require pharmaceutical companies to negotiate agreements that provide discounts or rebates from list prices and that protect the payers from price increases above a specified annual limit. We and our commercialization partner have agreed to provide such discounts and rebates to certain third party payers. We expect increasing pressure to offer larger discounts and rebates or discounts and rebates to a greater number of third party payers to maintain acceptable reimbursement levels for and access to our products for patients at co-pay levels that are reasonable and customary. Consolidation among large third party payers may increase their leverage in negotiations with pharmaceutical companies. If we or our commercialization partner are forced to provide additional discounts and rebates to third party payers to maintain acceptable access to our products for patients, our results of operations and financial condition could be adversely affected. If third party payers do not accurately and timely report the eligibility and utilization of our products under their plans, our reserves for rebates or other amounts payable to third party payers may be lower than the amount we are invoiced and we may be required to dispute the amount payable, which would adversely affect our business, financial condition and results of operations. For example, we have had, and continue to have, disputes with managed care providers over rebates related to our products. Even when rebate claims made by such managed care providers are without merit, we may be forced to pay such disputed amounts to the extent our failure to do so could otherwise adversely impact our business, such as our ability to maintain a favorable position on such provider's formulary. In addition, if competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce sales of our products and harm our results of operations. The process for determining whether a third party payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that such third party payer will pay for the product once coverage is approved. Third party payers may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, including one or more of our products. Any third party payer decision not to approve pricing for, or provide adequate coverage and reimbursement of, our products, including by reducing, limiting or denying reimbursement for new products or excluding products that were previously eligible for reimbursement, would limit the market acceptance and commercial prospects of our products and harm our business, financial condition and results of operations. In addition, any third party payer decision to impose restrictions, limitations or conditions on prescribing or reimbursement of our products, including on the dosing or duration of prescriptions for our products, would harm our business, financial condition and results of operations.

There have been, and there will continue to be, legislative, regulatory and third party payer proposals to change the healthcare system in ways that could impact our ability to commercialize our products profitably. We anticipate that the federal and state legislatures and the private sector will continue to consider and may adopt and implement healthcare policies, such as the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (ACA), intended to curb rising healthcare costs. These cost containment measures may include: controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third party payers to make coverage and payment decisions. In California, voters rejected Proposition 61 in November 2016, a ballot initiative that would have prohibited the state from buying prescription drugs from a drug manufacturer at a price over the lowest price paid for such drug by U.S. Department of Veterans Affairs. Although Proposition 61 was defeated, these and other cost containment or price control measures, if adopted at the federal or state level, could significantly decrease the price that we or our commercialization partner receive for our products and any product that we may develop or acquire, which would harm our business, financial condition and results of operations.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of our products, our business will be materially and adversely affected.

Under the FDCA, the FDA can approve an ANDA for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage, form, inactive ingredients or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug.

The FDCA requires an applicant for a drug that relies, at least in part, on the patent of one of our branded drugs to notify us of their application and potential infringement of our patent rights. Upon receipt of this notice we have 45 days to bring a patent infringement suit in federal district court against the company seeking approval of a product covered by one of our patents. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. Such litigation is often time-consuming and quite costly and may result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe such patents. If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs.

We have been involved in patent litigation lawsuits against filers of ANDAs (the Filers) seeking to market generic versions of NUCYNTA and NUCYNTA ER before the expiration of the patents listed in the Patent and Exclusivity Information Addendum of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for these two products. A two-week bench trial was completed on April 27, 2016. On September 30, 2016, the Court issued its opinion finding all three of the Orange Book patents valid and enforceable. On April 11, 2017, the Court entered a final judgment, which included an injunction enjoining the Filers from engaging in certain activities with regard to tapentadol (the active ingredient in NUCYNTA) and ordering the effective date of any approval of Actavis, Actavis UT, and Roxane's ANDAs, and Alkem's

ANDA for NUCYNTA IR to be no earlier than the expiry of the '364 Patent (June 27, 2025), and the effective date of any approval of Alkem's ANDA for NUCYNTA ER to be no early than the expiry of the '130 Patent (September 22, 2028). The foregoing periods of exclusivity may in the future be extended with the award of pediatric exclusivity. The Court's final judgment remains subject to the results of the appeals filed by the parties. It is estimated that the Federal Circuit will issue a written decision in the first quarter of 2019. If we do not prevail with regard to such appeal, we may be unable to maintain the currently anticipated period of patent exclusivity with regard to NUCYNTA and NUCYNTA ER. Any introduction of one or more generic versions of NUCYNTA or NUCYNTA ER would adversely affect Collegium's ability to commercialize such products, and in turn would adversely affect our business, results of operations and financial condition.

Any introduction of one or more products generic to NUCYNTA ER, NUCYNTA, Gralise, CAMBIA, or Zipsor, whether as a result of an ANDA or otherwise, would harm our business, financial condition and results of operations. The filing of the ANDAs described above, or any other ANDA or similar application in respect to any of our products, could have an adverse impact on our stock price. Moreover, if the patents covering our products are not upheld in litigation or if a generic competitor is found not to infringe these patents, the resulting generic competition would have a material adverse effect on our business, financial condition and results of operations.

Any failure by us or our commercialization or collaborative partners to comply with applicable statutes or regulations relating to controlled substances could adversely affect our business.

Each of NUCYNTA and NUCYNTA ER are opioid analgesics that contain tapentadol. Tapentadol is a regulated "controlled substance" under the CSA. The CSA establishes, among other things, certain registration, production quotas, security, record keeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule II substances being the pharmaceutical products that present the highest risk of abuse. Tapentadol is listed by the DEA as a Schedule II substance under the CSA. The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation. For example, generally all Schedule II substance prescriptions must be written and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The DEA also conducts periodic inspections of certain registered establishments that handle controlled substances. Facilities that conduct research, manufacture, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could adversely affect our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations and in certain circumstances, violations could lead to criminal proceedings against us or our manufacturing and distribution partners, and our respective employees, officers and directors.

In addition to federal regulations, many individual states also have controlled substances laws. Although state controlled substances laws generally mirror federal law, because the states are separate jurisdictions they may separately schedule our products. Any failure by us or our partners to obtain separate state registrations, permits or licenses to obtain, handle and distribute tapentadol or to meet applicable regulatory requirements could lead to enforcement and sanctions by state or federal authorities, including the DEA. Such an enforcement action or sanction could adversely affect our business, results of operations and financial condition.

Limitations on the production of Schedule II substances in the U.S. could limit the ability of Collegium to successfully commercialize NUCYNTA and NUCYNTA ER which, in turn, could have a material adverse impact on our business.

The availability and production of all Schedule II substances, including tapentadol, is limited by the DEA through a quota system that includes a national aggregate quota, production quotas for individual manufacturers and procurement quotas that authorize the procurement of specific quantities of Schedule II controlled substances for use in drug product manufacturing. The DEA annually establishes an aggregate quota for total tapentadol production in the U.S. based on the DEA's estimate of the quantity needed to meet commercial and scientific needs. The aggregate quota of tapentadol that the DEA allows to be produced in the U.S. annually is allocated among applicable individual drug manufacturers, each of whom must submit applications at least annually to the DEA for individual production quotas. In turn, our third party manufacturers of NUCYNTA and NUCYNTA ER have to obtain a procurement quota to source tapentadol for the production of NUCYNTA and NUCYNTA ER.

The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas for these activities. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether to make such adjustments. Based on a variety of factors, including public policy considerations, the DEA may set the aggregate quota lower for tapentadol than the total amount requested by individual manufacturers. Through our manufacturing partner we are permitted to ask the DEA to increase our manufacturer's procurement quota after it is initially established. However, we cannot be certain that the DEA would act favorably upon such a request. In addition, our manufacturers obtain a procurement quota for tapentadol for all tapentadol products manufactured at their facility, which is allocated to NUCYNTA and NUCYNTA ER, as applicable, at the manufacturer's discretion. The DEA recently proposed reducing the quota for controlled substances to be manufactured in the U.S. in 2019, although no changes to the quotas for tapentadol were recommended. Additionally, the DEA has proposed various changes to its process for setting production and procurement quota. Any delay or refusal by the DEA or our manufacturers in establishing the production or procurement quota or granting sufficient production or procurement quota to meet commercial demand or clinical needs, or any reduction by the DEA or our manufacturer in the allocated quota for tapentadol, could adversely affect the ability of Collegium to commercialize NUCYNTA and NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition.

The FDA-mandated Risk Evaluation and Mitigation Strategy program may limit the commercial success of NUCYNTA ER and NUCYNTA.

NUCYNTA ER and NUCYNTA are subject to a FDA-mandated Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) protocol. This REMS protocol requires opioid manufacturers to make training available to health care practitioners (and their patients) who practice pain management and prescribe immediate and extended release opioids concerning the safe use of opioid analgesics. The FDA-mandated REMS protocol may reduce the number of physicians, health care practitioners and pharmacies that are willing to prescribe opioid products including NUCYNTA ER and/or NUCYNTA, as well as the number of patients who are willing to use these products. Because of these factors, if Collegium is not able to successfully promote NUCYNTA ER and NUCYNTA, our business, results of operations and financial condition could be adversely affected.

Business interruptions could limit our ability to operate our business and may also effect the success of our commercialization partners.

Our operations and infrastructure, and those of our partners, third party suppliers and vendors are vulnerable to damage or interruption from cyber-attacks and security breaches, human error, natural disasters, fire, flood, the effects of climate change, power loss, telecommunications failures, equipment failures, intentional acts of theft, vandalism, terrorism and similar events. We have not established a formal disaster recovery plan, and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses that occur. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

For example, Hurricanes Irma and Maria caused significant devastation and damage throughout Puerto Rico in 2017, including widespread flooding and power loss. As a result, we experienced delays in the manufacture, packaging and delivery of certain dosage strengths of NUCYNTA ER in fourth quarter of 2017 and the first quarter of 2018. We and Collegium may continue to experience further outages in the future. Any delay in the manufacture, packaging or delivery of NUCYNTA ER and NUCYNTA could adversely affect the success of our commercialization partner Collegium, which in turn could adversely affect our business, financial condition and results of operations.

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage to our business.

In the ordinary course of our business, we collect, maintain and transmit sensitive data on our computer networks and information technology systems, including our intellectual property and proprietary or confidential business information. The secure maintenance of this information is critical to our business. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state-sponsored attack and motives (including corporate espionage). Cyber threats may be generic, or they may be custom-crafted to target our information systems. Cyber-attacks are becoming increasingly more prevalent and much harder to detect and defend against. Our network and storage applications and those of our third party vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions.

Although our Board of Directors, through our Audit Committee, regularly discusses with management our policies and practices regarding information technology systems, information management systems and related infrastructure, including our information technology and information management security, risk management and back-up policies, practices and infrastructure, it is often difficult to anticipate or immediately detect such incidents and the damage that may be caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information, including our financial information or the information of our business partners. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. Our network security and data recovery measures and those of our third party vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our business.

Our ability to successfully manage our business following our headquarters relocation depends on our ability to successfully transition institutional knowledge and to successfully attract and retain qualified personnel at our new location.

We relocated our corporate headquarters from Newark, California to Lake Forest, Illinois in the third quarter of 2018 and have reduced our staff throughout 2018. Although our relocation and transition is substantially complete, there may be continued costs and delays associated with relocation and such costs may exceed our projections. Further, with our transition, we may face challenges in maintaining the continuity of our operations and historical knowledge. Management may be required to devote substantial time to transitioning institutional knowledge, which time could otherwise be devoted to focusing on ongoing business operations and other initiatives and opportunities. Our business could also be materially adversely affected if we are unable to retain key employees or recruit qualified personnel in a timely fashion, or if we are required to incur unexpected compensation costs to retain key employees. Any such difficulties could have an adverse effect on our business, results of operations or financial condition.

We have recently experienced a significant transition in our executive management team.

We recently experienced changes in our executive management team as we transitioned our corporate headquarters to Lake Forest, Illinois. If our newly appointed executive team is not able, in a timely manner, to develop, implement and execute successful business strategies and plans to maintain and increase our product revenues, our business, financial condition and results of operations will be materially and adversely affected. Moreover, the changes to our executive management team may result in disruption to the operation of our business. While our Chief Executive Officer and newly appointed executive officers have significant industry-related experience, it may take time for the team to become fully integrated and such team may continue to evolve until a fully integrated team is established. Any delay in the integration of our executive management team could affect our ability to develop, implement and execute our business strategies and plans, which could have a material adverse effect on our business, financial condition and results of operations.

Further, with our new executive team, our future business strategies and plans may differ materially, or may continue to evolve, from those we previously pursued. If our business strategies and plans, including our commercialization arrangement with Collegium, cause disruption in our business or operations or do not achieve the level of success or results we anticipate, our business, financial condition and results of operations will be materially and adversely affected.

Our success is dependent in large part upon the continued services of our executive management with whom we do not have employment agreements.

Our success is dependent in large part upon the continued services of members of our executive management team, and on our ability to attract and retain key management and operating personnel, especially in light of our headquarters relocation. We do not have agreements with any of our executive officers that provide for their continued employment with us. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates.

Risks Related to Product Development

The development of drug candidates such as long-acting cosyntropin, is inherently difficult and uncertain, and we cannot be certain that any of our product candidates or those of our collaborative partners will be approved for marketing or, if approved, will achieve market acceptance.

Clinical development is a long, expensive and uncertain process and is subject to delays and failures. As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. Positive or encouraging results of prior clinical trials are not necessarily indicative of the results obtained in later clinical trials, as has occurred in the past in certain of our Phase 3 trials. Further, product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed in development. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

In November 2017 we acquired the exclusive rights to market the specialty drug long-acting cosyntropin (synthetic ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the FDA for our 505(b)(2) NDA for our novel injectable formulation of long-acting cosyntropin. We, together with our development partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency. As previously announced, enrolling and dosing in pediatric patients continues in a new clinical trial evaluating long-acting cosyntropin for the treatment of infantile spasms, a specific seizure type present in the infantile epilepsy spectrum, a rare pediatric disorder. The expected timing of NDA filings and related approvals, the successful execution of the clinical trial and our overall strategy with regard to its application may not achieve our intended results. Our overall strategy to bring our injectable formulation of long-acting cosyntropin to market in the U.S. and Canada is subject to certain risks and uncertainties. The NDA may not be successful. Further, if our product manufacturing processes or facilities do not satisfy regulatory requirements, FDA approval may not be granted. Even if we receive FDA approval for our intended diagnostic indication, the ability to commercialize the product for diagnostic use may not generate significant revenue.

Product candidates, such as long-acting cosyntropin, are subject to the risk that any or all of them may be found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. The FDA or other applicable regulatory agencies may determine that our data is not sufficiently compelling to warrant marketing approval and require us to engage in additional clinical trials or provide further analysis, which may be costly and time-consuming. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in preclinical studies or earlier clinical trials. If our current or future product candidates fail at any stage of development, they will not receive regulatory approval, we will not be able to commercialize them and we will not receive any return on our investment in those product candidates.

Other factors could delay or result in the termination of our current and future clinical trials and related development programs, including:

- negative or inconclusive results;
- patient enrollment rates;
- patient noncompliance with the protocol;
- adverse medical events or side effects among patients during the clinical trials;

- FDA inspections of our clinical operations;
- failure to meet FDA preferred or recommended clinical trial design, end points or statistical power;
- failure to comply with good clinical practices;
- failure of our third party clinical trial vendors to comply with applicable regulatory laws and regulations;
- compliance with applicable laws and regulations;
- inability of our third party clinical trial vendors to satisfactorily perform their contractual obligations, comply with applicable laws and regulations or meet deadlines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in our clinical trials
- delays or failures in recruiting qualified patients to participate in our clinical trials; and
- actual or perceived lack of efficacy or safety of the product candidate.

We are unable to predict whether any product candidates, including long-acting cosyntropin, will receive regulatory clearances or be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frame for commercializing a product is long and uncertain. Even if long-acting cosyntropin and any other product candidates receive regulatory clearance, these products may not achieve or maintain market acceptance. If it is discovered that our or our collaborators' products or technologies could have adverse effects or other characteristics that indicate they may be ineffective as therapeutics, our product development efforts and our business could be significantly harmed.

Even assuming our or our collaborative partners' products obtain regulatory approval, successful commercialization requires:

- market acceptance;
- a cost-effective commercial scale production; and
- reimbursement under private or governmental health plans.

Any material delay or failure in the governmental approval process and/or the successful commercialization of our potential products or those of our collaborative partners could adversely impact our business, financial condition and results of operations.

We and our collaborative partners customarily depend on third party contract research organizations, clinical investigators and clinical sites to conduct clinical trials with regard to product candidates, and if they do not perform their regulatory, legal and contractual obligations, or successfully enroll patients in and manage our clinical trials, we and our collaborative partners may not be able to obtain regulatory approvals for product candidates, including long-acting cosyntropin.

We and our collaborative partners customarily rely on third party contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise conducting clinical trials. We and our collaborative partners do not control these third parties and, as a result, we and our collaborative partners may be unable to control the amount and timing of resources that they devote to our or our collaborative partners' clinical trials.

Although we and our collaborative partners rely on third parties to conduct clinical trials, we and our collaborative partners are responsible for confirming that each clinical trial is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and other applicable

regulatory agencies' requirements, including good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. If we, contract research organizations or other third parties assisting us or our collaborative partners with clinical trials fail to comply with applicable good clinical practices, the clinical data generated in such clinical trials may be deemed unreliable and the FDA, or other applicable regulatory agencies, may require us or our collaborative partners to perform additional clinical trials before approving any marketing applications with regard to product candidates. We cannot be certain that, upon inspection, the FDA or other applicable regulatory agencies will determine that any of our clinical trials or our collaborative partners comply with good clinical practices. In addition, clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our or our collaborative partners' failure, or the failure of our product manufacturers, to comply with these regulations may require the repeat or redesign of clinical trials, which would delay the regulatory approval process.

We and our collaborative partners also customarily rely on clinical investigators and clinical sites to enroll patients and other third parties to manage clinical trials and to perform related data collection and analysis. If clinical investigators and clinical sites fail to enroll a sufficient number of patients in such clinical trials or fail to enroll them on the planned schedule, these trials may not be completed or completed as planned, which could delay or prevent us or our collaborative partners from obtaining regulatory approvals for product candidates.

Agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, clinical trials if these parties fail to perform as expected. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to clinical protocols or for other reasons, clinical trials may be extended, delayed or terminated, and we and our collaborative partners may be unable to obtain regulatory approval for, or successfully commercialize, product candidates.

If we or our collaborative partners are unable to obtain or maintain regulatory approval for our products, our raw materials or product candidates, we will be limited in our ability to commercialize our products, and our business will suffer.

The regulatory process is expensive and time consuming. Even after investing significant time and expenditures on clinical trials, we may not obtain regulatory approval of our product candidates. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval, and the FDA may not agree with our methods of clinical data analysis or our conclusions regarding safety and/or efficacy. For example, the FDA may determine that data regarding our product candidate, long-acting cosyntropin, is not sufficiently compelling to warrant regulatory approval, and the FDA may require us to engage in additional clinical trials or provide further analysis, which may be costly and time-consuming. Significant clinical trial delays could impair our ability to commercialize our products and could allow our competitors to bring products to market before we do. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections. Even if we receive regulatory approval, this approval may entail limitations on the indicated uses for which we can market a product.

Further, with respect to our approved products, once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of approved products are also subject to ongoing regulation and inspection, including compliance with

FDA regulations governing cGMP or Quality System Regulation (QSR). The FDCA, the CSA and other federal and foreign statutes and regulations govern and influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. In addition, we and our partners are also subject to ongoing DEA regulatory obligations, including annual registration renewal, security, record keeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The failure to comply with these regulations could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, non-renewal of marketing applications or authorizations or criminal prosecution, which could adversely affect our business, results of operations and financial condition.

We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns could result in labeling changes, recalls, market withdrawals or other regulatory actions. Recalls may be issued at our discretion or at the discretion of the FDA or other empowered regulatory agencies. For example, in June 2010, we instituted a voluntary class 2 recall of 52 lots of our 500mg Glumetza product after chemical traces of 2,4,6-tribromoanisole (TBA) were found in the product bottle.

We are subject to risks associated with NDAs submitted under Section 505(b)(2) of the Food, Drug and Cosmetic Act.

The products we develop or acquire generally are or will be submitted for approval under Section 505(b)(2) of the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For instance, the NDA for Gralise relies on the FDA's prior approval of Neurontin, the immediate release formulation of gabapentin initially approved by the FDA.

For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as "Paragraph IV certifications," that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505(b)(2) application are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Under the Hatch-Waxman Act, the holder of the NDA which the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one-time automatic 30-month stay of the FDA's ability to approve the 505(b)(2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all. A Section 505(b)(2) application may also not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. The FDA may also reject our future Section 505(b)(2) submissions and may require us to file such submissions under Section 501(b)(1) of the FDCA, which could be considerably more expensive and time consuming.

Risks Related to Our Industry

Changes in laws and regulations applicable to, and increased scrutiny and investigations of, the pharmaceutical industry, including the opioid market, may adversely affect our business, financial condition and results of operations.

The manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations applicable to, and increased scrutiny and investigations of, the pharmaceutical industry, including the opioid market, could adversely affect our business and our ability to commercialize Gralise, CAMBIA and Zipsor as well as Collegium's ability to commercialize NUCYNTA and NUCYNTA ER, thereby adversely affecting our financial condition and results of operations.

For instance, federal, state, and local governments have for the last several years given significant attention to the public health issue of opioid abuse. In 2016, the Centers for Disease Control and Prevention (CDC) issued national, non-binding guidelines on the prescribing of opioids, providing recommended considerations for primary care providers when prescribing opioids, including specific considerations and cautionary information about opioid dosage increases and morphine milligram equivalents (MME). A number of third party payers have adopted or are considering adopting some or all of these CDC guidelines to limit access to higher doses of opioids. Industry associations and trade groups are also changing or considering changes to guidelines relevant to opioid prescriptions along similar lines. In addition, a number of state legislatures across the country have enacted legislation with some type of limit, guidance, or requirement related to opioid prescribing, including to limit the duration and quantity of initial prescriptions of opioids and to mandate the use by prescribers of prescription drug databases. At the federal level, the White House Office of National Drug Control Policy (ONDCP) and the National Institutes of Health (NIH) are coordinating efforts between the FDA, the DEA, the U.S. Department of Health and Human Services, and pharmaceutical industry groups to research and develop effective non-opioid pain relievers. In July 2018, the DEA issued a final rule, "Controlled Substances Quotas," to strengthen the process for setting controls over diversion of controlled substances and to make other improvements in the quota management regulatory system for production, manufacturing, and procurement of controlled substances. The DEA also continues to increase its efforts to hold manufacturers, distributors, prescribers, and pharmacies accountable through various enforcement actions as well as the implementation of compliance practices for controlled substances. The DEA also recently proposed reducing the quota for controlled substances to be manufactured in the U.S. in 2018. Further, the FDA has updated the "black-box" warnings on immediate release opioids highlighting the risk of misuse, abuse, addiction, overdose, and death in conjunction with the implementation of a Risk Evaluation and Mitigation Strategies (REMS) for these same products. The FDA has also emphasized that it will continue to evaluate patient risk associated with exposure to opioids, and that it will work to reduce the number, dosages and the duration of opioid prescriptions, where appropriate. In October 2018 Congress approved H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, and President Trump signed such legislation into law. These regulatory actions, including the SUPPORT Act and other similar legislation or policy initiatives, may adversely impact the commercialization of opioids generally, including NUCYNTA and NUCYNTA ER.

In addition, various federal and state governmental entities, including the DOJ and a number of state attorneys general, have launched investigations into the marketing and sales practices of pharmaceutical companies that market or have marketed opioid and non-opioid pain medications, including us. For instance, we have received subpoenas or civil investigative demands from the DOJ and several State Attorneys General and other state regulators seeking documentation and information in connection with our historical sales and marketing of opioid products. We also received a subpoena from the State of California Department of Insurance seeking information relating to our historical sales and marketing of Gralise. There has been recent regulatory attention focused on gabapentin as a

result of a perceived risk of the compound being used as a potentiator for opioid abuse. Although gabapentin is neither an opioid nor classified as a controlled substance by the DEA, as a result of the perceived risks relating to opioid abuse, several states have scheduled gabapentin as a controlled substance. Continued changes in regulations and legislation applicable to gabapentin could have a material adverse impact the commercial prospects of Gralise which could, in turn, have a material adverse effect on our business, financial condition and results of operations.

The regulatory actions described above, as well as the related litigation and investigations, not only create financial and operational pressure on our company, but could also put pressure on other companies in our industry and with which we have contractual arrangements. Such pressures could negatively impact our contractual counterparties and may give rise to contract cancellations, breaches or rejections in bankruptcy. Furthermore, in the event that a contract counterparty seeks to reject a contract, we may have an unsecured claim for damages, which may not be paid in full (if at all), and we may be forced to return payments made within 90 days of the date of filing for bankruptcy protection. If any of these events should occur, it may have a material adverse effect on our business, financial condition and results of operations.

The foregoing and other similar initiatives and actions, whether taken by governmental authorities or other industry stakeholders, may result in the reduced availability, prescribing, sales and use of our products, which could adversely affect our ability to commercialize Gralise, CAMBIA and Zipsor, as well as Collegium's ability to commercialize NUCYNTA and NUCYNTA ER, thereby adversely affecting our business, financial condition and results of operations.

Heightened attention on the problems associated with the abuse of opioids could adversely affect Collegium's ability to commercialize NUCYNTA and NUCYNTA ER, which would adversely affect our financial condition and results of operations.

In recent years, there has been increased public attention on the public health issue of opioid abuse. The ability of drug abusers to discover previously unknown ways to abuse and misuse opioid products; public inquiries and governmental investigations into prescription drug abuse; litigation and heightened regulatory activity regarding the sales, marketing, distribution or storage of opioid products, among other things, could cause additional unfavorable publicity regarding the use and misuse of opioids, which could have a material adverse effect on opioid products, the reputation of the opioid manufacturers and the ability of our commercialization partner to successfully commercialize NUCYNTA and NUCYNTA ER. Such negative publicity could reduce the potential size of the market for NUCYNTA and NUCYNTA ER, and decrease the revenues Collegium is able to generate from their sale, which in turn would adversely affect our financial condition and results of operations. Additionally, such increased scrutiny of opioids generally, whether focused on NUCYNTA and NUCYNTA ER or otherwise, could have the effect of negatively impacting relationships with healthcare providers and other members of the healthcare community, reducing the overall market for opioids or reducing the prescribing and use of NUCYNTA and NUCYNTA ER.

Pharmaceutical marketing is subject to substantial regulation in the U.S. and any failure by us or our commercial and collaborative partners to comply with applicable statutes or regulations could adversely affect our business.

All marketing activities of Collegium associated with NUCYNTA and NUCYNTA ER, and of us associated with Gralise, CAMBIA, and Zipsor, as well as marketing activities related to any other products that we may acquire, or for which we or our collaborative partners obtain regulatory approval, are and will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products. The FDA regulates post-approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under

government healthcare programs. For example, the federal healthcare program anti-kickback statute prohibits giving things of value to induce the prescribing or purchase of products that are reimbursed by federal healthcare programs, such as Medicare and Medicaid. In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Under this law, in recent years, the federal government has brought claims against drug manufacturers alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, and, in some states, such statutes or regulations apply regardless of the payer.

Governmental authorities may also seek to hold us responsible for any failure of our commercialization or collaborative partners to comply with applicable statutes or regulations. If we, or our commercial or collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunctions and exclusion of our products from reimbursement under government programs, as well as other regulatory or investigatory actions against our product candidates, our commercial or collaborative partners or us.

We may incur significant liability if it is determined that we are promoting or have in the past promoted the “off-label” use of drugs.

Companies may not promote drugs for “off-label” use—that is, uses that are not described in the product’s labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the U.S. Department of Health and Human Services (OIG), the FDA, and the U.S. Department of Justice (DOJ) all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If any of the investigations of the DOJ, the Attorneys General identified above, and the State of California Department of Insurance, as well as the actions filed by state and municipalities against us, result in a finding that we engaged in wrongdoing, including sales and marketing practices for our current and future products that violate applicable laws and regulations, we would incur significant liabilities. Such liabilities would harm our business, financial condition and results of operations as well as divert management’s attention from our business operations and damage our reputation. For additional information regarding potential liability, see also “—Governmental investigations and inquiries, regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our historical commercialization of opioids could adversely affect our business, financial condition and results of operations.”

Health care reform could increase our expenses and adversely affect the commercial success of our products.

The ACA includes numerous provisions that affect pharmaceutical companies. For example, the ACA seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The ACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in the U.S. The ACA also requires increased disclosure obligations and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost-containment measures that could reduce reimbursement levels for pharmaceutical products. The ACA also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs, biologics,

devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and/or penalties. These and other aspects of the ACA, including regulations that may be imposed in connection with the implementation of the ACA, such as the 340B Program, could increase our expenses and adversely affect our ability to successfully commercialize our products and product candidates.

Many members of Congress and President Trump have pledged to repeal the ACA. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the ACA and permits such legislation to pass with a majority vote in the Senate. President Trump also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the ACA and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of burdensome provisions of the ACA to the maximum extent permitted by law. Although several attempts to repeal and replace the ACA failed to pass both houses of Congress, there is still uncertainty with respect to the impact President Trump's administration and the Congress may have, if any, and any changes will likely take time to unfold. Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our products and product candidates. In addition, President Trump, members of Congress, and state elected officials have indicated that reducing the price of prescription drugs will be a priority. The implementation of any price controls, caps on prescription drugs or price transparency requirements, whether at the federal level or state level, could adversely affect our business, operating results and financial condition.

Risks Related to the Historical Commercialization of Opioids

Governmental investigations and inquiries, regulatory actions and lawsuits brought against us by government agencies and private parties with respect to our historical commercialization of opioids could adversely affect our business, financial condition and results of operations.

As a result of the greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers generally by federal, state and local regulatory and governmental agencies, as well as increased legal action brought by state and local governmental entities and private parties. For example, we are currently named as a defendant, along with numerous other manufacturers and distributors of opioid drugs, in multiple lawsuits alleging common-law and statutory causes of action for alleged misleading or otherwise improper marketing and promotion of opioid drugs. Such litigation and related matters are described in "Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies."

We received a letter from Senator Claire McCaskill, the then-Ranking Member on the U.S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information regarding our historical commercialization of opioid products. We voluntarily furnished information responsive to Sen. McCaskill's request. We have also received subpoenas or civil investigative demands focused on historical promotion and sales of Lazanda, NUCYNTA, and NUCYNTA ER from various State Attorneys General seeking documents and information regarding our historical sales and marketing of opioid products. In addition, the State of California Department of Insurance has issued a subpoena to us seeking information relating to our historical sales and marketing of Lazanda. The State of California Department of Insurance subpoena also seeks information on Gralise, a non-opioid product

in our portfolio. We are cooperating with each of the foregoing states and the State of California Department of Insurance in their investigations. We have received subpoenas from the DOJ seeking documents and information regarding our historical sales and marketing of opioid products. We are cooperating with the DOJ in its investigations. We also from time to time receive and comply with subpoenas from governmental authorities related to investigations primarily directed at third parties, including health care practitioners, pursuant to which our records related to agreements with and payments made to those third parties, among other items, are produced. These matters are described in “Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies.”

These and other governmental investigations or inquiries, as well as lawsuits, in which we are and may become involved may result in additional claims and lawsuits being brought against us by governmental agencies or private parties. It is not possible at this time to predict either the outcome or the potential financial impact of the opioid-related lawsuits mentioned above or any governmental investigations or inquiries of us or any lawsuits or regulatory responses that may result from such investigations or inquiries or otherwise. It is also not possible at this time to predict the additional expenses related to such ongoing opioid-related litigation and investigations, which may be significant. The initiation of any additional investigation, inquiry or lawsuit relating to us, the costs and expenses associated therewith, or any assertion, claim or finding of wrongdoing by us, could:

- adversely affect our business, financial condition and results of operations;
- result in reputational harm and reduced market acceptance and demand for our products;
- harm our and our commercial partner’s ability to market our products;
- cause us to incur significant liabilities, costs and expenses; and
- cause our senior management to be distracted from execution of our business strategy.

To the extent governmental investigations and inquiries or lawsuits similar to those matters described above are, or may be, initiated against Collegium, such proceedings, and any assertion, claim or finding of wrongdoing by Collegium, could adversely affect Collegium’s ability to commercialize NUCYNTA or NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition. Furthermore, these pending investigations, inquiries and lawsuits could negatively affect our ability to raise capital and impair our ability to engage in strategic transactions.

Furthermore, governmental regulators could take measures that could have a negative effect on our business and our products. For example, in 2017 Endo Pharmaceuticals, Inc. voluntarily withdrew, at the FDA’s request, OPANA ER from the market due to the FDA’s view that the risks associated with the use of the product outweighed the potential benefits. Any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to NUCYNTA or NUCYNTA ER would adversely affect Collegium’s ability to commercialize NUCYNTA and NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition. Further, the FDA is in the process of issuing guidance to encourage the development of nonaddictive alternatives to opioid pain medications. Such efforts intended to spur the development of non-opioid medications for chronic pain could negatively impact the commercialization of opioids generally, including NUCYNTA and NUCYNTA ER. Likewise, any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to our other products could adversely affect our business, results of operations, and financial condition.

We may incur product liability losses and other litigation liability for which we may be unable to maintain or obtain adequate protection.

We are or may be involved in various legal proceedings, lawsuits and certain government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability,

personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, opioid-related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. For example, we, along with other opioid manufacturers and, often, distributors, have been named in lawsuits related to the manufacturing, distribution, marketing and promotion of opioids. In addition, we have also received various subpoenas and requests for information related to the distribution, marketing and sale of our opioid products. Moreover, our primary product liability insurer has sought a declaratory judgment that opioid litigation claims noticed by us are not covered by our policies with such insurer. Such litigation and related matters are described in “Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies.” If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows.

We have obtained product liability insurance for sales of our products and clinical trials currently underway, but:

- we may be unable to maintain product liability insurance on acceptable terms;
- we may be unable to obtain product liability insurance for future trials;
- we may be unable to obtain product liability insurance for future products; or
- our insurance may not provide adequate protection against potential liabilities (including pending and future claims relating to opioid litigation), or may provide no protection at all.

Our inability to obtain or maintain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Collegium’s inability to obtain or maintain adequate insurance coverage with regard to its commercialization of NUCYNTA and NUCYNTA ER could prevent or inhibit Collegium’s commercialization of NUCYNTA and NUCYNTA ER and in turn adversely affect our business, results of operations and financial condition. Defending a lawsuit could be costly and significantly divert management’s attention from conducting our business. If third parties were to bring a successful product liability or other claims, or series of claims, against us, or Collegium relating to NUCYNTA and NUCYNTA ER, for uninsured liabilities or in excess of our insured liability limits, or Collegium’s insured liability limits with respect to NUCYNTA and NUCYNTA ER, respectively, our business, results of operations and financial condition could be adversely affected.

Risks Related to Our Intellectual Property

We may be unable to protect our intellectual property and may be liable for infringing the intellectual property of others.

Our success will depend in part on our ability to obtain and maintain patent protection for our products and technologies, and to preserve our trade secrets. Our policy is to seek to protect our proprietary rights by, among other methods, filing patent applications in the U.S. and foreign jurisdictions to cover certain aspects of our technology. We hold issued U.S. patents and have patent applications pending in the U.S. In addition, we are pursuing patent applications relating to our technologies in the U.S. and abroad. We have also applied for patents in numerous foreign countries. Some of those countries have granted our applications and other applications are still pending. Our pending patent applications may lack priority over other applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or may not provide us with competitive advantages against competing products. We also rely on trade secrets and proprietary know-how, which are difficult to protect. We seek to protect such information, in part, by entering into confidentiality agreements with employees, consultants, collaborative partners and others before such

persons or entities have access to our proprietary trade secrets and know-how. These confidentiality agreements may not be effective in certain cases, due to, among other things, the lack of an adequate remedy for breach of an agreement or a finding that an agreement is unenforceable. In addition, our trade secrets may otherwise become known or be independently developed by competitors.

Our ability to develop our technologies and to make commercial sales of products using our technologies also depends on not infringing other patents or intellectual property rights. We are not aware of any such intellectual property claims directly against us. The pharmaceutical industry has experienced extensive litigation regarding patents and other intellectual property rights. Patents issued to third parties relating to sustained release drug formulations or particular pharmaceutical compounds could in the future be asserted against us, although we believe that we do not infringe any valid claim of any patents. For example, in February 2018 Purdue sued Collegium for infringement of three patents owned by Purdue that were issued in January 2018 and expire in 2022 arising from Collegium's commercialization of the NUCYNTA franchise of products. If claims concerning any of our products were to arise and it was determined that these products infringe a third party's proprietary rights, we or our commercial partners could be subject to substantial damages for past infringement or could be forced to stop or delay activities with respect to any infringing product, unless we or our commercial partner, as applicable, can obtain a license, or our product may need to be redesigned so that it does not infringe upon such third party's patent rights, which may not be possible or could require substantial funds or time. Such a license may not be available on acceptable terms, or at all. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which could give our competitors access to the same intellectual property. In addition, any public announcements related to litigation or interference proceedings initiated or threatened against us, even if such claims are without merit, could cause our stock price to decline.

From time to time, we may become aware of activities by third parties that may infringe our patents. Infringement of our patents by others may reduce our market shares (if a related product is approved) and, consequently, our potential future revenues and adversely affect our patent rights if we do not take appropriate enforcement action. We may need to engage in litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. For instance, we have previously been engaged in ANDA litigation involving NUCYNTA, NUCYNTA ER and NUCYNTA oral solution as well as Gralise and Zipsor. It is possible our issued or licensed patents may not be held valid by a court of competent jurisdiction or the PTAB. Whether or not the outcome of litigation or the PTAB proceeding is favorable to us, the litigation and the proceedings may take significant time, may be expensive and may divert management's attention from other business concerns. We may also be required to participate in derivation proceedings or other post-grant proceedings declared by the U.S. Patent and Trademark Office for the purposes of, respectively, determining the priority of inventions in connection with our patent applications or determining validity of claims in our issued patents. Adverse determinations in litigation or proceedings at the U.S. Patent and Trademark Office could adversely affect our business, results of operations and financial condition and could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities to third parties. If we need but cannot obtain a license, we may be prevented from marketing the affected product.

Risks Related to Our Financial Position

Our failure to generate sufficient cash flow from our business to make payments on our debt would adversely affect our business, financial condition and results of operations.

We have incurred significant indebtedness under the senior secured notes we issued in April 2015 (the Senior Notes) and the convertible notes we issued in September 2014 (the Convertible Notes). Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Convertible Notes, the Senior Notes and any additional debt obligations we may incur depends on our

future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and to make necessary capital expenditures. Further, our results of operations may cause us to fail to comply with the financial covenants contained in the Note Purchase Agreement described in “Item 8. Financial Statements and Supplementary Data—Note 10. Debt,” which event of default could result in all of our debt becoming immediately due and payable. If we are unable to generate sufficient cash flow or if our results of operations cause us to fail to comply with our financial covenants, we may be required to take one or more actions, including refinancing our debt, significantly reducing expenses, renegotiating our debt covenants, restructuring our debt, selling assets or obtaining additional capital, each of which may be on terms that may be onerous, highly dilutive or disruptive to our business. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on commercially reasonable or acceptable terms, which could result in a default on our obligations, including the Convertible Notes and the Senior Notes.

In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences to our business. For example, it could:

- make it more difficult for us to meet our payment and other obligations under the Convertible Notes, the Senior Secured Notes or our other indebtedness;
- result in other events of default under our Convertible Notes, Senior Secured Notes or our other indebtedness, which events of default could result in all of our debt becoming immediately due and payable;
- make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- limit our ability to borrow additional amounts for working capital and other general corporate purposes, including funding possible acquisitions of, or investments in, new and complementary businesses, products and technologies which is a key element of our corporate strategy;
- subject us to the risk of increased sensitivity to interest rate increases on our indebtedness with variable interest rates, including the Senior Notes;
- require the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including working capital, clinical trials, research and development, business development activities, capital expenditures and other general corporate purposes;
- prevent us from raising funds necessary to repurchase the Convertible Notes in the event we are required to do so following a “fundamental change,” as specified in the indenture governing the Convertible Notes, to repurchase the Senior Notes in the event we are required to do so following a “major transaction” or as required in the event that the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than \$100.0 million, as specified in the Note Purchase Agreement or to settle conversions of the Convertible Notes in cash;
- result in dilution to our existing shareholders as a result of the conversion of the Convertible Notes into shares of common stock;
- limit our flexibility in planning for, or reacting to, changes in our business and our industry; and
- put us at a disadvantage compared to our competitors who have less debt.

Any of these factors could adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

Acquisition of new and complementary businesses, products and technologies is a key element of our corporate strategy. If we are unable to successfully identify and acquire such businesses, products or technologies, our business growth and prospects will be limited.

Since June 2012, we have acquired NUCYNTA, NUCYNTA ER, CAMBIA, and Zipsor, exclusively in-licensed the right to develop and commercialize cebranopadol, and in-licensed the right to market long-acting cosyntropin. An important element of our business strategy is to actively seek to acquire products or companies and to in-license or seek co-promotion rights to additional products. We cannot be certain that we will be able to successfully identify, pursue and complete any further acquisitions or whether we would be able to successfully integrate or develop any acquired business, product or technology or retain any key employees. If we are unable to enhance and broaden our product offerings, our business and prospects will be limited.

If we engage in strategic transactions that fail to achieve the anticipated results and synergies, our business will suffer.

We may seek to engage in strategic transactions with third parties, such as product or company acquisitions, strategic partnerships, joint ventures, divestitures or business combinations. We may face significant competition in seeking potential strategic partners and transactions, and the negotiation process for acquiring any product or engaging in strategic transactions can be time-consuming and complex. Engaging in strategic transactions, such as our acquisition in 2015 of the rights to NUCYNTA and NUCYNTA ER, our completion in 2018 of the commercialization arrangement covering NUCYNTA and NUCYNTA ER with Collegium, and our acquisition of the right to market the specialty drug long-acting cosyntropin in the U.S. and Canada may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, pose integration challenges and fail to achieve the anticipated results or synergies or distract our management and business, which may harm our business.

As part of an effort to acquire a product or company or to enter into other strategic transactions, we conduct business, legal and financial due diligence with the goal of identifying, evaluating and assessing material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining, evaluating and accurately assessing all such risks and, as a result, might not realize the intended advantages of the transaction. We may also assume liabilities and legal risks in connection with a transaction, including those relating to activities of the seller prior to the consummation of the transaction and contracts that we assume. Failure to realize the expected benefits from acquisitions or strategic transactions that we may consummate, or that we have completed, such as the acquisition in 2015 of the U.S. rights to NUCYNTA and NUCYNTA ER, and the recently completed commercialization arrangement covering NUCYNTA and NUCYNTA ER with Collegium, whether as a result of identified or unidentified risks, integration difficulties, regulatory setbacks, governmental investigations, litigation or other events, could adversely affect our business, results of operations and financial condition.

If we are unable to successfully integrate any business, product or technology we may acquire, our business, financial condition and operating results will suffer.

Integrating any business, product or technology we acquire is expensive, time consuming and can disrupt and adversely affect our ongoing business, including product sales, and distract our

management. Our ability to successfully integrate any business, product or technology we acquire depends on a number of factors, including, but not limited to, our ability to:

- minimize the disruption and distraction of our management and other employees, including our sales force, in connection with the integration of any acquired business, product or technology;
- maintain and increase sales of our existing products;
- establish or manage the transition of the manufacture and supply of any acquired product, including the necessary active pharmaceutical ingredients, excipients and components;
- identify and add the necessary sales, marketing, manufacturing, regulatory and other related personnel, capabilities and infrastructure that are required to successfully integrate any acquired business, product or technology;
- manage the transition and migration of all commercial, financial, legal, clinical, regulatory and other pertinent information relating to any acquired business, product or technology;
- comply with legal, regulatory and contractual requirements applicable to any acquired business, product or technology;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third- party payers with respect to any acquired product; and
- maintain and extend intellectual property protection for any acquired product or technology.

If we are unable to perform the above functions or otherwise effectively integrate any acquired businesses, products or technologies, our business, financial condition and operating results will suffer.

Our existing capital resources may not be sufficient to fund our future operations or product acquisitions and strategic transactions that we may pursue.

We fund our operations primarily through revenues from product sales and do not have any committed sources of capital. To the extent that our existing capital resources and revenues from ongoing operations are insufficient to fund our future operations, or product acquisitions and strategic transactions that we may pursue, we will have to raise additional funds through the sale of our equity securities, through additional debt financing, from development and licensing arrangements or from the sale of assets. We may be unable to raise such additional capital on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions.

We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash, to repurchase the Convertible Notes upon a fundamental change or to repurchase the Senior Notes upon a major transaction put or as required in the event that the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than \$100.0 million.

Holders of the Convertible Notes will have the right to require us to repurchase all or a portion of their Convertible Notes upon the occurrence of certain events, including events deemed to be a "fundamental change," at a repurchase price equal to 100% of the principal amount of the outstanding Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. Upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted.

Furthermore, holders of the Senior Notes will have the right to require us to repurchase all of their Senior Notes (i) if the principal amount outstanding under the Convertible Notes as of March 31, 2021 is greater than \$100.0 million, at a repurchase price equal to 100% of the principal amount of the

outstanding Senior Notes to be repurchased, plus accrued and unpaid interest, if any, or (ii) upon the occurrence of certain events deemed to be a “major transaction” at a repurchase price equal to: (a) 100% of the principal amount of the outstanding Senior Notes to be repurchased, plus (b) accrued and unpaid interest, if any, plus (c) a prepayment premium, which may be substantial.

However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes or Senior Notes or pay cash with respect to Convertible Notes being converted. In addition, our ability to repurchase or to pay cash upon conversion of the Convertible Notes may be limited by law, regulatory authority or agreements governing our future indebtedness. An event of default under the indenture governing the Convertible Notes, including our failure to repurchase Convertible Notes when required by the indenture governing the Convertible Notes, would constitute a default under the Note Purchase Agreement. In addition, an event of default under the Note Purchase Agreement, including our failure to repurchase Senior Notes when the repurchase is required by the Note Purchase Agreement, would constitute a default under the indenture governing the Convertible Notes. Moreover, the occurrence of a fundamental change under the indenture governing the Convertible Notes or a major transaction under the Note Purchase Agreement could constitute an event of default under either the indenture governing the Convertible Notes or the Note Purchase Agreement, as applicable and any agreements that may govern any future indebtedness. Following an event of default, if the payment of our outstanding indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay such indebtedness.

The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Convertible Notes is triggered, holders of Convertible Notes will be entitled to convert the Convertible Notes at any time during specified periods at their option. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The market price of our common stock historically has been volatile. Our results of operations may fluctuate and affect our stock price.

The trading price of our common stock has been, and is likely to continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors affecting our operating results and that could adversely affect our stock price include:

- the degree of commercial success and market acceptance of NUCYNTA and NUCYNTA ER achieved by Collegium;
- the degree of commercial success and market acceptance of Gralise, CAMBIA and Zipsor achieved;
- the current and future market conditions for short-acting and long-acting opioids;
- filings and other regulatory or governmental actions, investigations or proceedings related to our products and product candidate and those of our commercialization and collaborative partners;
- the outcome of the appeal of the court’s favorable ruling in our patent infringement litigation against the filers of ANDAs for NUCYNTA and NUCYNTA ER;

- the regulatory strategy for long-acting cosyntropin and our and our collaborative partner's ability to successfully develop and execute such strategy;
- our ability to successfully commercialize long-acting cosyntropin if regulatory approval is obtained;
- developments concerning proprietary rights, including patents, infringement allegations, inter party review proceedings and litigation matters;
- legal and regulatory developments in the U.S.;
- actions taken by industry stakeholders affecting the market for our products;
- our ability to generate sufficient cash flow from our business to make payments on our indebtedness;
- our and our commercialization and collaborative partners' compliance or non-compliance with legal and regulatory requirements and with obligations under our collaborative agreements;
- our ability to successfully develop and execute our sales and marketing strategies;
- our plans to acquire, in-license or co-promote other products, compounds or acquire or combine with other companies, and our degree of success in realizing the intended advantages of, and mitigating any risks associated with, any such transaction;
- adverse events related to our products, including recalls;
- interruptions of manufacturing or supply, or other manufacture or supply difficulties;
- variations in revenues obtained from commercialization and collaborative agreements, including contingent milestone payments, royalties, license fees and other contract revenues, including non-recurring revenues, and the accounting treatment with respect thereto;
- adverse events or circumstances related to our peer companies or our industry or the markets for our products;
- adoption of new technologies by us or our competitors;
- the outcome of our opioid-related investigations and litigation;
- the outcome and impact of a proxy contest initiated by an activist shareholder;
- our compliance with the terms and conditions of the agreements governing our indebtedness;
- decisions by collaborative partners to proceed or not to proceed with subsequent phases of a collaboration or program;
- our ability to generate additional revenues from our intellectual property rights;
- sales of large blocks of our common stock or the dilutive effect of our Convertible Notes; and
- variations in our operating results, earnings per share, cash flows from operating activities, deferred revenue, and other financial metrics and non-financial metrics, and how those results are measured, presented and compare to analyst expectations.

As a result of these and other such factors, our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Any significant drops in our stock price could give rise to shareholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved in our favor.

In addition, if the market for pharmaceutical stocks or the stock market in general experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results or financial condition. For example, if one or more securities or industry analysts downgrades our stock or publishes an inaccurate research report about our company, the market price for our common stock would likely decline. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us.

We have incurred operating losses in the past and may incur operating losses in the future.

To date, we have recorded revenues from product sales, license fees, royalties, collaborative research and development arrangements and feasibility studies. In 2017, 2016 and 2015 we incurred net losses of \$102.5 million, \$88.7 million and \$75.7 million, respectively. We may continue to incur operating losses in future years. Any such losses may have an adverse impact on our total assets, shareholders' equity and working capital.

We have significant amounts of intangible assets which depend upon future positive cash flows to support the values recorded in our balance sheet. We may have an increased risk of future impairment charges should actual financial results differ materially from our projections.

Our consolidated balance sheet contains significant amounts of intangible assets representing the product rights which we have acquired over the last few years. We review the carrying value of our intangible assets when indicators of impairment are present. Conditions that could indicate impairment of intangible assets include, but are not limited to, a significant adverse change in market conditions, significant competing product launches by our competitors and adverse legal or regulatory outcomes.

In performing our impairment tests, which assess the recoverability of our assets, we utilize our future projections of cash flows. Projections of future cash flows are inherently subjective and reflect assumptions that may or may not ultimately be realized. Significant assumptions utilized in our projections include, but are not limited to, our evaluation of the market opportunity for our products, the current and future competitive landscape and resulting impacts to product pricing, future regulatory actions, planned strategic initiatives and the realization of benefits associated with our existing patents. Given the inherent subjectivity and uncertainty in projections, we could experience significant unfavorable variances in future periods or revise our projections downward. This would result in an increased risk that our intangible assets may be impaired. If an impairment were recognized, this could have a material adverse effect on our financial condition and results of operations.

Our customer concentration may materially adversely affect our financial condition and results of operations.

We and our commercialization partners sell a significant amount of our products to a limited number of independent wholesale drug distributors. If we, or our commercialization partners, were to lose the business of one or more of these distributors, if any of these distributors failed to fulfill their obligations, if any of these distributors experienced difficulty in paying us or our commercialization partners on a timely basis, or if any of these distributors negotiated lower pricing terms, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. See also “—We rely on Collegium Pharmaceutical Inc. to commercialize NUCYNTA and NUCYNTA ER and their failure to successfully commercialize these products could have a material adverse effect on our business, financial condition and results of operations.”

Our product revenues have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year, which may cause our stock price to decline.

Our product revenues have historically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year. We believe this arises primarily as a result of wholesalers' reductions of inventory of our products in the first quarter and annual changes in health insurance plans that occur at the beginning of the calendar year.

Our wholesalers typically end the calendar year with higher levels of inventory of our products than at the end of the first quarter of the following year. As a result, in such first quarters, net sales are typically lower than would otherwise have been the case as a result of the reduction of product inventory at our wholesalers. Any material reduction by our wholesalers of their inventory of our products in the first quarter of any calendar year as compared to the fourth quarter of the preceding calendar year, could adversely affect our operating results and may cause our stock price to decline.

Many health insurance plans and government programs reset annual limits on deductibles and out-of-pocket costs at the beginning of each calendar year and require participants to pay for substantially all of the costs of medical services and prescription drug products until such deductibles and annual out-of-pocket cost limits are met. In addition, enrollment in high-deductible health insurance plans has increased significantly in recent years. As a result of these factors, patients may delay filling or refilling prescriptions for our products or substitute less expensive generic products until such deductibles and annual out-of-pocket cost limits are met. Any reduction in the demand for our products, including those marketed by our commercialization partners as a result of the foregoing factors or otherwise, could adversely affect our business, operating results and financial condition.

Changes in fair value of contingent consideration assumed as part of our acquisitions could adversely affect our results of operations.

Contingent consideration obligations arise from the Zipsor and CAMBIA acquisitions and relate to the potential future contingent milestone payments and royalties payable under the respective agreements. The contingent consideration is initially recognized at its fair value on the acquisition date and is re-measured to fair value at each reporting date until the contingency is resolved with changes in fair value recognized in earnings. The estimates of fair values for the contingent consideration contain uncertainties as it involves assumptions about the probability assigned to the potential milestones and royalties being achieved and the discount rate. Significant judgment is employed in determining these assumptions as of the acquisition date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period.

The accounting method for convertible debt securities that may be settled in cash, such as the Convertible Notes could have a material effect on our reported financial results.

In May 2008, FASB issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options (ASC 470-20). Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Convertible Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Convertible Notes is that the equity component is required to be included in the additional paid-in capital within shareholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the Convertible Notes. As a result, we have been required to record a greater amount of non-cash interest expense as a result of the accretion of the discounted carrying value of the Convertible Notes to their face amount over

the term of the notes. We will report lower net income (or larger net losses) in our financial results because ASC 470-20 requires interest to include both the accretion of the debt discount and the instrument's non-convertible coupon interest rate, which adversely affects our reported or future financial results and may adversely affect the trading price of our common stock.

In addition, if the Convertible Notes become convertible, we are required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than a long-term liability, which would result in a material reduction of our net working capital. Finally, we use the if-converted method to compute diluted earnings per share with respect to our convertible debt, which could be more dilutive than assuming the debt would be settled in cash.

Any of these factors could cause a decrease in the market price of our common stock.

If we are unable to satisfy regulatory requirements relating to internal controls, our stock price could suffer.

Section 404 of the Sarbanes-Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of the effectiveness of their internal control over financial reporting. At the end of each fiscal year, we must perform an evaluation of our internal control over financial reporting, include in our annual report the results of the evaluation and have our external auditors also publicly attest to the effectiveness of our internal control over financial reporting.

Our ability to produce accurate financial statements and comply with applicable laws, rules and regulations is largely dependent on our maintenance of internal control and reporting systems, as well as on our ability to attract and retain qualified management and accounting personnel to further develop our internal accounting function and control policies. If we fail to effectively establish and maintain such reporting and accounting systems or fail to attract and retain personnel who are capable of designing and operating such systems, these failures will increase the likelihood that we may be required to restate our financial results to correct errors or that we will become subject to legal and regulatory infractions, which may entail civil litigation and investigations by regulatory agencies including the SEC. In addition, if material weaknesses are found in our internal controls in the future, if we fail to complete future evaluations on time or if our external auditors cannot attest to the effectiveness of our internal control over financial reporting, we could fail to meet our regulatory reporting requirements and be subject to regulatory scrutiny and a loss of public confidence in our internal controls, which could have an adverse effect on our stock price or expose us to litigation or regulatory proceedings, which may be costly or divert management attention.

Our financial results are impacted by management's assumptions and use of estimates.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as sales discounts and returns, depreciable and amortizable lives, share-based compensation assumptions, fair value of contingent consideration and taxes on income. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of our business and operations, actual results could differ materially from these estimates.

Risks Related to Share Ownership and Other Stockholder Matters

Our business could be negatively affected as a result of any future proxy fight or the actions of activist shareholders.

On October 17, 2016, we and Starboard Value LP (Starboard) entered into a settlement agreement pursuant to which, among other things, (i) three independent directors appointed by Starboard joined our Board of Directors, (ii) we amended our bylaws to move the window for shareholders director nominations and other shareholder proposals for consideration at the 2017 annual meeting of shareholders to March 15, 2017 through April 15, 2017 and (iii) Starboard agreed to withdraw its request for the Special Meeting scheduled to be held on November 15, 2016. On March 28, 2017, we and Starboard entered into a cooperation and support agreement pursuant to which, among other things, two additional independent directors appointed by Starboard joined our Board of Directors and the parties agreed to certain standstill commitments.

Another proxy contest or related activities with Starboard or other activist shareholders, could adversely affect our business for a number of reasons, including, but not limited to the following:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;
- perceived uncertainties as to our future direction may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel, business partners, customers and others important to our success, any of which could negatively affect our business and our results of operations and financial condition; and
- if nominees advanced by activist shareholders are elected or appointed to our Board of Directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans or to realize long-term value from our assets, and this could in turn have an adverse effect on our business and on our results of operations and financial condition.

A proxy contest could also cause our stock price to experience periods of volatility. Further, if a proxy contest results in a change in control of our Board of Directors, such an event could give third parties certain rights under our existing contractual obligations, which could adversely affect our business.

We may be subject to disruptive unsolicited takeover attempts in the future.

We have in the past and may in the future be subject to unsolicited attempts to gain control of our company. Responding to any such attempt would distract management attention away from our business and would require us to incur significant costs. Moreover, any unsolicited takeover attempt may disrupt our business by causing uncertainty among current and potential employees, producers, suppliers, customers and other constituencies important to our success, which could negatively impact our financial results and business initiatives. Other disruptions to our business include potential volatility in our stock price and potential adverse impacts on the timing of, and our ability to consummate, acquisitions of products and companies.

Certain provisions applicable to the Convertible Notes and the Senior Notes could delay or prevent an otherwise beneficial takeover or takeover attempt.

Certain provisions applicable to the Convertible Notes and the indenture governing the Convertible Notes, the Senior Notes and the Note Purchase Agreement, could make it more difficult or more expensive for a third party to acquire us. For example, if an acquisition event constitutes a

fundamental change under the indenture for the Convertible Notes or a major transaction under the Note Purchase Agreement, holders of the Convertible Notes or the Senior Notes, as applicable, will have the right to require us to repurchase their notes in cash. In addition, if an acquisition event constitutes a “make-whole fundamental change” under the indenture, we may be required to increase the conversion rate for holders who convert their Convertible Notes in connection with such make-whole fundamental change. In any of these cases, and in other cases, our obligations under the Convertible Notes and the indenture, the Senior Notes and the Note Purchase Agreement, as well as provisions of our organizational documents and other agreements, could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

We do not intend to pay dividends on our common stock so any returns on shares of our common stock will be limited to changes in the value of our common stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our common stock may be prohibited or limited by the terms of any future debt financing arrangement. Any return to shareholders will therefore be limited to the increase, if any, of our stock price.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Lake Forest, Illinois, where we lease approximately 31,000 square feet of office space (the Lake Forest Lease). Our prior corporate headquarters was located in Newark, California where we entered into an office and laboratory lease agreement to lease approximately 52,500 rentable square feet commencing in December 2012 and approximately 8,000 additional rentable square feet commencing in July 2015 (the Newark Lease). Following the relocation of our corporate headquarters from Newark, California to Lake Forest, Illinois, we entered into subleases for the Newark facility. For additional information regarding the Lake Forest Lease and the Newark Lease, see “Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies.”

ITEM 3. LEGAL PROCEEDINGS

For a description of our material pending legal proceedings, see “Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies.”

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders of Common Stock

Our common stock trades on the NASDAQ Global Market (NASDAQ) under the symbol "ASRT." As of December 31, 2018, there were 19 shareholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one shareholder.

Dividends

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends on our common stock may be prohibited or limited by the terms of any future debt financing arrangement. Any return to shareholders will therefore be limited to the increase, if any, of our stock price.

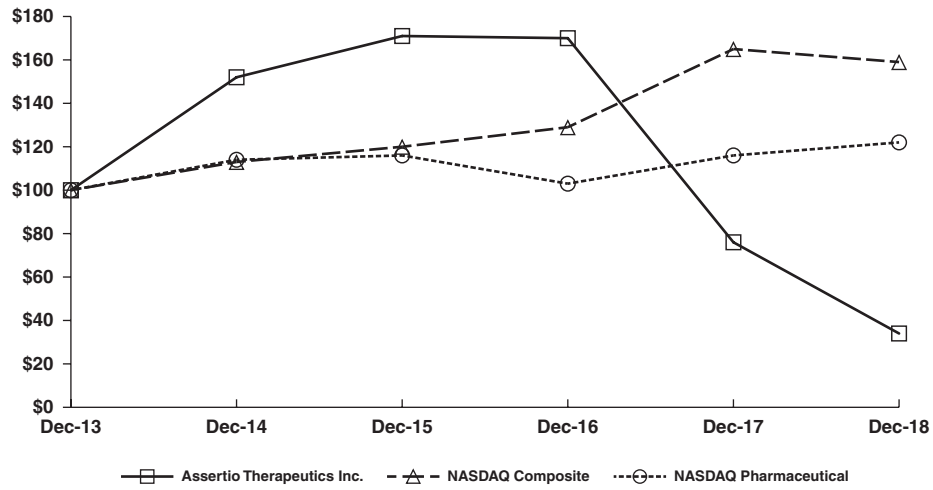
Stock Price Performance Graph

The performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or Exchange Act

The following graph compares the cumulative total return on an investment in our common stock with the cumulative total return on an investment in each of the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index. The total return for our common stock and for each index assumes the reinvestment of all dividends, although cash dividends have never been declared on our common stock.

Comparison of 5-Years Cumulative Total Return

Among Assertio Therapeutics, Inc., the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index Assumes Initial Investment of \$100



	<u>12/31/2013</u>	<u>12/31/2014</u>	<u>12/31/2015</u>	<u>12/31/2016</u>	<u>12/31/2017</u>	<u>12/31/2018</u>
Assertio Therapeutics, Inc.	\$100	\$152	\$171	\$170	\$ 76	\$ 34
NASDAQ Composite Index	\$100	\$113	\$120	\$129	\$165	\$159
NASDAQ Pharmaceutical Index	\$100	\$114	\$116	\$103	\$116	\$122

ITEM 6. SELECTED FINANCIAL DATA

The data set forth below is not necessarily indicative of the results of future operations and should be read in conjunction with the Consolidated Financial Statements and the Notes to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K and also with “ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.”

	2018	2017	2016	2015	2014
Consolidated Statement of Operations Data (in thousands, except per share amounts)					
Revenues:					
Product sales, net	129,966	\$ 379,880	\$455,066	\$ 341,750	\$114,219
Royalties and milestones	26,061	844	831	985	1,821
Commercialization Agreement and other revenue(1)	155,743	—	—	—	31,515
Non-cash PDL royalty revenue(1)	—	—	—	—	242,808
Total revenues	311,770	380,724	455,897	342,735	390,363
Total costs and expenses	268,111	422,904	431,388	393,135	153,549
Income (loss) from operations	43,659	(42,180)	24,509	(50,400)	236,814
Net income (loss) before income taxes	37,975	(103,925)	(64,502)	(123,237)	213,108
Benefit from (provision for) income taxes	(1,067)	1,429	(24,218)	47,499	(81,346)
Net income (loss)	36,908	\$(102,496)	\$(88,720)	\$ (75,738)	\$131,762
Basic net income (loss) per share	\$ 0.58	\$ (1.63)	\$ (1.45)	\$ (1.26)	\$ 2.26
Diluted net income (loss) per share	\$ 0.57	\$ (1.63)	\$ (1.45)	\$ (1.26)	\$ 2.05
Shares used in computing basic net income (loss) per share	63,794	62,702	61,297	60,117	58,293
Shares used in computing diluted net income (loss) per share	64,208	62,702	61,297	60,117	66,307
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data (in thousands)					
Cash, cash equivalents and short term investments(3)	\$ 110,949	\$ 128,089	\$ 177,420	\$ 209,768	\$566,402
Total assets	932,866	1,038,617	1,225,337	1,357,249	711,065
Total current liabilities(1)(2)	246,036	310,580	227,242	219,632	57,499
Contingent consideration liability, non-current	1,038	1,457	10,247	11,653	14,252
Senior Notes(3)	158,309	274,720	466,051	563,012	—
Convertible Notes	287,798	269,510	252,725	237,313	223,150
Other long-term liabilities	19,350	12,842	18,284	10,584	12,387
Accumulated (deficit) earnings	(182,600)	(219,508)	(116,744)	(28,024)	47,717
Total shareholders’ equity	220,335	169,508	250,788	315,055	364,447

- (1) Effective January 8, 2018, the Company entered into a Commercialization Agreement to sub-license NUCYNTA, which results in royalty income. The Company recognized the entire remaining balance of the liability related to sale of future royalties and milestones of approximately \$147.0 million as non-cash PDL royalty revenue during 2014.
- (2) The increase in current liabilities as of December 31, 2017, is primarily due to the reclassification of principal payments due on our Senior Notes in 2018. The increase in total current liabilities as of December 31, 2015 is primarily due to the acquisition of NUCYNTA in April 2015.
- (3) The Company made principal payments of \$82.5 million in 2018. The Company prepaid \$114.4 million and \$105.0 million of its Senior Notes, including prepayment premiums of \$4.4 million and \$5.0 million in 2017 and 2016, respectively.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

We are a specialty pharmaceutical company focused on neurology, orphan and specialty medicines. Our current specialty pharmaceutical business includes the following three products which we market in the U.S.:

- Gralise® (gabapentin), a once daily product for the management of postherpetic neuralgia (PHN), that we launched in October 2011.
- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, that we acquired in December 2013.
- Zipsor® (diclofenac potassium liquid filled capsules), a non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain, that we acquired in June 2012.

We also have the exclusive rights to market long-acting cosyntropin (synthetic ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the FDA for our 505(b)(2) NDA for our novel injectable formulation of long-acting cosyntropin. We, together with our development partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

We maintain a Commercialization Agreement with Collegium Pharmaceutical, Inc. (Collegium) pursuant to which we granted Collegium the right to commercialize the NUCYNTA® franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. We receive a royalty on all NUCYNTA revenues based on certain net sales thresholds.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A detailed discussion of our significant accounting policies can be found in Note 1 of the Notes to Consolidated Financial Statements, and the impact and risks associated with our accounting policies are discussed throughout this Annual Report on Form 10-K and in the Notes to the Consolidated Financial Statements. Critical accounting policies are those that require significant judgment and/or estimates by management at the time that financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, accrued liabilities, and use of estimates to be critical policies. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

Revenue Recognition

We account for revenue arising from contracts and customers in accordance with Accounting Standards Update (ASU or Update) 2014-9, Revenue from Contracts with Customers (ASC 606), which was adopted on January 1, 2018 using the modified retrospective transition method. There was no adjustment to our opening balance of accumulated deficit resulting from the adoption of this guidance.

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. 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) the Company satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation, when (or as) the performance obligation is satisfied.

Variable consideration arising from sales or usage-based royalties, promised in exchange for a license of the Company's Intellectual Property, is recognized at the later of (i) when the subsequent product sales occur or (ii) the performance obligation, to which some or all of the sales-based royalty has been allocated, has been satisfied.

We recognize a contract asset relating to our conditional right to consideration for completed performance obligations. Accounts receivable are recorded when the right to consideration becomes unconditional. A contract liability is recorded for payments received in advance of the related performance obligation being satisfied under the contract.

Commercialization Agreement

We derive revenue from Commercialization Agreement with Collegium whereby we granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. We entered into the Commercialization agreement in December 2017, which became effective in January 2018, and amended the agreement in November 2018. Prior to the amendment, we recognized the portion of the transaction price allocated to the license and facilitation services ratably over the term as we views our performance obligations as a series of distinct goods or services that are substantially the same and that have the same pattern of transfer. Following the Commercialization Agreement amendment, the royalty payments represent variable compensation that is subject to the sales based royalty exception for licenses of intellectual property because the License is the predominant component of this arrangement.

Product Sales

We sell commercial products to wholesale distributors and retail pharmacies. Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which typically occurs upon delivery to the customer. Our performance obligation is to deliver product to the customer, and the performance obligation is completed upon delivery. The transaction price consists of a fixed invoice price and variable product sales allowances, which include rebates, discounts and returns. Product sales revenues are recorded net of applicable reserves for these product sales allowances. Receivables related to product sales are typically collected one to two months after delivery.

Product Sales Allowances—We consider products sales allowances to be variable consideration and estimates and recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on actual or estimated amounts owed on the related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the

distribution channel, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. We use the most likely method in estimating product sales allowances. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. Our sales allowances include:

Product Returns—We allow customers to return product for credit with respect to that product within six months before and up to 12 months after its product expiration date. We estimate product returns and associated credit on NUCYNTA ER and NUCYNTA, Gralise, CAMBIA, Zipsor and Lazanda. Estimates for returns are based on historical return trends by product or by return trends of similar products, taking into consideration the shelf life of the product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels and consideration of the introduction of competitive products. Under the Commercialization Agreement with Collegium for NUCYNTA ER and NUCYNTA and the divestiture of Lazanda to Slán, we are only financially responsible for product returns for product that were sold by us, which are identified by specific lot numbers.

The shelf life of NUCYNTA ER and NUCYNTA is 24 months to 36 months from the date of tablet manufacture. The shelf life of Gralise is 24 months to 36 months from the date of tablet manufacture. The shelf life of CAMBIA is 24 months to 48 months from the manufacture date. The shelf life of Zipsor is 36 months from the date of tablet manufacture. The shelf life of Lazanda is 24 to 36 months from the manufacture date. Because of the shelf life of our products and its return policy of issuing credits with respect to product that is returned within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credit on a returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments.

Wholesaler and Retail Pharmacy Discounts—We offer contractually determined discounts to certain wholesale distributors and retail pharmacies that purchase directly from it as well as specialty pharmacies. These discounts are either taken off invoice at the time of shipment or paid to the customer on a quarterly basis one to two months after the quarter in which product was shipped to the customer.

Prompt Pay Discounts—We offer cash discounts to its customers (generally 2% of the sales price) as an incentive for prompt payment. Based upon our experience, we expect our customers to comply with the payment terms to earn the cash discount.

Patient Discount Programs—We offer patient discount co-pay assistance programs in which patients receive certain discounts off their prescriptions at participating retail pharmacies. The discounts are reimbursed by us approximately one month after the prescriptions subject to the discount are filled.

Medicaid Rebates—We participates in Medicaid rebate programs, which provide assistance to certain low income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally two to three months after the quarter in which prescriptions subject to the rebate are filled.

Chargebacks—We provide discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back the difference between the current retail price and the price the federal entity paid for the product.

Managed Care Rebates—We offer discounts under contracts with certain managed care providers. We generally pay managed care rebates one to three months after the quarter in which prescriptions subject to the rebate are filled.

Medicare Part D Coverage Gap Rebates—We participate in the Medicare Part D Coverage Gap Discount Program under which it provides rebates on prescriptions that fall within the “donut hole” coverage gap. We generally pay Medicare Part D Coverage Gap rebates two to three months after the quarter in which prescriptions subject to the rebate are filled.

Royalties

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, we recognize royalty revenue at the later of (1) when the related sales occur, or (2) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

We currently receive royalties based on sales of CAMBIA in Canada and sales of NUCYNTA ER in Canada and Japan, which are recognized as revenue when the related sales occur as there are no continuing performance obligations by the Company under those agreements.

We believe our estimates related to gross-to-net sales adjustments for wholesaler and retail pharmacy fees and discounts, prompt payment discounts, patient discount programs and other government chargebacks do not have a high degree of estimation complexity or uncertainty as the related amounts are settled within a relatively short period of time. We believe that our estimated product return allowances, managed care rebates and Medicaid rebates are judgmental and are subject to change based on our experience and certain quantitative and qualitative factors. Adjustments to estimates for these allowances have not been material.

Our product sales allowances and related accruals are evaluated each reporting period and adjusted when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could affect our results of operations and financial position.

A roll-forward of our product revenue allowances for the three years ended December 31, 2018 is as follows:

(in thousands)	Contract Sales Discounts(1)(2)	Product Returns(2)	Cash Discounts(2)	Total
Balance at December 31, 2015	\$ 103,031	\$ 18,027	\$ 1,458	\$ 122,516
Revenue Allowances:				
Provision related to current period sales	314,611	9,997	15,898	340,506
Changes in estimates related to sales made in prior years	549	(1,961)	—	(1,412)
Payments and credits related to sales made in current period	(206,684)	—	(13,789)	(220,473)
Payments and credits related to sales made in prior periods	<u>(103,580)</u>	<u>(2,454)</u>	<u>(1,457)</u>	<u>(107,491)</u>
Balance at December 31, 2016	\$ 107,927	\$ 23,609	\$ 2,110	\$ 133,646
Revenue Allowances:				
Provision related to current period sales	325,489	13,555	14,858	353,902
Changes in estimates related to sales made in prior years	1,483	7,875	—	9,358
Payments and credits related to sales made in current period	(224,002)	—	(13,358)	(237,360)
Payments and credits related to sales made in prior periods	<u>(104,751)</u>	<u>(15,357)</u>	<u>(2,110)</u>	<u>(122,218)</u>
Balance at December 31, 2017	\$ 106,146	\$ 29,682	\$ 1,500	\$ 137,328
Revenue Allowances:				
Provision related to current period sales	123,623	5,716	5,024	134,363
Changes in estimates related to sales made in prior years	(19,210)	7,327	—	(11,883)
Payments and credits related to sales made in current period	(75,380)	—	(4,605)	(79,985)
Payments and credits related to sales made in prior periods	<u>(86,936)</u>	<u>(14,986)</u>	<u>(1,500)</u>	<u>(103,422)</u>
Balance at December 31, 2018	<u>\$ 48,243</u>	<u>\$ 27,739</u>	<u>\$ 419</u>	<u>\$ 76,401</u>

(1) Includes wholesaler fees and retail discounts, patient support programs, managed care rebates, and government chargebacks and rebates.

(2) In November 2017 we divested the rights to Lazanda to Slán. In January 2018, we entered into an agreement which granted commercialization rights of NUCYNTA to Collegium. NUCYNTA was acquired from Janssen Pharma in April 2015.

Milestones

For arrangements that include milestones, we recognize such revenue using the most likely method. As part of adopting ASC 606, we evaluated whether the future milestones should have been included as part of the transaction price in periods before January 1, 2018. We concluded that because of development and regulatory risks at the time, it was probable that a significant revenue reversal could have occurred. At the end of each subsequent reporting period, we re-evaluate the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts our estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Stock-Based Compensation

We use the Black Scholes option valuation model to determine the fair value of stock options and employee stock purchase plan (ESPP) shares. The determination of the fair value of stock based payment awards on the date of grant using an option valuation model is affected by our stock price as well as assumptions, which include our expected term of the award, the expected stock price volatility, risk free interest rate and expected dividends over the expected term of the award. The fair value of restricted stock units equals the market value of the underlying stock on the date of grant.

We use historical option exercise data to estimate the expected term of the options. We estimate the volatility of our common stock price by using the historical volatility over the expected term of the options. We base the risk free interest rate on U.S. Treasury zero coupon issues with terms similar to the expected term of the options as of the date of grant. We do not anticipate paying any cash dividends in the foreseeable future, and therefore, uses an expected dividend yield of zero in the option valuation model.

Intangible Assets

Intangible assets consist of purchased developed technology and trademarks. We determine the fair values of acquired intangible assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to, developing appropriate discount rates and estimating future cash flows from product sales and related expenses. We evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense. We have not recorded any impairment charges relating to our intangible assets since their acquisition.

Income Taxes

Our income tax policy is to record the estimated future tax effects of temporary differences between the tax bases of assets and liabilities and amounts reported in our accompanying consolidated balance sheets, as well as operating loss and tax credit carryforwards. We follow the guidelines set forth in the applicable accounting guidance regarding the recoverability of any tax assets recorded on the consolidated balance sheet and provide any necessary allowances as required. Determining necessary allowances requires us to make assessments about the timing of future events, including the probability of expected future taxable income and available tax planning opportunities. When we determine that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance. The valuation allowance is sufficient to reduce the deferred tax assets to the amount that we determine is more likely than not to be realized. At this time, we have recorded a valuation allowance against the net deferred tax assets.

We are subject to examination of our income tax returns by various tax authorities on a periodic basis. We regularly assess the likelihood of adverse outcomes resulting from such examinations to determine the adequacy of our provision for income taxes. We have applied the provisions of the applicable accounting guidance on accounting for uncertainty in income taxes, which requires application of a more-likely-than-not threshold to the recognition and de-recognition of uncertain tax positions. If the recognition threshold is met, the applicable accounting guidance permits us to recognize a tax benefit measured at the largest amount of tax benefit that, in our judgment, is more than 50 percent likely to be realized upon settlement. It further requires that a change in judgment

related to the expected ultimate resolution of uncertain tax positions be recognized in earnings in the period of such change.

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act (the Tax Act). The Tax Act includes significant changes to the U.S. corporate income tax system including, but not limited to, a federal corporate rate reduction from 35% to 21% and limitations on the deductibility of interest expense and executive compensation. In order to calculate the effects of the new corporate tax rate on our deferred tax balances, ASC 740 *Income Taxes* (ASC 740) required the re-measurement of our deferred tax balances as of the enactment date of the Tax Act, based on the rates at which the balances were expected to reverse in the future. Due to our valuation allowance position and deferred tax liabilities, there is no change to the presentation of the deferred tax balances on the financial statements, except for the re-measurement of these deferred tax balances in the income tax footnote which were fully offset by a corresponding change to our valuation allowance. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As of December 31, 2018, we completed our accounting for all tax effects related to the Tax Act, and there were no material adjustments recorded during the year to the previously recorded provisional amounts reflected in our 2017 financial statements.

RESULTS OF OPERATIONS

Our results of operations in 2018 differ significantly from our reported results for 2017 and 2016.

In December 2017, we entered into the Commercialization Agreement pursuant to which we granted to Collegium the rights to commercialize NUCYNTA. As a result, we only recognized NUCYNTA product sales from January 1, 2018 through January 8, 2018. For the remainder of 2018 we recognized royalty revenue with respect to the Commercialization Agreement.

In November 2017, we entered into agreements with Slán pursuant to which we acquired Slán's rights to market long-acting cosyntropin (synthetic ACTH) in the U.S., and Slán acquired our rights to Lazanda. The fair value of the rights to market long-acting cosyntropin was estimated to be approximately \$24.9 million and, in accordance with the applicable accounting rules, was recorded as "acquired in process research and development" in the accompanying consolidated statements of operations for the year ended December 31, 2017, as long-acting cosyntropin was deemed to have no alternative future use. The related divestiture of Lazanda resulted in a gain of approximately \$17.1 million and was recorded as "gain on divestiture of Lazanda" in the accompanying consolidated statements of operations.

Revenues

Total revenues are summarized in the following table:

(in thousands)	2018	2017	2016
Product sales, net:			
Gralise	\$ 58,077	\$ 77,034	\$ 88,446
CAMBIA	35,803	31,597	31,273
Zipsor	16,387	16,700	27,539
Total neurology product sales, net	110,267	125,331	147,258
NUCYNTA products(1)	18,944	239,539	281,261
Lazanda(2)	755	15,010	26,547
Total product sales, net	129,966	379,880	455,066
Commercialization agreement:			
Commercialization rights and facilitation services, net	100,038	—	—
Revenue from transfer of inventory	55,705	—	—
Royalties and milestone revenue	26,061	844	831
Total revenues	<u>\$311,770</u>	<u>\$380,724</u>	<u>\$455,897</u>

(1) NUCYNTA product sales for the year ended December 31, 2018 reflect our sales of NUCYNTA between January 1 and January 8, 2018. During the year ended December 31, 2018, we recognized sales reserve estimate adjustments related to sales recognized for NUCYNTA and Lazanda in prior periods. During the first quarter of 2018, in connection with the Collegium transaction, we recognized revenue of \$12.5 million related to the release of NUCYNTA sales reserves which were primarily recorded in the fourth quarter of 2017, as financial responsibility for those reserves transferred to Collegium upon closing of the Commercialization Agreement.

(2) We divested Lazanda in November 2017. Product sales for the year ended December 31, 2018 relate to sales reserve estimate adjustments.

Product sales

NUCYNTA. Product sales of NUCYNTA for the year ended December 31, 2018 reflect product sales solely between January 1 and January 8, 2018 prior to closing of the Commercialization Agreement and the release of approximately \$12.5 million of rebate reserves that Collegium assumed pursuant to the terms of the Commercialization Agreement. We will not record NUCYNTA product net sales during the remainder of the term of the Commercialization Agreement. See Note 4, “Revenue” of the Notes to the Consolidated Financial Statements for further discussion of the Commercialization Agreement and the revenue recognized related to such agreement in 2018.

The decrease in NUCYNTA product sales for the year ended December 31, 2017 compared to 2016 was primarily the result of lower unit demand for NUCYNTA attributable to declines in both the long-acting and short-acting opioid prescription markets. In addition, Hurricanes Irma and Maria caused significant devastation and damage throughout Puerto Rico in 2017, including widespread flooding and power loss. As a result, we experienced delays in the manufacture, packaging and delivery of certain dosage strengths of NUCYNTA IR in the third quarter and NUCYNTA ER in the fourth quarters of 2017, from our manufacturer in Puerto Rico, which negatively impacted our results by approximately \$8.0 million. We also experienced spot outages of certain NUCYNTA ER strengths in the first quarter of 2018. We and Collegium may continue to experience such further outages in the future.

Gralise. The decrease in Gralise product sales for the year ended December 31, 2018 compared to 2017 was primarily due to lower prescription demand and higher managed care rebates. The decrease in Gralise product sales for the year ended December 31, 2017 compared to 2016 was primarily due to lower unit demand resulting, in part, from a decline in the number of sales representatives promoting Gralise.

CAMBIA. The increase in CAMBIA product sales for the year ended December 31, 2018 compared to 2017 was primarily the result of increased prices. The increase in CAMBIA product sales for the year ended December 31, 2017 compared to 2016 was primarily a result of lower managed care rebates and lower co-pay assistance programs, partially offset by lower prescription demand.

Zipsor. The decrease in Zipsor product sales for the year ended December 31, 2018 compared to 2017 was primarily the result of reduced demand and increased product returns. The decrease in Zipsor product sales for the year ended December 31, 2017 as compared to the same period in 2016 was a result of reduced unit demand and increased product returns offset, in part, by price increases.

Lazanda. We ceased recording revenues and related costs associated with Lazanda after we divested the product to Slán in November 2017. Product sales for the year ended December 31, 2018 reflect adjustments made for previously recorded sales reserve estimates. The decrease in Lazanda product sales in 2017 as compared to 2016 is primarily a result of lower unit demand attributable to a decline in the Transmucosal Immediate Release Fentanyl (TIRF) prescription market and the cessation of promotion of Lazanda by our salesforce in May 2017 and the divestiture of Lazanda to Slán in November 2017 offset, in part, by price increases.

Pharmacy Benefit Manager. During the three months ended March 31, 2017, we established a reserve with respect to a dispute with a pharmacy benefit manager (PBM) over rebates relating to NUCYNTA ER, NUCYNTA and Gralise. The dispute relates to rebate claims submitted with respect to the year ended December 31, 2015 and the first half of 2016. As of December 31, 2016, we established a reserve for \$1.0 million with respect to these claims, and had determined the likely amount payable on settlement would not be material to the consolidated financial statements. However, as a result of further communication with the PBM during the three months ended March 31, 2017, it became clear that our failure to pay the disputed amount would adversely impact our ability to maintain a favorable position on the PBM's formulary. Accordingly, despite our belief that the claims in dispute were invalid, we increased the reserve against this matter by \$4.7 million which was an offset to net sales for the three months ended March 31, 2017. We paid this amount in the fourth quarter of 2017. There was no impact to the 2018 financial statements as a result of this matter.

Royalties

PDL BioPharma, Inc. In October 2013, we sold our interests in royalty and milestone payments under our license agreements relating to our Acuform technology in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for \$240.5 million. On August 2, 2018, we sold our remaining interest in such payments to PDL for \$20.0 million. The \$20.0 million of revenue was recognized as royalty revenue in the third quarter of 2018.

License and other revenue

Ironwood Pharmaceuticals, Inc. In July 2011, we entered into a collaboration and license agreement with Ironwood granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to our Acuform drug delivery technology for IW-3718, an Ironwood product candidate under evaluation for refractory GERD. During the second and third quarters of 2018, we recognized and collected, respectively, a \$5.0 million contingent milestone payment related to the

dosing of the first patient in a Phase 3 trial for IW 3718. There was no revenue under this agreement in 2017 or 2016.

Cost of Sales

Cost of sales consists of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs, royalties payable to third-parties, inventory write-downs, amortization of inventory write-ups associated with business acquisitions, product quality testing, internal employee costs related to the manufacturing process, distribution costs and shipping costs related to our product sales. Cost of sales excludes the amortization of intangible assets described separately below under “Amortization of Intangible Assets.” Total cost of sales for 2018, 2017 and 2016 was as follows:

(in thousands)	<u>2018</u>	<u>2017</u>	<u>2016</u>
Cost of Sales	\$ 18,476	\$ 72,598	\$87,414
Dollar change from prior year	(54,122)	(14,816)	19,516
Percentage change from prior year	-74.6%	-16.9%	28.7%

NUCYNTA cost of sales for the twelve months ended December 31, 2017 and 2016 was approximately 25%. NUCYNTA cost of sales decreased in 2018, because pursuant to the terms of our Commercialization Agreement, beginning on January 8, 2018, we did not record net sales of NUCYNTA and NUCYNTA ER and, as a result, did not record the cost of sales of such products.

The cost of sales for Gralise, CAMBIA and Zipsor, combined, for the twelve months ended December 31, 2018, 2017 and 2016 was 8.3%, 7.7% and 9.3%, respectively.

Research and Development Expenses & Acquired in-process Research and Development

Our research and development expenses currently include salaries, clinical trial costs, consultant fees, supplies, manufacturing costs for research and development programs and allocations of corporate costs. It is extremely difficult to predict the scope and magnitude of future research and development expenses for our product candidates in research and development, as it is extremely difficult to determine the nature, timing and extent of clinical trials and studies and the FDA’s requirements for a particular drug. As potential products proceed through the development process, each step is typically more extensive, and therefore more expensive, than the previous step. Therefore, success in development generally results in increasing expenditures until actual product approval. Total research and development expenses were as follows:

(in thousands)	<u>2018</u>	<u>2017</u>	<u>2016</u>
Research and development expenses	\$ 8,042	\$ 13,718	\$32,631
Dollar change from prior year	(5,676)	(18,913)	15,090
Percentage change from prior year	-41.4%	-58.0%	86.0%
Acquired in-process research and development	\$ —	24,900	\$ —

Research and development expenses in 2018 decreased compared to 2017 primarily as a result of a \$6.1 million reduction in research related to pediatric trials for NUCYNTA which completed during the second quarter of 2017. In January of 2018, we gave to Grünenthal 120 days’ written notice of termination of the cebranopadol license agreement and did not incur related research and development costs related to cebranopadol in 2018 compared to \$0.9 million in 2017.

Research and development expenses in 2017 decreased compared to 2016 primarily as a result of a reduction in the development costs associated with cebranopadol, completion of certain portions of our ongoing pediatric trials for NUCYNTA during the second quarter of 2017, and delays in the next steps of those pediatric trials.

The acquired in-process research and development costs in 2017 represent the fair value of exclusive rights to market long-acting cosyntropin in the United States, which were acquired in November 2017. The fair value of the rights to market long-acting cosyntropin was estimated to be approximately \$24.9 million and, in accordance with the applicable accounting rules, was recorded as “acquired in-process research and development” as long-acting cosyntropin was deemed to have no alternative future use. In February 2019, notification of acceptance for filing was received from the FDA for our 505(b)(2) NDA for our novel injectable formulation of long-acting cosyntropin. We, together with our development partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency. Cosyntropin was granted orphan drug status in infantile spasms by the FDA in August 2017.

Selling, General and Administrative Expenses

Selling, general and administrative expenses primarily consist of personnel, contract personnel, marketing and promotion expenses associated with our commercial products, personnel expenses to support our administrative and operating activities, facility costs, and professional expenses, such as legal fees. Total selling, general and administrative expenses were as follows:

<i>(in thousands)</i>	<u>2018</u>	<u>2017</u>	<u>2016</u>
Selling, general and administrative expenses	\$119,218	\$195,696	\$204,498
Dollar change from prior year	(76,478)	(8,802)	5,146
Percentage change from prior year	-39.1%	-4.3%	2.6%

The decrease in selling, general and administrative expenses in 2018 compared to 2017 was primarily related to the Commercialization Agreement, which resulted in the elimination of Nucynta related marketing costs and the termination of our pain sales force during the first quarter of 2018, consisting of approximately 255 sales representative and sales manager positions, and our decision to significantly reduce our office staff and reduce our headquarters office space by approximately 50%. In addition, in 2018, we incurred \$2.25 million related to our obligations related to the commercialization of long-acting cosyntropin

The decrease in selling, general and administrative expense in 2017 as compared to 2016 was primarily due to our decision to pay no corporate bonus with respect to the year ended December 31, 2017, the reduction in the stock-based compensation expense and a \$7.7 million reduction in the fair value of contingent consideration relating primarily to our Lazanda acquisition and, to a lesser extent, our CAMBIA and Zipsor acquisitions. The reduction in the fair value of contingent consideration relating to Lazanda reflects the continued deterioration of the market and the cessation of promotion of Lazanda by our salesforce in May 2017. The decrease in the fair value of contingent consideration relating to the CAMBIA and Zipsor acquisitions resulted from a reduction in our estimate of future sales of these products in light of the lower than expected results in 2017. Selling, general and administrative expenses in 2017 include a \$3.4 million adjustment booked in the three months ended March 31, 2017 related to an increase in estimates associated with the branded prescription drug fee of which \$1.4 million related to the year ended 2016.

Amortization of Intangible Assets

(in thousands)	<u>2018</u>	<u>2017</u>	<u>2016</u>
Amortization of intangible assets—NUCYNTA . . .	\$ 94,301	\$ 94,302	\$ 98,207
Amortization of intangible assets—CAMBIA	5,136	5,136	5,136
Amortization of intangible assets—Zipsor	2,337	2,337	2,337
Amortization of intangible assets—Lazanda	—	970	1,165
Total amortization of intangible assets	<u>\$101,774</u>	<u>\$102,745</u>	<u>\$106,845</u>

Following our 2017 divestiture, no amortization expense was recorded relating to Lazanda subsequent to its divestiture. This resulted in lower amortization in 2018 compared to 2017 and was a partial driver of the decrease in amortization in 2017 compared to 2016. The reduction in amortization expense in 2017 as compared to 2016 was primarily due to the change in the estimated useful life of NUCYNTA in the fourth quarter of 2016. In September 2016, the United States District Court for the District of New Jersey ruled in favor of the Company in our patent litigation against all three filers of ANDAs for the NUCYNTA franchise. With the court’s ruling, we expect market exclusivity until December 2025 for NUCYNTA ER, NUCYNTA and NUCYNTA oral solution (an unmarketed form of NUCYNTA). In light of this court ruling, we reviewed the useful life of the NUCYNTA product rights and extended that from the previous estimate of June 2025 to December 2025.

Restructuring Charges

(in thousands)	<u>2018</u>	<u>2017</u>	<u>2016</u>
Employee compensation costs	\$16,852	\$13,247	\$—
Fixed Asset disposals and accelerated depreciation of leasehold improvements	3,511	—	—
Other exit costs	238	—	—
Total restructuring costs	<u>\$20,601</u>	<u>\$13,247</u>	<u>\$—</u>

In June 2017, we announced a reduction-in-force in order to streamline operations and achieve operating efficiencies. In December 2017, we continued our restructuring plans by initiating a company-wide restructuring designed to help position the Company for sustainable, long-term growth that we believe will align our staff and office locations to our strategy. These restructuring activities primarily focused on a reduction of our workforce. Pursuant to our restructuring plans, in February 2018, we eliminated our pain sales force, consisting of approximately 230 sales representative and 25 manager positions. We reduced the staff at our headquarters office during the second quarter of 2018. In the third quarter of 2018, we relocated our corporate headquarters from Newark, California to Lake Forest, Illinois and reduced our headquarters office space by 50%.

We expected to incur total costs related to the December 2017 restructuring plan, including costs incurred in 2017, to be in the range of \$27.0 million to \$33.0 million. For the year ended December 31, 2018 and 2017, restructuring expenses and one-time termination costs were \$20.6 million and \$13.2 million, respectively, and we expect to incur insignificant costs in 2019.

Other Income and Expense

<i>(in thousands)</i>	<u>2018</u>	<u>2017</u>	<u>2016</u>
Litigation settlement	\$ 62,000	\$ —	\$ —
Gain on divestiture of Lazanda	—	17,064	—
Interest and other income	1,197	681	485
Loss on prepayment of Senior Notes	—	(5,938)	(5,777)
Interest expense	<u>\$(68,881)</u>	<u>\$(73,552)</u>	<u>\$(83,719)</u>
	<u>\$ (5,684)</u>	<u>\$(61,745)</u>	<u>\$(89,011)</u>

For the year ended December 31, 2018, other income includes the Settlement Agreement with the Purdue, as further described in “Item 8. Financial Statements and Supplemental Data—Note 12, “Commitments and Contingencies—Legal Matters”. The total settlement amount was \$62.0 million of which \$30.0 million was paid during the three months ended September 30, 2018 and the remaining \$32.0 million was paid in January 2019.

For the year ended December 31, 2017, we recognized a gain related to the divestiture of Lazanda of \$17.1 million.

During the year ended December 31, 2018 we made \$82.5 million of principal payments of the Senior Notes. Additionally, we prepaid and retired \$100.0 million of principal of the Senior Notes in April 2017 and \$10.0 million of principal of the Senior Notes in November 2017. In April 2016, we prepaid and retired \$100.0 million of the Senior Notes. The loss on prepayment of Senior Notes in 2017 and 2016 represents the prepayment fees paid to the lender as well as the acceleration of the unamortized balances of the debt discount and debt issuance costs associated with these prepayments of our debt.

The decrease in interest expense in 2018 compared to 2017 and in 2017 as compared to 2016 is also due to these principal prepayments, offset in part by the impact of increasing interest rates in 2017 and 2018.

Income Tax Provision (Benefit)

During 2018, we recognized income tax expense of approximately \$1.1 million that represents an effective tax rate of 2.81% on income from continuing operations. The difference between income tax provision of \$1.1 million and the tax at the statutory rate of 21% on current year operations is principally due the change in the valuation allowance and accrued interest and penalty related to uncertain tax positions.

During 2017, we recorded a benefit from income taxes of approximately \$1.4 million that represents an effective tax rate of 1.38% on income from continuing operations. The difference between the income tax benefit of \$1.4 million and the tax at the statutory rate of 35% on current year operations is principally due to the change in valuation allowance and the release of liabilities with respect to uncertain tax positions due to the lapse of State statute of limitations.

During 2016, we recognized income tax expense of approximately \$24.2 million that represents an effective tax rate of 37.5% on income from continuing operations. The difference between income tax expense of \$24.2 million and the tax benefit at the statutory rate of 35% was principally due to the recording of a full valuation allowance against our net deferred tax assets in the fourth quarter of 2016.

LIQUIDITY AND CAPITAL RESOURCES

(in thousands)	As of December 31,	
	2018	2017
Cash, cash equivalents and short-term investments	\$110,949	\$128,089

The decrease in cash, cash equivalents and short-term investments during 2018 is primarily attributable to the repayment of \$82.5 million of secured indebtedness. These payments were partially offset by the cash generated from the settlement of the Purdue litigation which resulted in a \$62.0 million gain, of which \$30.0 million was received in 2018, the sale of PDL royalties for \$20.0 million, the milestone royalty received from Ironwood of \$5.0 million and cash generated from operations. We made a scheduled principal payment of secured indebtedness of \$25.0 million in January 2019 and we are required to make additional payments of \$55.0 million in April 2019 and \$20.0 million quarterly thereafter, with a final payment of \$62.5 million in April 2021.

Since inception and through December 31, 2018, we have financed our product development efforts and operations primarily from product sales, private and public sales of equity securities, including convertible debt securities, the proceeds of secured borrowings, the sale of rights to future royalties and milestones to PDL, upfront license, milestone and termination fees from collaborative and license partners, and product sales. In April 2015, we issued \$575.0 million aggregate principal amount of senior secured notes (the Senior Notes) for aggregate gross proceeds of approximately \$562.0 million. In September 2014, we issued \$345.0 million aggregate principal amount of convertible notes due 2021 (the Convertible Notes) resulting in net proceeds to us of \$334.2 million.

During January 2019, we entered into a Fourth Amendment to Note Purchase Agreement (the “Amendment”) with respect to the Note Purchase Agreement, dated as of March 12, 2015, between us, the other credit parties party thereto, the purchasers party thereto and Deerfield. Pursuant to the Amendment, the minimum EBITDA covenant was replaced with a senior secured debt leverage ratio covenant and a minimum net sales covenant, the prepayment premium was adjusted to be 3% of the principal amount of notes prepaid on or prior to April 14, 2020 and 1% of the principal amount of notes prepaid thereafter, flexibility to sell certain royalty assets and/or modify the terms thereof was added, certain definitions were amended and certain other amendments were made.

We were in compliance with our covenants with respect to the Senior Notes as of December 31, 2018. While we are currently in compliance, and anticipate continued compliance with such covenants, we may seek to refinance or restructure our debt, sell assets or obtain additional capital, each of which may be on terms that may be onerous, highly dilutive or disruptive to our business. Any prepayment of the Senior Notes would be subject to a prepayment fee of up to 3% of the principal amount of the Senior Notes prepaid. In addition, in connection with any refinancing of our debt, we would also accelerate the recognition of the balance of the unamortized debt discount and the debt issuance costs as of the date of any refinancing.

We may incur operating losses in future years. We believe that our existing cash and investment balances and cash we expect to generate from operations will be sufficient to fund our operations, and to meet our existing obligations for the foreseeable future, including our obligations under the Senior Notes and the Convertible Notes. We base this expectation on our current operating plan and the anticipated impact of the cash expected to be received from Collegium pursuant to the Commercialization Agreement, which may change as a result of many factors.

Our cash needs may vary materially from our current expectations because of numerous factors, including:

- payments from Collegium pursuant to our Commercialization Agreement;
- acquisitions or licenses of complementary businesses, products, technologies or companies;

- sales of our marketed products;
- expenditures related to our commercialization of Gralise, CAMBIA, and Zipsor;
- expenditures related to our product candidates;
- milestone and royalty revenue we receive under our collaborative development arrangements;
- interest and principal payments on our current and future indebtedness;
- financial terms of definitive license agreements or other commercial agreements we may enter into; and
- changes in the focus and direction of our business strategy and/or research and development programs.

The inability to raise any additional capital that may be required to fund our future operations or product acquisitions and strategic transactions which we may pursue could have a material adverse effect on our company.

The following table summarizes our cash flow activities:

(in thousands)	Year ended December 31,		
	2018	2017	2016
Cash provided by operating activities	\$ 72,497	\$ 62,167	71,263
Cash (used in) provided by investing activities	(7,082)	57,894	45,536
Cash (used in) financing activities	(81,350)	(110,886)	(100,174)
Net (decrease) increase in cash and cash equivalents	<u>\$(15,935)</u>	<u>\$ 9,175</u>	<u>\$ 16,625</u>

Cash Flows from Operating Activities

Cash provided by operating activities was \$72.5 million in 2018, \$62.2 million in 2017 and \$71.3 million in 2016.

The increase in Cash provided by operating activities in 2018 compared to 2017 is due to increased net income from the settlement of the Purdue Litigation, the sale of royalties to PDL and the milestone payment from Ironwood. The decrease in Cash provided by operating activities in 2017, as compared to 2016, is a result lower sales as compared to 2016.

Cash Flows from Investing Activities

Cash used in investing activities in 2018 relates to purchases and property and equipment related primarily to our new headquarters office space in Lake Forest, IL and also includes a \$3.0 million investment in a company engaged in medical research. Cash provided by investing activities during 2017 was approximately \$57.9 million and primarily relates to the timing of maturity of marketable securities in anticipation of the prepayment of debt in April 2017. Cash provided by investing activities during 2016 was approximately \$45.5 million and primarily relates to the timing of maturity of marketable securities in anticipation of the prepayment of debt in April 2016.

Cash Flows from Financing Activities

Cash used in financing activities in 2018 is primarily related to the \$82.5 million of repayments of our Senior Notes. Cash used in financing activities during 2017 was approximately \$110.9 million and reflects the prepayment of \$110.0 million of our Senior Notes as well as an associated prepayment fees of \$4.4 million in 2017 which was partially off-set by proceeds from employee stock option exercises and purchase of common stock under the employee stock purchase plan. Cash used in financing

activities during 2016 was approximately \$100.2 million and reflects the prepayment of \$100.0 million of our Senior Notes as well as an associated prepayment fee of \$5.0 million in April 2016 which was partially off-set by proceeds from employee stock option exercises and purchase of common stock under the employee stock purchase plan.

Contractual Obligations

As of December 31, 2018, our contractual obligations are shown in the following table:

(in thousands)	1 Year	2 - 3 Years	4 - 5 Years	More than 5 Years	Total
Senior Notes—principal	\$120,000	162,500	—	—	\$282,500
Senior Notes—interest	26,125	16,993	—	—	43,118
Convertible Debt—principal	—	345,000	—	—	345,000
Convertible Debt—interest	8,625	17,250	—	—	25,875
Operating leases(1)	2,624	4,848	2,820	—	10,292
Purchase commitments	3,000	3,000	—	—	6,000
Total	<u>\$160,374</u>	<u>\$549,591</u>	<u>\$2,820</u>	<u>\$—</u>	<u>\$712,785</u>

(1) Amounts represent payments under a non-cancelable office and laboratory lease and under an operating lease for vehicles used by our sales force.

At December 31, 2018, we had non-cancelable purchase orders related to consulting services.

Our corporate headquarters is located in Lake Forest, Illinois, where we lease approximately 31,000 square feet of office space (the Lake Forest Lease). Our prior corporate headquarters was located in Newark, California where we entered into an office and laboratory lease agreement to lease approximately 52,500 rentable square feet commencing in December 2012 and approximately 8,000 additional rentable square feet commencing in July 2015 (the Newark Lease). Following the relocation of our corporate headquarters from Newark, California to Lake Forest, Illinois, we entered into subleases for the Newark facility. For additional information regarding the Lake Forest Lease and the Newark Lease, see “Item 8. Financial Statements and Supplementary Data—Note 12. Commitments and Contingencies.”

OFF-BALANCE SHEET ARRANGEMENTS

None.

RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

See “Item 8. Financial Statements and Supplemental Data—Note 1, “Organization and Summary of Significant Accounting Policies” for additional information on recent accounting pronouncements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We had cash and cash equivalents totaling \$110.9 million as of December 31, 2018. A portion of our cash and cash equivalents were invested in corporate debt securities and money market funds. Cash and cash equivalents are held for working capital purposes.

We are subject to interest rate fluctuation exposure through our borrowings under the Senior Secured Credit Facility and our investment in money market accounts which bear a variable interest rate. Borrowings under the Senior Secured Credit Facility bear interest at a rate equal to the lesser of three month LIBOR plus 9.75% per annum, subject to a 1.0% LIBOR floor and 12.95%. Current LIBOR rates are above the 1.0% LIBOR floor, and the interest rate on our borrowings under the Senior Secured Credit Facility is currently 12.15% per annum. An increase in the three month LIBOR of 100 basis points above the current three-month LIBOR rates would increase our interest expense by approximately \$1.7 million for 2019, assuming we timely make the scheduled principal payments. Such increase is limited as our interest rate for our Senior Secured Credit Facility is capped at 12.95%. As of December 31, 2018, we had \$345 million aggregate principal amount of convertible senior notes outstanding, which are fixed rate instruments.

The goals of our investment policy are the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds and short-term corporate debt securities. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

Foreign Currency Risk

We have not had any significant transactions in foreign currencies, nor did we have any significant balances that were due or payable in foreign currencies at December 31, 2018. Accordingly, significant changes in foreign currency rates would not have a material impact on our financial position and results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**ASSERTIO THERAPEUTICS, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Assertio Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Assertio Therapeutics, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) (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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 March 11, 2019 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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1997.

Chicago, Illinois
March 11, 2019

ASSERTIO THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 110,949	\$ 126,884
Short-term investments	—	1,205
Accounts receivable, net	37,211	72,482
Inventories, net	3,396	13,042
Prepaid and other current assets	56,551	17,238
Total current assets	208,107	230,851
Property and equipment, net	13,064	13,024
Intangible assets, net	692,099	793,873
Investments	11,784	—
Other long-term assets	7,812	869
Total assets	\$ 932,866	\$1,038,617
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,138	\$ 14,732
Accrued rebates, returns and discounts	75,759	135,828
Accrued liabilities	31,361	60,496
Income taxes payable	—	126
Current portion of Senior Notes	120,000	82,500
Contingent consideration liability, current portion	—	156
Interest payable	11,645	13,220
Other current liabilities	1,133	3,522
Total current liabilities	246,036	310,580
Contingent consideration liability, long-term portion	1,038	1,457
Senior Notes	158,309	274,720
Convertible Notes	287,798	269,510
Other long-term liabilities	19,350	12,842
Total liabilities	712,531	869,109
Commitments and contingencies		
Shareholders' equity:		
Common stock, \$0.0001 par value, 200,000,000 shares authorized; 64,185,224 and 63,400,348 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	6	6
Additional paid-in capital	402,934	389,015
Accumulated deficit	(182,600)	(219,508)
Accumulated other comprehensive loss	(5)	(5)
Total shareholders' equity	220,335	169,508
Total liabilities and shareholders' equity	\$ 932,866	\$1,038,617

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

ASSERTIO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except per share data)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales, net	\$129,966	\$ 379,880	\$455,066
Commercialization agreement, net	155,743	—	—
Royalties and milestones	26,061	844	831
Total revenues	311,770	380,724	455,897
Costs and expenses:			
Cost of sales (excluding amortization of intangible assets)	18,476	72,598	87,414
Research and development expenses	8,042	13,718	32,631
Acquired in-process research and development	—	24,900	—
Selling, general and administrative expenses	119,218	195,696	204,498
Amortization of intangible assets	101,774	102,745	106,845
Restructuring charges	20,601	13,247	—
Total costs and expenses	268,111	422,904	431,388
Income (loss) from operations	43,659	(42,180)	24,509
Other income (expense):			
Litigation settlement	62,000	—	—
Gain on divestiture of Lazanda	—	17,064	—
Interest and other income	1,197	681	485
Loss on prepayment of Senior Notes	—	(5,938)	(5,777)
Interest expense	(68,881)	(73,552)	(83,719)
Income (loss) before income taxes	37,975	(103,925)	(64,502)
Income tax (expense) benefit	(1,067)	1,429	(24,218)
Net income (loss)	\$ 36,908	\$(102,496)	\$(88,720)
Basic net income (loss) per share	\$ 0.58	\$ (1.63)	\$ (1.45)
Diluted net income (loss) per share	\$ 0.57	\$ (1.63)	\$ (1.45)
Shares used in computing basic net income (loss) per share	63,794	62,702	61,297
Shares used in computing diluted net income (loss) per share	64,208	62,702	61,297

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

ASSERTIO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME / LOSS
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net income (loss)	\$36,908	\$(102,496)	\$(88,720)
Unrealized gain on available-for-sale securities, net of tax	—	14	35
Comprehensive income (loss)	\$36,908	\$(102,482)	\$(88,685)

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

ASSERTIO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Earnings (Deficit)	Accumulated Other Comprehensive Loss	Shareholders' Equity
	Shares	Amount				
Balances at December 31, 2015	60,787	\$ 264,511	\$ 78,622	\$ (28,024)	\$(54)	\$ 315,055
Reclassification due to reincorporation		(264,505)	264,505			
Balances at December 31, 2015	60,787	6	343,127	(28,024)	(54)	315,055
Issuance of common stock upon exercise of options	716	—	6,693	—	—	6,693
Issuance of common stock under employee stock purchase plan . .	201	—	3,258	—	—	3,258
Issuance of common stock in conjunction with vesting of restricted stock units	262	—	—	—	—	—
Stock-based compensation	—	—	17,172	—	—	17,172
Shares withheld for payment of employee's withholding tax liability	—	—	(3,342)	—	—	(3,342)
Windfall tax benefit	—	—	637	—	—	637
Net loss	—	—	—	(88,720)	—	(88,720)
Unrealized gain on available-for-sale securities	—	—	—	—	35	35
Balances at December 31, 2016	61,966	\$ 6	\$367,545	\$(116,744)	\$(19)	\$ 250,788
Issuance of common stock upon exercise of options	1,001	—	6,979	—	—	6,979
Issuance of common stock under employee stock purchase plan . .	262	—	1,960	—	—	1,960
Issuance of common stock in conjunction with vesting of restricted stock units	171	—	—	—	—	—
Stock-based compensation	—	—	13,016	—	—	13,016
Cumulative effect adjustment from adoption of ASU No. 2016-09 . .	—	—	268	(268)	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	(753)	—	—	(753)
Net loss	—	—	—	(102,496)	—	(102,496)
Unrealized gain on available-for-sale securities	—	—	—	—	14	14
Balances at December 31, 2017	63,400	\$ 6	\$389,015	\$(219,508)	\$ (5)	\$ 169,508
Issuance of common stock upon exercise of options	278	—	1,493	—	—	1,493
Issuance of common stock under employee stock purchase plan . .	107	—	527	—	—	527
Issuance of common stock in conjunction with vesting of restricted stock units	400	—	—	—	—	—
Stock-based compensation	—	—	12,585	—	—	12,585
Shares withheld for payment of employee's withholding tax liability	—	—	(686)	—	—	(686)
Net income	—	—	—	36,908	—	36,908
Balances at December 31, 2018	64,185	\$ 6	\$402,934	\$(182,600)	\$ (5)	\$ 220,335

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

ASSERTIO THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Operating Activities			
Net income (loss)	\$ 36,908	\$(102,496)	\$ (88,720)
Adjustments for non-cash items:			
Depreciation and amortization	106,426	105,502	109,375
Accretion of debt discount and debt issuance costs	21,877	19,415	17,673
Loss on prepayment of Senior Notes	—	5,938	5,777
Provision for inventory obsolescence	598	2,673	1,179
(Gain) loss on disposal of property and equipment	669	(271)	—
Stock-based compensation	12,585	13,016	17,172
Change in fair value of contingent consideration	(391)	(8,024)	1,637
Deferred income taxes	—	—	23,632
Gain on divestiture of Lazanda	—	(17,064)	—
Acquired in-process research and development	—	24,900	—
Other	1,023	240	611
Changes in assets and liabilities:			
Accounts receivable	35,271	30,107	(30,902)
Inventories	9,048	(1,873)	(3,718)
Prepaid and other assets	(56,136)	(5,114)	(2,464)
Income taxes receivable	—	—	6,359
Accounts payable and other accrued liabilities	(33,610)	(6,436)	5,862
Accrued rebates, returns and discounts	(60,069)	4,292	10,478
Interest payable	(1,576)	(2,705)	(2,747)
Income taxes payable	(126)	67	59
Net cash provided by operating activities	<u>72,497</u>	<u>62,167</u>	<u>71,263</u>
Investing Activities			
Purchases of property and equipment	(5,507)	(666)	(2,860)
Investment in convertible instrument	(3,000)	—	—
Proceeds from disposal of property and equipment	145	280	—
Purchases of marketable securities	—	(8,277)	(68,818)
Proceeds from sale of other assets	80	66,557	115,207
Sales of marketable securities	1,200	—	2,007
Net cash provided (used in) by investing activities	<u>(7,082)</u>	<u>57,894</u>	<u>45,536</u>
Financing Activities			
Payment of contingent consideration liability	(184)	(1,673)	(1,783)
Repayment of Senior Notes	(82,500)	(110,000)	(100,000)
Fees for early repayment and modifications of Senior Notes	—	(7,400)	(5,000)
Proceeds from issuance of common stock	2,020	8,940	9,951
Shares withheld for payment of employee's withholding tax liability	(686)	(753)	(3,342)
Net cash (used in) financing activities	<u>(81,350)</u>	<u>(110,886)</u>	<u>(100,174)</u>
Net increase (decrease) in cash and cash equivalents	(15,935)	9,175	16,625
Cash and cash equivalents at beginning of year	126,884	117,709	101,084
Cash and cash equivalents at end of period	<u>\$110,949</u>	<u>\$ 126,884</u>	<u>\$ 117,709</u>
Supplemental Disclosure of Cash Flow Information			
Net cash paid (received) for income taxes	\$ 6,472	\$ 121	\$ (14,425)
Cash paid for interest	\$ 48,440	\$ 55,542	\$ 71,093
Non-cash consideration for in-process research and development	\$ —	\$ 19,900	\$ —
Accrued research and development	\$ —	\$ 5,000	\$ —
Capital expenditures incurred but not yet paid	\$ 212	\$ —	\$ 402

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Assertio is a specialty pharmaceutical company focused on neurology, orphan and specialty medicines. The Company's current specialty pharmaceutical business includes the following three products which the Company markets in the U.S.:

- Gralise® (gabapentin), a once daily product for the management of postherpetic neuralgia (PHN), that was launched in October 2011.
- CAMBIA® (diclofenac potassium for oral solution), a non-steroidal anti-inflammatory drug for the acute treatment of migraine attacks, that was acquired by the Company in December 2013.
- Zipsor® (diclofenac potassium liquid filled capsules), a non-steroidal anti-inflammatory drug for the treatment of mild to moderate acute pain, that was acquired by the Company in June 2012.

The Company also has the exclusive rights to market long-acting cosyntropin (synthetic adrenocorticotrophic hormone, or ACTH) in the U.S. and Canada. Long-acting cosyntropin is an alcohol-free formulation of a synthetic analogue of ACTH. In February 2019, notification of acceptance for filing was received from the U.S. Food and Drug Administration (FDA) for our 505(b)(2) New Drug Application (NDA) for the novel injectable formulation of long-acting cosyntropin. The Company, together with its development partner, seek approval for the use of this product as a diagnostic drug in the screening of patients presumed to have adrenocortical insufficiency.

The Company maintains a Commercialization Agreement with Collegium Pharmaceutical, Inc. (Collegium) pursuant to which the Company granted Collegium the right to commercialize the NUCYNTA® franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. The Company receives a royalty on all NUCYNTA revenues based on certain net sales thresholds.

Basis of Preparation

The Company's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and US Securities and Exchange Commission (SEC) regulations for annual reporting.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Depomed Bermuda Ltd (Depo Bermuda), Depo NF Sub, LLC (Depo NF Sub) and Depo DR Sub, LLC (Depo DR Sub). All intercompany accounts and transactions have been eliminated on consolidation.

On November 17, 2015, the Company entered into a definitive agreement to acquire the U.S. and Canadian rights to cebranopadol and its related follow-on compound from Grünenthal GmbH (Grünenthal). The acquisition of these rights closed on December 30, 2015 at which point the Company assigned its rights under the agreement to Depo Bermuda, a Company which was formed in Bermuda on December 22, 2015.

Depo NF Sub was formed on March 26, 2015, in connection with a Note Purchase Agreement dated March 12, 2015 (Note Purchase Agreement) governing the Company's issuance of \$575.0 million

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

aggregate principal amount of Senior Notes on April 2, 2015, for aggregate gross proceeds of approximately \$562.0 million. On April 2, 2015, the Company and Depo NF Sub entered into a Pledge and Security Agreement with the Collateral Agent pursuant to which the Company and Depo NF Sub each granted the Collateral Agent (on behalf of the Purchasers) a security interest in substantially all of their assets, other than specifically excluded assets.

Depo DR Sub was formed in October 2013 for the sole purpose of facilitating the PDL Transaction. The Company contributed to Depo DR Sub all of its rights, title and interests in each of the license agreements to receive royalty and contingent milestone payments. Immediately following the transaction, Depo DR Sub sold to PDL, among other things, such rights to receive royalty and contingent milestone payments, for an upfront cash purchase price of \$240.5 million.

The Company and Depo DR Sub continue to retain certain administrative duties and obligations under the specified license agreements. These include the collection of the royalty and milestone amounts due and enforcement of related provisions under the specified license agreements, among others. In addition, the Company and Depo DR Sub must prepare a quarterly distribution report relating to the specified license agreements, containing, among other items, the amount of royalty payments received by the Company, reimbursable expenses and set-offs. The Company and Depo DR Sub must also provide PDL with notice of certain communications, events or actions with respect to the specified license agreements and infringement of any underlying intellectual property.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as sales discounts and returns, depreciable and amortizable lives, share-based compensation assumptions and taxes on income. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of the Company's business and operations, actual results could differ materially from these estimates.

Cash, Cash Equivalents, Short-term Investments and Marketable Securities

The Company considers all highly liquid investments with an original maturity (at date of purchase) of three months or less to be cash equivalents. All marketable securities with original maturities at the date of purchase greater than three months and remaining maturities of less than one year are classified as short-term investments. Cash and cash equivalents consist of cash on deposit with banks, money market instruments and commercial paper. The Company places its cash, cash equivalents, short-term investments and marketable securities with high quality U.S. government and financial institutions and to date has not experienced material losses on any of its balances.

Accounts Receivable

Trade accounts receivable are recorded net of allowances for cash discounts for prompt payment. To date the Company has not recorded a bad debt allowance since the majority of its product revenue comes from sales to a limited number of financially sound companies who have historically paid their balances timely. The need for a bad debt allowance is evaluated each reporting period based on the

**NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)**

Company's assessment of the credit worthiness of its customers or any other potential circumstances that could result in bad debt.

Inventories

Inventories are stated at the lower of cost or net realizable value with cost determined by specific manufactured lot. Inventories consist of costs of the active pharmaceutical ingredient, contract manufacturing and packaging costs. The Company writes-off the value of inventory for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and projected demand.

Investments

Assertio has two long-term investments as of December 31, 2018. During the year ended December 31, 2018, Assertio invested \$3.0 million in a company engaged in medical research. This investment is structured as a long-term loan receivable with a convertible feature. The loan is valued at recoverable cost, which is \$3.0 million and following an impairment assessment, it has been concluded that there is no impairment.

Assertio received warrants to purchase Collegium stock in conjunction with the November 2018 amendment to the Commercialization Agreement. Such warrants are measured at fair value with changes in fair value recorded in other income and expense on the Company's Consolidated Statements of Operation.

Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at date of acquisition at their respective fair values. The fair value of the consideration paid, including contingent consideration, is assigned to the underlying net assets of the acquired business based on their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Significant judgments are used in determining the estimated fair values assigned to the assets acquired and liabilities assumed and in determining estimates of useful lives of long-lived assets. Fair value determinations and useful life estimates are based on, among other factors, estimates of expected future net cash flows, estimates of appropriate discount rates used to present value expected future net cash flows, the assessment of each asset's life cycle, and the impact of competitive trends on each asset's life cycle and other factors. These judgments can materially impact the estimates used to allocate acquisition date fair values to assets acquired and liabilities assumed and the resulting timing and amounts charged to, or recognized in current and future operating results. For these and other reasons, actual results may vary significantly from estimated results.

Any changes in the fair value of contingent consideration resulting from a change in the underlying inputs is recognized in operating expenses until the contingent consideration arrangement is settled. Changes in the fair value of contingent consideration resulting from the passage of time are recorded within interest expense until the contingent consideration is settled.

If the acquired net assets do not constitute a business under the acquisition method of accounting, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, the amount allocated to acquired in-process research and development (IPR&D) with no alternative future use is charged to expense at the acquisition date.

**NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)**

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets, as follows:

Furniture and office equipment	3 - 5 years
Machinery and equipment	5 - 7 years
Laboratory equipment	3 - 5 years
Leasehold improvements	Shorter of estimated useful life or lease term

Intangible Assets

Intangible assets consist of purchased developed technology and trademarks. The Company determines the fair values of acquired intangible assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to, developing appropriate discount rates and estimating future cash flows from product sales and related expenses. The fair value recorded is amortized on a straight-line basis over the estimated useful life of the asset. The Company evaluates purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when the fair value of the asset is lower than the carrying amount. To test for impairment, the Company estimates undiscounted future cash flows expected to result from the use of the asset and its eventual disposition and compares that amount to the asset's carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions.

Revenue Recognition

The Company adopted ASC 606, Revenue from Contracts with Customers (ASC 606) on January 1, 2018 using the modified retrospective transition method. There was no adjustment to the Company's opening balance of accumulated deficit resulting from the adoption of this guidance.

Prior to the adoption of ASC 606, the Company recognized revenue from the sale of its products, royalties earned, and payments received and services performed under contractual arrangements in accordance with ASC 605. Under ASC 605, Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable and the Company is reasonably assured of collecting the resulting receivable. Revenue arrangements with multiple elements are evaluated to determine whether the multiple elements meet certain criteria for dividing the arrangement into separate units of accounting, including whether the delivered element(s) have stand-alone value to the Company's customer or licensee. Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the performance period.

Under ASC 606, the Company recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company 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

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation, when (or as) the performance obligation is satisfied. The Company assesses the term of the contract based upon the contractual period in which the Company and Collegium have enforceable rights and obligations.

Variable consideration arising from sales or usage-based royalties, promised in exchange for a license of the Company's Intellectual Property, is recognized at the later of (i) when the subsequent product sales occur or (ii) the performance obligation, to which some or all of the sales-based royalty has been allocated, has been satisfied.

The Company recognizes a contract asset relating to its conditional right to consideration for completed performance obligations. Accounts receivable are recorded when the right to consideration becomes unconditional. A contract liability is recorded for payments received in advance of the related performance obligation being satisfied under the contract.

Commercialization Agreement

The Company derives revenue under its Commercialization Agreement with Collegium whereby the Company granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. The Company entered into the Commercialization Agreement in December 2017, which became effective in January 2018, and amended the agreement in August 2018 and again in November 2018. The Company views its performance obligations as a series of distinct goods or services that are substantially the same and that have the same pattern of transfer. Prior to the November 2018 amendment, the consideration related to the license and facilitation services was fixed and recognized ratably over the contract term. Following the November 2018 amendment, the royalty payments owed to the Company from Collegium, pursuant to the terms of the Commercialization Agreement, represent variable compensation that is subject to the sales based royalty exception for licenses of intellectual property because the License is the predominant component of this arrangement.

The Company is responsible for royalty payments to a third party related to sales of NUCYNTA. Under the terms of the Commercialization Agreement, a portion of these payments are remitted from Collegium to the third party and a portion are the responsibility of the Company. Following the November 2018 amendment, Collegium will reimburse the Company for all royalties paid to the third party. As the Company is not actively commercializing NUCYNTA, such royalties are recorded by the Company on a systematic basis in proportion to the underlying net product sales and are included as gross-to-net adjustments in the related revenue line in the Company's Statements of Operations.

Product Sales

The Company sells commercial products to wholesale distributors, specialty pharmacies and retail pharmacies. Product sales revenue is recognized when title has transferred to the customer and the customer has assumed the risks and rewards of ownership, which typically occurs on delivery to the customer. The Company's performance obligation is to deliver product to the customer, and the

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

performance obligation is completed upon delivery. The transaction price consists of a fixed invoice price and variable product sales allowances, which include rebates, discounts and returns. Product sales revenues are recorded net of applicable reserves for these product sales allowances. Receivables related to product sales are typically collected one to two months after delivery.

Product Sales Allowances—The Company considers products sales allowances to be variable consideration and estimates and recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on actual or estimated amounts owed on the related sales. These estimates take into consideration the terms of the Company’s agreements with customers, historical product returns, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product and specific known market events, such as competitive pricing and new product introductions. The Company uses the most likely method in estimating product sales allowances. If actual future results vary from the Company’s estimates, the Company may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. The Company’s sales allowances include:

Product Returns—The Company allows customers to return product for credit with respect to that product within six months before and up to 12 months after its product expiration date. The Company estimates product returns and associated credit on NUCYNTA ER and NUCYNTA, Gralise, CAMBIA, Zipsor and Lazanda. Estimates for returns are based on historical return trends by product or by return trends of similar products, taking into consideration the shelf life of the product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels and consideration of the introduction of competitive products. The Company did not assume financial responsibility for returns of NUCYNTA ER and NUCYNTA previously sold by Janssen Pharma or Lazanda product previously sold by Archimedes Pharma US Inc. Under the Commercialization Agreement with Collegium for NUCYNTA ER and NUCYNTA and the divestiture of Lazanda to Slán, the Company is only financially responsible for product returns for product that were sold by the Company, which are identified by specific lot numbers.

The shelf life of NUCYNTA ER and NUCYNTA is 24 months to 36 months from the date of tablet manufacture. The shelf life of Gralise is 24 months to 36 months from the date of tablet manufacture. The shelf life of CAMBIA is 24 months to 48 months from the manufacture date. The shelf life of Zipsor is 36 months from the date of tablet manufacture. The shelf life of Lazanda is 24 to 36 months from the manufacture date. Because of the shelf life of the Company’s products and its return policy of issuing credits with respect to product that is returned within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when the Company issues credit on a returned product. Accordingly, the Company may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments.

Wholesaler and Retail Pharmacy Discounts—The Company offers contractually determined discounts to certain wholesale distributors and retail pharmacies that purchase directly from it. These discounts are either taken off invoice at the time of shipment or paid to the customer on a quarterly basis one to two months after the quarter in which product was shipped to the customer.

Prompt Pay Discounts—The Company offers cash discounts to its customers (generally 2% of the sales price) as an incentive for prompt payment. Based on the Company’s experience, the Company expects its customers to comply with the payment terms to earn the cash discount.

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

Patient Discount Programs—The Company offers patient discount co-pay assistance programs in which patients receive certain discounts off their prescriptions at participating retail pharmacies. The discounts are reimbursed by the Company approximately one month after the prescriptions subject to the discount are filled.

Medicaid Rebates—The Company participates in Medicaid rebate programs, which provide assistance to certain low income patients based on each individual state’s guidelines regarding eligibility and services. Under the Medicaid rebate programs, the Company pays a rebate to each participating state, generally two to three months after the quarter in which prescriptions subject to the rebate are filled.

Chargebacks—The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract with the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product.

Managed Care Rebates—The Company offers discounts under contracts with certain managed care providers. The Company generally pays managed care rebates one to three months after the quarter in which prescriptions subject to the rebate are filled.

Medicare Part D Coverage Gap Rebates—The Company participates in the Medicare Part D Coverage Gap Discount Program under which it provides rebates on prescriptions that fall within the “donut hole” coverage gap. The Company generally pays Medicare Part D Coverage Gap rebates two to three months after the quarter in which prescriptions subject to the rebate are filled.

Royalties

For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes royalty revenue at the later of (1) when the related sales occur, or (2) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Milestones

For arrangements that include milestones, the Company recognizes such revenue using the most likely method. As part of adopting ASC 606, the Company evaluated whether the future milestones should have been included as part of the transaction price in periods before January 1, 2018. The Company concluded that because of development and regulatory risks at the time, it was probable that a significant revenue reversal could have occurred. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment.

Stock-Based Compensation

The Company uses the Black Scholes option valuation model to determine the fair value of stock options and employee stock purchase plan (ESPP) shares. The determination of the fair value of these awards on the date of grant uses an option valuation model and is affected by the Company’s stock price as well as assumptions, which include the Company’s expected term of the award, the expected stock price volatility, risk free interest rate and expected dividends over the expected term of the

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

award. The Company uses historical option exercise data to estimate the expected term of the options. The Company estimates the volatility of its common stock price by using the historical volatility over the expected term of the options. The Company bases the risk free interest rate on U.S. Treasury zero coupon issues with terms similar to the expected term of the options as of the date of grant. The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model. The fair value of restricted stock units equals the market value of the underlying stock on the date of grant.

As a result of adopting ASU 2016-9 *Improvements to Employee Share-Based Payment Accounting*, the Company made an accounting policy election to account for forfeitures as they occur, rather than estimating expected forfeitures at the time of the grant.

Research and Development Expense and Accruals

Research and development expenses include salaries, clinical trial costs, consultant fees, supplies, manufacturing costs for research and development programs and allocations of corporate costs. All such costs are charged to research and development expense as incurred. These expenses result from the Company's independent research and development efforts as well as efforts associated with collaborations. The Company reviews and accrues clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Acquired In-Process Research and Development

The initial costs of rights to IPR&D projects acquired in an asset acquisition are expensed as IPR&D unless the project has an alternative future use. Development costs incurred after an acquisition are expensed as incurred.

Shipping and Handling Costs

Shipping and handling costs incurred for product shipments are recorded in cost of sales in the Statements of Operations.

Advertising Costs

Costs associated with advertising are expensed as incurred. Advertising expense for the years ended December 31, 2018, 2017 and 2016 were \$0.8 million, \$3.7 million and \$4.1 million, respectively.

Restructuring

Restructuring costs are included in income (loss) from operations in the consolidated statements of operations. The Company has accounted for these costs in accordance with ASC Topic 420, *Exit or Disposal Cost Obligations*. One-time termination benefits are recorded at the time they are communicated to the affected employees. In December 2017, the Company announced a restructuring plan which was substantially complete as of December 31, 2018.

**NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)**

Income Taxes

The Company's income tax policy is to record the estimated future tax effects of temporary differences between the tax bases of assets and liabilities and amounts reported in the Company's accompanying consolidated balance sheets, as well as operating loss and tax credit carryforwards. The Company follows the guidelines set forth in the applicable accounting guidance regarding the recoverability of any tax assets recorded on the consolidated balance sheet and provides any necessary allowances as required. Determining necessary allowances requires the Company to make assessments about the timing of future events, including the probability of expected future taxable income and available tax planning opportunities.

The Company is subject to examination of its income tax returns by various tax authorities on a periodic basis. The Company regularly assesses the likelihood of adverse outcomes resulting from such examinations to determine the adequacy of its provision for income taxes. The Company has applied the provisions of the applicable accounting guidance on accounting for uncertainty in income taxes, which requires application of a more-likely-than-not threshold to the recognition and de-recognition of uncertain tax positions. If the recognition threshold is met, the applicable accounting guidance permits the Company to recognize a tax benefit measured at the largest amount of tax benefit that, in the Company's judgment, is more than 50 percent likely to be realized upon settlement. It further requires that a change in judgment related to the expected ultimate resolution of uncertain tax positions be recognized in earnings in the period of such change.

Segment Information

The Company operates in one operating segment and has operations and long-lived assets solely in the United States. To date, all of the Company's revenues from product sales are related to sales in the United States.

Concentration of Risk

The Company invests cash that is currently not being used for operational purposes in accordance with its investment policy in low-risk debt securities of the U.S. Treasury, U.S. government sponsored agencies and very highly rated banks and corporations. The Company is exposed to credit risk in the event of a default by the institutions holding the cash equivalents and available-for sale securities to the extent recorded on the consolidated balance sheet.

The Company is subject to credit risk from its accounts receivable related to product sales and royalties. The three large, national wholesale distributors represent the vast majority of the Company's

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

business and represented the following percentages of product shipments and accounts receivable for the years ended December 31, 2018, 2017 and 2016.

	Consolidated revenue			Accounts Receivable related to product sales		
	2018	2017	2016	2018	2017	2016
McKesson Corporation	14%	36%	36%	28%	41%	39%
AmerisourceBergen Corporation	13%	27%	27%	28%	27%	33%
Cardinal Health	11%	26%	25%	32%	23%	20%
Collegium	55%	—%	—%	—%	—%	—%
All others	7%	11%	12%	12%	9%	8%
Total	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>	<u>100%</u>

Accounts receivable balances related to product sales were \$23.1 million and \$71.9 million for the years ended December 31, 2018 and 2017, respectively. The Company relies on a single third-party contract manufacturer organization in Puerto Rico to manufacture Gralise and one third-party supplier for the supply of gabapentin, the active pharmaceutical ingredient in Gralise. The Company also relies on single third party contract suppliers: MiPharm, S.p.A., Catalent Ontario Limited and Renaissance Lakewood, Inc. for supply of CAMBIA, Zipsor and Lazanda respectively. Janssen Pharmaceuticals is the sole source supplier of NUCYNTA ER and Halo is the sole supplier of NUCNYTA.

Receivables related to Collegium following the commencement of the Commercialization Agreement in 2018 were \$14.0 million at December 31, 2018. Inventory held on behalf of Collegium, which is in production at contract manufacturers and will be provided to Collegium following the completion of production of \$2.8 million is held in prepaid and other assets on the Company's Consolidated Balance Sheets as of December 31, 2018. The Company had a receivable related to the Cosyntropin collaboration from our collaboration partner, an affiliate of Slán Medicinal Holdings of \$4.6 million. Accounts receivable related to royalties were zero and \$0.5 million at December 31, 2018 and 2017, respectively.

To date, the Company has not experienced any losses with respect to the collection of its accounts receivable and believes that its entire accounts receivable balances are collectible.

The Company is dependent upon third-party manufacturers to supply product for commercialize use. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for all commercialized products. Such production arrangements could be adversely affected by a significant interruption which would negatively impact the supply of final drug product.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-9, Revenue from Contracts with Customers. This guidance outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model requires revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services.

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

The Company adopted ASC 606 using the modified retrospective method as of January 1, 2018. The Company determined that there was no cumulative effect of applying the new guidance to all contracts with customers that were not completed as of January 1, 2018, therefore no adjustment was required to the accumulated deficit as of the adoption date. Furthermore, upon adoption of the new guidance no adjustments to any prior year periods would have been reportable to present the condensed consolidated balance sheets, statements of operations, or statements of cash flows on a comparable basis to any current year reported balances or amounts.

In January 2017, the FASB issued ASU No. 2017-1, Business Combinations (Topic 805): Clarifying the Definition of a Business, which provides clarification on the definition of a business and adds guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The standard was effective for the Company beginning January 1, 2018. The future impact of ASU No. 2017-1 will be dependent upon the nature of the Company's future acquisition or disposition transactions, if any.

In May 2017, the FASB issued accounting guidance to clarify which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was required to be applied prospectively. The guidance was effective for the Company beginning January 1, 2018. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In March 2018, the FASB issued ASU No. 2018-5, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, which provides clarification and guidance on the income tax accounting implications of the Tax Cuts and Jobs Act. The standard was effective for the Company beginning January 1, 2018. The adoption of this guidance did not materially affect the Company's consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-1, Financial Instruments—Overall (Subtopic 405-20), Recognition and Measurement of Financial Assets and Financial Liabilities. ASU 2016-1 changed accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, it clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The guidance became effective for the Company on January 1, 2018 and required adoption using a modified retrospective approach, with certain exceptions. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-2, Leases. This guidance requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. The Company has adopted the standard as of January 1, 2019. The Company has elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows for the carryforward of the historical lease classification. The Company did not elect the hindsight practical expedient to determine the reasonably certain lease term for existing leases and will make an accounting policy election to keep leases with an initial term

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES
(Continued)

of 12 months or less off of the balance sheet. The Company will recognize the cost of those leases in the Consolidated Statements of Operations on a straight-line basis over the lease term.

The Company estimates the adoption of the standard will result in recognition of additional lease assets and lease liabilities which are expected to be equal to each other, in the range of approximately \$8.5 million to \$9.5 million, as of January 1, 2019. The recognition of lease assets will be offset by deferred rent and tenant improvement allowances recognized by the Company as of December 31, 2018. The new standard will not materially affect the Company's consolidated net income nor have a notable impact on its liquidity. The standard will have no impact on the Company's debt-covenant compliance under its current agreements.

In June 2016, the FASB issued ASU 2016-13 (ASU 2016-13) Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. ASU 2016-13 is effective for annual reporting periods, and interim periods within those years beginning after December 15, 2019. The Company is currently in the process of evaluating the impact of the adoption of ASU 2016-13 on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-18 (ASU 2018-18) Collaborative Arrangements which clarifies the interaction between ASC 808, Collaborative Arrangements and ASC 606, Revenue from Contracts with Customers. The update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This update will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606 and early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption of ASU 2018-18 on the Company's consolidated financial statements.

NOTE 2. LICENSE AND COLLABORATIVE ARRANGEMENTS

Ironwood Pharmaceuticals, Inc.

In July 2011, the Company entered into a collaboration and license agreement with Ironwood Pharmaceuticals, Inc. (Ironwood Agreement) granting Ironwood a license for worldwide rights to certain patents and other intellectual property rights to the Company's Acuform drug delivery technology for IW 3718, an Ironwood product candidate under development for refractory GERD. During the third quarter of 2018, the Company recognized, within Royalties and Milestones on the Company's Consolidated Statements of Operations, a \$5.0 million milestone payment related to the dosing of the first patient in a Phase 3 trial for IW-3718. The Company will receive additional contingent milestone payments upon the occurrence of certain development milestones and royalties on net sales of the product, if approved.

Slán Medicinal Holdings, Ltd.

In November 2017, the Company entered into definitive agreements (Slán Agreements) with Slán Medicinal Holdings Limited and certain of its affiliates (Slán) pursuant to which the Company acquired

NOTE 2. LICENSE AND COLLABORATIVE ARRANGEMENTS (Continued)

Slán’s rights to market the specialty drug long-acting cosyntropin in the U.S. and Canada. As outlined in the Slán Agreements, each party will support the development, including clinical development, of the licensed product and efforts to obtain regulatory approval of the initial NDA. The Slán Agreements also detail commercialization activities which are included in the commercialization plan. Subsequent to approval of the initial NDA, Assertio and Slán will share in the net sales of long acting cosyntropin for a 10-year period (after which time the product will revert back to Slán). The Company has committed to invest \$15.0 million in the collaboration with Slán for the commercialization efforts of long-acting cosyntropin. As of the December 31, 2018 the Company had incurred \$4.6 million of development expenses which are reimbursable by Slán and have been recognized within Prepaid and Other Assets on the Company’s Consolidated Balance Sheet. The Company also recognized expenses of \$2.25 million which are payable to Slán following the initial NDA filing in December 2018.

NOTE 3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Securities classified as cash and cash equivalents and short-term investments as of December 31, 2018 and 2017 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

<u>December 31, 2018</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash and cash equivalents:				
Cash	\$ 95,660	\$—	\$—	\$ 95,660
Money market funds	11	—	—	11
Agency Bond	1,250	—	—	1,250
Commercial paper	14,028	—	—	14,028
Total cash and cash equivalents	<u>110,949</u>	<u>—</u>	<u>—</u>	<u>110,949</u>
<u>December 31, 2017</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash and cash equivalents:				
Cash	\$103,119	\$—	\$—	\$103,119
Money market funds	95	—	—	95
Commercial paper	23,670	—	—	23,670
Total cash and cash equivalents	126,884	—	—	126,884
Short-term investments				
Corporate debt securities and commercial paper with maturities less than 1 year	1,210	—	(5)	1,205
Total short-term investments	<u>1,210</u>	<u>—</u>	<u>(5)</u>	<u>1,205</u>
Total	<u>\$128,094</u>	<u>\$—</u>	<u>\$(5)</u>	<u>\$128,089</u>

The Company considers all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash and cash equivalents generally consist of cash on deposit with banks, money market instruments, U.S. Agency discount notes, commercial paper and corporate debt securities.

The Company invests its cash in money market funds and marketable securities including U.S. Treasury and government agency securities, commercial paper, and high quality debt securities of

NOTE 3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS (Continued)

financial and commercial institutions. To date, the Company has not experienced material losses on any of its balances. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in “accumulated other comprehensive loss” within shareholders’ equity on the consolidated balance sheets. The Company uses the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in “interest and other income” in the consolidated statement of operations.

At December 31, 2018, the Company had zero securities in an unrealized loss position. The following table shows the gross unrealized losses and fair value of the Company’s investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2017 (in thousands):

	<u>Less than 12 months</u>		<u>12 months or greater</u>		<u>Total</u>	
	<u>Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>	<u>Gross Unrealized Losses</u>
Corporate debt securities	<u>\$1,205</u>	<u>\$(5)</u>	<u>\$—</u>	<u>\$—</u>	<u>\$1,205</u>	<u>\$(5)</u>

The gross unrealized losses above were caused by interest rate increases. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of the securities held by the Company. Based on the Company’s review of these securities, including the assessment of the duration and severity of the unrealized losses and the Company’s ability and intent to hold the investments until maturity, there were no material other-than-temporary impairments for these securities at December 31, 2018. Gross realized gains and losses on marketable securities were not material for the years ended December 31, 2018, 2017 and 2016.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

NOTE 3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS (Continued)

The following table represents the Company’s fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2018 (in thousands):

<u>December 31, 2018</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Money market funds	\$11	\$ —	\$ —	\$ 11
Agency bond	—	1,250	—	1,250
Commercial paper	—	14,028	—	14,028
Collegium warrants	—	8,784	—	8,784
Total	<u>\$11</u>	<u>\$24,062</u>	<u>\$ —</u>	<u>\$24,073</u>
Liabilities:				
Contingent consideration—Zipsor	\$—	\$ —	\$ 531	\$ 531
Contingent consideration—CAMBIA	—	—	507	507
Total	<u>\$—</u>	<u>\$ —</u>	<u>\$1,038</u>	<u>\$ 1,038</u>

The fair value of the warrants to purchase Collegium’s common stock was calculated using the Black-Scholes option pricing model. As of November 8, 2018, the significant inputs included the fair value of Collegium’s common stock of \$15.56, an expected term of 4 years and a risk-free rate of 3.05%. As of December 31, 2018, the significant inputs included the fair value of Collegium’s common stock of \$17.17, an expected term of 3.86 years and a risk-free rate of 2.48%. The expected term was based on the remaining contractual period of 3.86 years, and the volatility was determined using Collegium’s historical common stock volatility over the expected term.

The fair value measurement of the contingent consideration obligations arises from the Zipsor, CAMBIA and Lazanda acquisitions and relates to fair value of the potential future contingent milestone payments and royalties payable under the respective agreements which are determined using Level 3 inputs. The remaining contingent consideration liability following the divestiture of Lazanda in November 2017 was \$0.2 million. This liability was settled in the first quarter of 2018. The key assumptions in determining the fair value are the discount rate and the probability assigned to the potential milestones and royalties being achieved. At each reporting date, the Company re-measures the contingent consideration obligation arising from the above acquisitions to their estimated fair values. Any changes in the fair value of contingent consideration resulting from a change in the underlying inputs are recognized in operating expenses until the contingent consideration arrangement is settled. Changes in the fair value of contingent consideration resulting from the passage of time are recorded within interest expense until the contingent consideration is settled.

The table below provides a summary of the changes in fair value recorded in interest expense, selling, general and administrative expense, and gain on divestiture of Lazanda measured at fair value

NOTE 3. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS (Continued)

on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	December 31,		
	2018	2017	2016
Fair value, beginning of the period	\$1,613	\$14,825	\$14,971
Changes in fair value recorded in interest expense	124	1,079	2,408
Changes in fair value recorded in selling, general and administrative expenses	(515)	(7,708)	(122)
Royalties and milestone paid	(184)	(3,068)	(2,432)
Divestiture of Lazanda	—	(3,515)	—
Total	<u>\$1,038</u>	<u>\$ 1,613</u>	<u>\$14,825</u>

The estimated fair value of the 2.50% Convertible Senior Notes Due 2021, which the Company issued on September 9, 2014 (the 2021 Notes), is based on a market approach. The estimated fair value was approximately \$231.8 million (par value \$345.0 million) as of December 31, 2018 and represents a Level 2 valuation. The principal amount of the Senior Notes approximates their fair value as of December 31, 2018 and represents a Level 2 valuation. When determining the estimated fair value of the Company's debt, the Company uses a commonly accepted valuation methodology and market-based risk measurements that are indirectly observable, such as credit risk.

There were no transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy during the years ended December 31, 2018 and December 31, 2017.

The following table represents the Company's fair value hierarchy for its financial assets measured at fair value on a recurring basis as of December 31, 2017 (in thousands):

<u>December 31, 2017</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets:				
Money market funds	\$95	\$ —	\$ —	\$ 95
Commercial paper	—	23,670	—	23,670
Corporate debt securities	—	1,205	—	1,205
Total	<u>\$95</u>	<u>\$24,875</u>	<u>\$ —</u>	<u>\$24,970</u>
Liabilities:				
Contingent consideration—Zipsor	\$—	\$ —	\$ 464	\$ 464
Contingent consideration—Lazanda	—	—	156	156
Contingent consideration—CAMBIA	—	—	993	993
	<u>\$—</u>	<u>\$ —</u>	<u>\$1,613</u>	<u>\$ 1,613</u>

NOTE 4. REVENUE

The following table summarizes revenue from contracts with customers for the years ended December 31, 2018, 2017 and 2016 (in thousands) into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors:

	December 31,		
	2018	2017	2016
Product sales, net:			
Gralise	\$ 58,077	\$ 77,034	\$ 88,446
CAMBIA	35,803	31,597	31,273
Zipsor	16,387	16,700	27,539
Total neurology product sales, net	110,267	125,331	147,258
NUCYNTA products	18,944	239,539	281,261
Lazanda	755	15,010	26,547
Total product sales, net	129,966	379,880	455,066
Commercialization agreement:			
Commercialization rights and facilitation services, net	100,038	—	—
Revenue from transfer of inventory	55,705	—	—
Royalties and milestone revenue	26,061	844	831
Total revenues	<u>\$311,770</u>	<u>\$380,724</u>	<u>\$455,897</u>

NUCYNTA product sales for the year ended December 31, 2018 reflect the Company's sales of NUCYNTA between January 1 and January 8, 2018. During the year ended December 31, 2018 the Company recognized sales reserve estimate adjustments related to sales recognized for NUCYNTA and Lazanda in prior periods. Separately, during the first quarter of 2018, in connection with the Collegium transaction, the Company recognized Nucynta product revenue of \$12.5 million related to the release of NUCYNTA sales reserves which were primarily recorded in the fourth quarter of 2017, as financial responsibility for those reserves transferred to Collegium upon closing of the Commercialization Agreement.

Original Commercialization Agreement with Collegium

In December 2017, the Company, Collegium and Collegium NF, LLC, a Delaware limited liability company and wholly owned subsidiary of Collegium (Newco), entered into a Commercialization Agreement (Commercialization Agreement), pursuant to which the Company granted Collegium the right to commercialize the NUCYNTA franchise of pain products in the United States. Pursuant to the Commercialization Agreement, Collegium assumed all commercialization responsibilities for the NUCYNTA franchise effective January 9, 2018, including sales and marketing. The Company also agreed to provide services to Collegium, including to arrange for the supply of NUCYNTA products by the Company's existing contract manufacturing organizations ("CMOs") (the "Facilitation Services"). The Company identified the following three promised goods and services under the Commercialization Agreement: (1) the license to commercialize the NUCYNTA pain products (License), (2) services to arrange for supplies of NUCYNTA pain products using the Company's existing contract manufacturing contracts with third parties (Facilitation Services); and (3) the transfer of control of all NUCYNTA finished goods held at closing (Inventory Transfer).

The Inventory Transfer was deemed to be a distinct performance obligation which was completed during the first quarter of 2018. The Company concluded that the License and the Facilitation Services are not distinct from one another as the Commercialization Agreement does not grant to Collegium a

NOTE 4. REVENUE (Continued)

license to manufacture NUCYNTA. The Company (i) exclusively controls the intellectual property underlying the NUCYNTA products for the United States market, (ii) retains responsibility for facilitating NUCYNTA product supply through its CMOs, and (iii) exclusively maintains all CMO contractual relationships. As a result, Collegium's right to commercialize NUCYNTA is inherently dependent upon the Facilitation Services. Because (i) Collegium is contractually required to use the Facilitation Services to arrange for product supply and (ii) tapentadol is a Schedule II controlled substance for which manufacturing arrangements are not easily transferred or bypassed, there is strong interdependency between the License and the Facilitation Services. These Facilitation Services are administrative in nature but necessary for the commercialization right to have utility to Collegium.

In January 2018, the Company determined the total fixed elements of the transaction price to be \$553.2 million, which consisted of \$537.0 million in total annual minimum royalty payments for years 2018 through 2021, a \$10.0 million upfront fee, and a \$6.2 million payment for NUCYNTA finished goods inventory. The Company determined that the duration of the Commercialization Agreement began on the effective date of January 9, 2018 and lasts through December 31, 2021, including the minimum royalty period and the period in which Collegium would incur a \$25.0 million termination penalty on terminating the Commercialization Agreement. Beginning January 1, 2022 and for each year of the Commercialization Agreement thereafter, royalties are: (i) 58% of net sales of NUCYNTA up to \$233 million, payable quarterly within 45 days of the end of each calendar quarter, plus (ii) 25% of annual net sales of NUCYNTA between \$233 million and \$258 million, plus (iii) 17.5% of annual net sales of NUCYNTA above \$258 million. Payments described in clauses (ii) and (iii) hereof will be paid annually within 60 days of the end of the calendar year.

The portion of the transaction price allocated to the Inventory Transfer was \$55.7 million and was recognized on the closing date as the control of such inventory was transferred to Collegium. The portion of the transaction price allocated to the License and Facilitation Services, as a combined performance obligation, was \$497.5 million and would be recognized over ratably through December 31, 2021.

In addition, Collegium assumed responsibility for a portion of the royalties owed by the Company to a third party on sales of NUCYNTA. The royalties owed by Collegium to the third party are 14% of sales with the Company ensuring a minimum royalty of \$34.0 million per year on net sales of NUCYNTA greater than \$180.0 million. The Company is obligated to cover any shortfall between the minimum royalty amount of \$34.0 million and the amounts paid to the third party by Collegium for each of the years ended December 31, 2018 through 2021, as a result of which the Company could be obligated to pay up to \$8.8 million per year for each of the years ended December 31, 2018 through 2021.

Amended Commercialization Agreement with Collegium

On November 8, 2018, the Company, Collegium and Newco entered into a third amendment to the Commercialization Agreement (Amendment). Pursuant to the Amendment, the royalties payable by Collegium to the Company in connection with Collegium's commercialization of NUCYNTA were amended such that effective as of January 1, 2019 through December 31, 2021, the Company will receive: (i) 65% of net sales of NUCYNTA up to \$180 million, plus (ii) 14% of annual net sales of NUCYNTA between \$180 million and up to \$210 million, plus (iii) 58% of annual net sales of NUCYNTA between \$210 million and \$233 million, plus (iv) 20% of annual net sales of NUCYNTA between \$233 million and up to \$258 million, plus (v) 15% of annual net sales of NUCYNTA above \$258 million. The Amendment does not change the royalties that the Company will receive on annual

NOTE 4. REVENUE (Continued)

net sales of NUCYNTA by Collegium for the period beginning January 1, 2022 and for each year of the Commercialization Agreement term thereafter.

The Amendment provides that Collegium shall reimburse the Company for the amount of any minimum annual royalties paid by the Company to the third party on net sales of NUCYNTA during the first four years of the Commercialization Agreement beginning in 2019. The Amendment also provides for Collegium to share certain costs related to the License. The reimbursement and the cost sharing are considered variable consideration. The Amendment is being accounted for prospectively.

In connection with the Amendment Collegium issued the Company a warrant to purchase up to 1,041,667 shares of Collegium common stock at an exercise price of \$19.20 per share (Warrant). The Warrant is exercisable for a period of four years and contains customary terms, including with regard to net exercise. The Warrant was valued at \$8.8 million as of the date of the Amendment and is considered to be a component of the fixed consideration associated with the Commercialization Agreement. These Warrants are included in Investments on the Company's Consolidated Balance Sheet, however, as they are non-cash they do not impact investing cash flows.

In November 2018, the Company determined the total fixed elements of the transaction price following the Amendment to be \$157.0 million, which consisted of \$132.0 million in total annual minimum royalty payments for 2018, the \$10.0 million upfront fee, the \$6.2 million payment for NUCYNTA finished goods inventory and the \$8.8 million attributed to the Warrant. There were no new performance obligations following the modification of the Commercialization Agreement and at the time of the modification, the remaining periods in the series of services related to the single performance obligation to deliver the license and provide facilitation services are distinct from those prior to the modification. As a result, the modification was accounted for as a termination of the old arrangement and the entering into of a new agreement, in accordance with the guidance of ASC 606.

Pursuant to the Amendment, Collegium may only terminate the Commercialization Agreement after December 31, 2020, with 12-months' notice. In the event any such termination notice has an effective date of termination prior to December 31, 2022, then Collegium shall pay a \$5 million termination fee to the Company concurrent with the delivery of such notice. The Company determined that the \$5 million termination fee is not substantive and therefore the duration of the Commercialization Agreement is unchanged by the Amendment and lasts through December 31, 2021, which is consistent with the contractual period in which the Company and Collegium have enforceable rights and obligations.

The Amendment provides that the Company may terminate the Commercialization Agreement upon 60 days' prior written notice to Collegium in the event that (i) the net sales of NUCYNTA by Collegium during any period of 12 consecutive calendar months ending on or before December 31, 2021 are less than \$180 million, or (ii) the net sales of NUCYNTA by Collegium during any period of 12 consecutive calendar months commencing on or after January 1, 2022 are less than \$170 million.

2018 Revenue from the Commercialization Agreement

For the year ended December 31, 2018, the Company recognized royalty revenue from the Commercialization agreement of \$155.7 million. The revenue recognized in 2018 under the Commercialization Agreement is impacted by both the original Commercialization Agreement and the Amendment and is comprised of the following components:

- The Company recognized \$55.7 million related to the transfer of inventory upon closing

NOTE 4. REVENUE (Continued)

- From the effective date of the Commercialization Agreement, January 8, 2018 through the date of the Amendment on November 8, 2018 the Company recognized fixed consideration of \$103.8 million which is the ratable recognition of the transaction price allocated to the combined license and facilitation performance obligation.
- Assertio recognized revenue and expenses related to the third party royalties in 2018 which resulted in a net gross-to-net adjustment of \$3.7 million, which reduces commercialization revenue, which is the Company’s obligation related to the shortfall discussed above.
- Of the variable components of the amended Commercialization Agreement, recognition of the variable royalty revenue which becomes effective for sales beginning January 1, 2019 and Collegium’s payment of royalties to a third party were constrained by the sales based royalty exception and revenue related to the reimbursement for certain costs related to the NUCYNTA license was insignificant for the post-modification period.

Cash collected from Collegium in 2018 includes the upfront payments of \$10.0 million for facilitation services and \$6.2 million for inventory as well as the annual minimum royalty amounts, payable by Collegium in equal quarterly installments which are \$30.8 million for the three months ended March 31, 2018 and \$33.8 million per a quarter for the second, third and fourth quarters of 2018. For the year ended December 31, 2018, \$132.0 million was received by the Company with respect to royalty payments.

Royalties obligations related to NUCYNTA sales for the year ended December 31, 2018 were \$34.0 million of which approximately \$29.5 million were paid directly by Collegium to the third party.

Contract Assets

The following table presents changes in the Company’s contract assets as of December 31, 2018 (in thousands):

	<u>Balance as of December 31, 2017</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance as of December 31, 2018</u>
Contract assets:				
Contract asset, net—Collegium	\$—	\$55,705	\$(53,289)	\$2,416
Contract asset—Ironwood	—	5,000	(5,000)	—
	<u>—</u>	<u>60,705</u>	<u>(58,289)</u>	<u>2,416</u>

The Collegium contract asset represents the conditional right to consideration for completed performance under the Commercialization Agreement arising from the transfer of inventory to Collegium on the date of closing of the agreement in January 2018 net of the contract liability of \$10.0 million resulting from the upfront payment received and the \$8.8 million of warrants received. Portions of the contract asset are reclassified to accounts receivable when the right to consideration becomes unconditional. As of December 31, 2018, \$0.8 million and \$1.6 million of the contract asset has been recorded within “Prepaid and other current assets” and “Other long-term assets,” respectively.

The Ironwood contract asset is discussed further below.

NOTE 4. REVENUE (Continued)***Collaboration and License Agreements***

Ironwood Pharmaceuticals, Inc. The future contingent milestones under the Ironwood Agreement are considered variable consideration and are estimated using the most likely method. As part of adopting ASC 606, the Company evaluated whether the future milestones under the Ironwood Agreement should have been included as part of the transaction price in periods before January 1, 2018. The Company concluded that because of development and regulatory risks at the time, it was probable that a significant revenue reversal could have occurred. Accordingly, the associated future contingent milestone values were not included in the transaction price for periods before January 1, 2018. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment. During the second and third quarter of 2018, the Company recognized and collected, respectively, a \$5.0 million milestone payment related to the dosing of the first patient in a Phase 3 trial. There was no revenue recognized under this agreement for the year ended December 31, 2017.

PDL BioPharma, Inc. In October 2013, the Company sold its interests in royalty and milestone payments under its license agreements relating to the Company's Acuform technology in the Type 2 diabetes therapeutic area to PDL BioPharma, Inc. (PDL) for \$240.5 million. On August 2, 2018 the Company sold its remaining interest in such payments to PDL for \$20.0 million. The \$20.0 million of revenue was recognized as royalty revenue in the third quarter of 2018.

ASC 606 Adoption

The Company considered the adoption of the new revenue standard, ASC 606, compared to what would have been recognized by the Company under the prior revenue standards, ASC 605. The adoption of ASC 606 did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2018.

NOTE 5. ACCOUNTS RECEIVABLES, NET

Accounts receivables, net, consist of the following (in thousands):

	December 31, 2018	December 31, 2017
Product sales, net	\$23,078	\$71,919
Receivables from Collegium	14,011	—
Other	122	563
Total accounts receivable, net	<u>\$37,211</u>	<u>\$72,482</u>

NOTE 6. INVENTORIES

Inventories consist of finished goods, raw materials and work in process and are stated at the lower of cost or net realizable value and consists of the following (in thousands):

	December 31, 2018	December 31, 2017
Raw materials	\$1,376	\$ 3,008
Work-in-process	732	204
Finished goods	1,288	9,830
Total	<u>\$3,396</u>	<u>\$13,042</u>

NOTE 7. PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

	December 31, 2018	December 31, 2017
Furniture and office equipment	\$ 2,237	\$ 5,986
Machinery and equipment	11,391	10,783
Laboratory equipment	351	3,335
Leasehold improvements	9,858	6,841
	<u>23,837</u>	<u>26,945</u>
Less: Accumulated depreciation and amortization	<u>(10,773)</u>	<u>(13,921)</u>
Property and equipment, net	<u>\$ 13,064</u>	<u>\$ 13,024</u>

Depreciation expense was \$4.7 million, \$2.0 million and \$2.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. Depreciation for the year ended December 31, 2018 includes \$2.7 million of accelerated depreciation related of leasehold improvements in our former Newark, California headquarters in anticipation of our exit of that facility on September 30, 2018.

NOTE 8. INTANGIBLE ASSETS

The gross carrying amounts and net book values of the Company's intangible assets were as follows (in thousands):

	Remaining Useful Life (In years)	December 31, 2018			December 31, 2017		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Product rights							
NUCYNTA	7.0	\$1,019,978	\$(360,891)	\$659,087	\$1,019,978	\$(266,590)	\$753,388
CAMBIA	5.0	51,360	(25,891)	25,469	51,360	(20,755)	30,605
Zipsor	3.3	27,250	(19,707)	7,543	27,250	(17,370)	9,880
		<u>\$1,098,588</u>	<u>\$(406,489)</u>	<u>\$692,099</u>	<u>\$1,098,588</u>	<u>\$(304,715)</u>	<u>\$793,873</u>

NOTE 8. INTANGIBLE ASSETS (Continued)

Future amortization expenses were estimated as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Estimated Amortization Expense</u>
2019	\$101,774
2020	101,774
2021	101,774
2022	99,969
2023	99,227
Thereafter	187,581
Total	<u>\$692,099</u>

NOTE 9. ACCRUED LIABILITIES

Accrued liabilities consist of the following (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Accrued compensation	\$ 5,475	\$ 7,345
Accrued royalties	2,773	17,370
Accrued restructuring and one-time termination costs	1,578	9,483
Other accrued liabilities	21,535	26,298
Total accrued liabilities	<u>\$31,361</u>	<u>\$60,496</u>

NOTE 10. DEBT*Senior Notes*

On April 2, 2015, the Company issued \$575.0 million aggregate principal amount of senior secured notes (the Senior Notes) for aggregate gross proceeds of approximately \$562.0 million pursuant to a Note Purchase Agreement dated March 12, 2015 (Note Purchase Agreement) among the Company and Deerfield Private Design Fund III, L.P., Deerfield Partners, L.P., Deerfield International Master Fund, L.P., Deerfield Special Situations Fund, L.P., Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., BioPharma Secured Investments III Holdings Cayman LP, Inteligo Bank Ltd. and Phemus Corporation (collectively, the Purchasers) and Deerfield Private Design Fund III, L.P., as collateral agent. The Company used \$550.0 million of the net proceeds received upon the sale of the Senior Notes to fund a portion of the Purchase Price paid to Janssen Pharma in connection with the NUCYNTA acquisition. The Company incurred debt issuance costs of \$0.5 million for 2015.

The Senior Notes will mature on April 14, 2021 (unless earlier prepaid or repurchased), are secured by substantially all of the assets of the Company and any subsidiary guarantors, and bear interest at the rate equal to the lesser of (i) 9.75% over the three month London Inter-Bank Offer Rate (LIBOR), subject to a floor of 1.0% and (ii) 11.95% (through the third anniversary of the purchase date) and 12.95% (thereafter). The interest rate is determined at the first business day of each fiscal quarter, commencing with the first such date following April 2, 2015. The interest rate for the three months ended December 31, 2018 and 2017 was 12.15% and 11.09%, respectively.

NOTE 10. DEBT (Continued)

In April 2017, the Company prepaid and retired \$100.0 million of the Senior Notes and paid a \$4.0 million prepayment fee; and in November 2017, the Company prepaid and retired an additional \$10 million of the Senior Notes and paid a \$0.4 million prepayment fee. The Company recorded a net loss on prepayment of the Senior Notes of \$5.9 million which represented the prepayment fees of \$4.4 million and the immediate recognition of unamortized balances of debt discount and debt issuance costs of \$1.5 million. This loss is recorded as a loss on prepayment of Senior Notes in the consolidated statements of operations for 2017.

The remaining \$282.5 million of Senior Notes can be prepaid, at the Company's option. The Company is required to repay the outstanding Senior Notes in full if the principal amount outstanding on its existing 2.50% Convertible Senior Notes due 2021 as of March 31, 2021, is greater than \$100.0 million. In addition, if the successor entity in a Major Transaction, as defined in the Note Purchase Agreement, does not satisfy specified qualification criteria, the Purchasers may require the Company to prepay the Senior Notes upon consummation of the Major Transaction in an amount equal to the principal amount of outstanding Senior Notes, accrued and unpaid interest and a prepayment premium in an amount equal to what the Company would have otherwise paid in an optional prepayment described in the following paragraph. The Company is required to make mandatory prepayments on the Senior Notes in an amount equal to the proceeds it receives in connection with asset dispositions in excess of \$10.0 million, together with accrued and unpaid interest on the principal amount prepaid.

Pursuant to the Note Purchase Agreement, upon the consummation of the sale of the Senior Notes on April 2, 2015, the Company and Depo NF Sub, LLC entered into a Pledge and Security Agreement with the Deerfield Private Design Fund III, L.P. (the Collateral Agent), pursuant to which the Company and Depo NF Sub each granted the Collateral Agent (on behalf of the Purchasers) a security interest in substantially all of their assets, other than specifically excluded assets.

On December 4, 2017, the Company and the Purchasers entered into an Amendment to the existing Note Purchase Agreement. The Amendment facilitated the Company's entry into the Collegium Commercialization Agreement.

In connection with its entry into the Commercialization Agreement, the Purchasers (i) waived the requirement that some or all of the Asset Disposition Proceeds realized from the granting of the Exclusive License be used to prepay the outstanding principal amount of the Notes pursuant to Section 2.7(b) of the Note Purchase Agreement and (ii) agreed to (a) replace the minimum net sales covenant in Section 6.7 of the Note Purchase Agreement with a minimum EBITDA covenant, and (b) made certain other amendments related to the amortization of the Notes. In addition, the prepayment premiums were amended to 4% of the principal amount of the Notes to be prepaid, if such prepayment occurs after the second anniversary of the Purchase Date but on or prior to the fifth anniversary of the Purchase Date; and (iii) zero, if such prepayment occurs after the fifth anniversary of the Purchase Date. The Amendment also modifies the repayment schedule; and required the Company to prepaying and retiring \$10.0 million of the Senior Notes and paying a \$0.4 million prepayment fee. The Company paid a \$3.0 million upfront non-refundable amendment fee which, pursuant to the terms of the modification, can be off-set dollar for dollar against any future prepayment fees. The Purchasers have also consented to terms and conditions of the Amendment to the Commercialization Agreement with Collegium described in Note 4 "Revenue".

The Company accounted for the December 2017 amendment as a debt modification in accordance with the applicable accounting standards. Accordingly, the \$3.0 million amendment fee paid to the Purchasers was capitalized and is being amortized over the remaining term of the Senior Notes.

NOTE 10. DEBT (Continued)

The Senior Notes and related indenture contain customary covenants, including, among other things, and subject to certain qualifications and exceptions, covenants that restrict the Company's ability and the ability of its subsidiaries to: incur or guarantee additional indebtedness; create or permit liens on assets; pay dividends on capital stock or redeem, repurchase or retire capital stock or subordinated indebtedness; make certain investments and other restricted payments; engage in mergers, acquisitions, consolidations and amalgamations; transfer and sell certain assets; and engage in transactions with affiliates.

The Company was in compliance with its covenants with respect to the Senior Notes as of December 31, 2018. See Note 18—Subsequent Events for discussion of Amendment four to the Senior Notes which was entered into in January 2019.

The remaining principal amount of the Senior Notes repayable each year is as follows (in thousands):

2019	\$120,000
2020	80,000
2021	82,500
Total	<u>\$282,500</u>

The Company is scheduled to make the Senior Notes principal payments of \$120.0 million prior to December 31, 2019 and has classified this portion of the Senior Notes within the current liabilities section of the consolidated balance sheet.

The following is a summary of the carrying value of the Senior Notes as of December 31, 2018 and 2017 (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Principal amount of the Senior Notes	\$282,500	\$365,000
Unamortized debt discount balance	(2,541)	(4,717)
Unamortized debt issuance costs	(1,650)	(3,063)
Total Senior Notes	<u>\$278,309</u>	<u>\$357,220</u>

The debt discount and debt issuance costs will be amortized as interest expense through April 2021. The following is a summary of Senior Notes interest expense (in thousands):

	<u>December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Contractual interest expense	\$38,242	\$44,212	\$54,722
Amortization of debt discount and debt issuance costs .	3,589	2,631	2,261
Total interest expense	<u>\$41,831</u>	<u>\$46,843</u>	<u>\$56,983</u>

Convertible Debt

On September 9, 2014, the Company issued \$345.0 million aggregate principal amount of 2.50% Convertible Senior Notes Due 2021 (the Convertible Notes) resulting in net proceeds to the Company of \$334.2 million after deducting the underwriting discount and offering expenses of \$10.4 million and \$0.4 million, respectively.

NOTE 10. DEBT (Continued)

The Convertible Notes were issued pursuant to an indenture, as supplemented by a supplemental indenture dated September 9, 2014, between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (the Trustee), and mature on September 1, 2021, unless earlier converted, redeemed or repurchased. The Convertible Notes bear interest at the rate of 2.50% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning March 1, 2015.

Prior to March 1, 2021, holders of the 2021 Convertible Notes can convert their securities, at their option: (i) during any calendar quarter commencing after December 31, 2015, if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to \$25.01 (130% of the \$19.24 conversion price) on each applicable trading day (ii) during the five business day period after any five consecutive trading day period in which the trading price 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 the Company's common stock and the conversion rate on each such trading day; and (iii) at any time upon the occurrence of specified corporate transactions, to include a change of control (as defined in the Notes Indenture). On or after March 1, 2021 to the close of business on the second scheduled trading day immediately preceding the maturity date, the holders of the 2021 Convertible Notes may convert all or any portion of their notes, in multiples of \$1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. The initial conversion rate of 51.9852 shares of common stock per \$1,000 principal amount of Convertible Notes is equivalent to a conversion price of approximately \$19.24 per share of common stock.

Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. If the conversion obligation is satisfied solely in cash or through payment and delivery of a combination of cash and shares, the amount of cash and shares, if any, due upon conversion will be based on a daily conversion value calculated on a proportionate basis for each trading day in a 40 trading day observation period.

The closing price of the Company's common stock did not exceed 130% of the \$19.24 conversion price, for the required period during the quarter ended December 31, 2018. As a result, the Convertible Notes are not convertible as of December 31, 2018.

The Convertible Notes were accounted for in accordance with ASC Subtopic 470-20, *Debt with Conversion and Other Options*. Pursuant to ASC Subtopic 470-20, since the Convertible Notes can be settled in cash, shares of common stock or a combination of cash and shares of common stock at the Company's option, the Company is required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The effective interest rate used in determining the liability component of the Convertible Notes was 9.34%. This resulted in the initial recognition of \$226.0 million as the liability component net of a \$119.0 million debt discount with a corresponding net of tax increase to paid-in capital of \$73.3 million representing the equity component of the Convertible Notes. The underwriting discount of \$10.4 million and offering expenses of \$0.4 million were allocated between debt issuance costs and equity issuance costs in proportion to the allocation of the proceeds. Equity issuance costs of \$3.7 million related to the convertible notes were recorded as an offset to additional paid-in capital.

NOTE 10. DEBT (Continued)

The following is a summary of the liability component of the Convertible Notes as of December 31, 2018 and 2017 (in thousands):

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Principal amount of the Convertible Notes	\$345,000	\$345,000
Unamortized discount of the liability component	(54,521)	(71,799)
Unamortized debt issuance costs	<u>(2,681)</u>	<u>(3,691)</u>
Total Convertible Notes	<u>\$287,798</u>	<u>\$269,510</u>

The debt discount and debt issuance costs will be amortized as interest expense through September 2021. The following is a summary of interest expense for 2018, 2017 and 2016 (in thousands):

	<u>December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Stated coupon interest	\$ 8,624	\$ 8,625	\$ 8,625
Amortization of debt discount and debt issuance costs	<u>18,288</u>	<u>16,784</u>	<u>15,412</u>
Total interest expense	<u>\$26,912</u>	<u>\$25,409</u>	<u>\$24,037</u>

NOTE 11. RESTRUCTURING CHARGES***Restructuring and One-Time Termination Costs***

In June 2017, the Company announced a limited reduction-in-force in order to streamline operations and achieve operating efficiencies, the activities related to that reduction-in-force were completed during the third quarter of 2017. In December 2017, the Company initiated a company-wide restructuring plan following the entry into the Commercialization Agreement with Collegium. Pursuant to this plan, in February 2018, the Company eliminated the pain sales force, consisting of approximately 230 sales representative and 25 manager positions. In addition, the Company reduced the staff at the headquarters office during the second quarter of 2018. In the third quarter of 2018, the corporate headquarters was relocated from Newark, California to Lake Forest, Illinois.

The following table summarizes the total expenses recorded related to the 2018 restructuring and one-time termination cost activities by type of activity and the locations recognized within the consolidated statements of operations as restructuring costs (in thousands):

	<u>December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
Employee compensation costs	\$16,852	\$13,247	\$—
Fixed Asset disposals and accelerated depreciation of leasehold improvements	3,511	—	—
Other exit costs	<u>238</u>	<u>—</u>	<u>—</u>
Total restructuring costs	<u>\$20,601</u>	<u>\$13,247</u>	<u>\$—</u>

NOTE 11. RESTRUCTURING CHARGES (Continued)

Selected information relating to accrued restructuring, severance costs and one-time termination costs is as follows (in thousands):

	<u>Employee separation costs</u>	<u>Other exit costs</u>	<u>Total</u>
Net accruals	13,247	—	13,247
Non-cash additions/(reductions)	—	—	—
Cash paid	<u>(3,764)</u>	<u>—</u>	<u>(3,764)</u>
Balance at Balance at December 31, 2017	<u>\$ 9,483</u>	<u>\$ —</u>	<u>\$ 9,483</u>
Net accruals	16,852	3,749	20,601
Non-cash additions/(reductions)	(2,146)	(3,511)	(5,657)
Cash paid	<u>(22,611)</u>	<u>(238)</u>	<u>(22,849)</u>
Balance at Balance at December 31, 2018	<u>\$ 1,578</u>	<u>\$ —</u>	<u>\$ 1,578</u>

As of December 31, 2018, the full \$1.6 million accrued restructuring liability balance was classified as a current liability in the Consolidated Balance Sheet. Non-cash charges related to stock based compensation and accelerated amortization of leasehold improvements at the Newark, CA headquarters. The Company expects costs related to the December 2017 restructuring plan, incurred in 2019, to be insignificant.

NOTE 12. COMMITMENTS AND CONTINGENCIES

Leases

The Company has non-cancelable operating leases for its office and laboratory facilities and it is obligated to make payments under non-cancelable operating leases for automobiles used by its sales force. Future minimum lease payments under the Company’s non-cancelable operating leases at December 31, 2018 were as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Lease Payments</u>
2019	\$ 2,624
2020	2,526
2021	2,322
2022	2,188
2023	632
Thereafter	<u>—</u>
Total	<u>\$10,292</u>

In April 2012, the Company entered into an office and laboratory lease agreement to lease approximately 52,500 rentable square feet in Newark, California commencing on December 1, 2012. The Company leased approximately 8,000 additional rentable square feet commencing in July 2015. The Lease is due to expire on November 30, 2022.

The Company was allowed to control physical access to the premises upon signing the lease. Therefore, in accordance with the applicable accounting guidance, the lease term was deemed to have commenced in April 2012. Accordingly, the rent free periods and the escalating rent payments contained within the lease are being recognized on a straight-line basis from April 2012.

NOTE 12. COMMITMENTS AND CONTINGENCIES (Continued)

The Company relocated its corporate headquarters from Newark, California to Lake Forest, Illinois in the third quarter of 2018. The Company has entered into two subleases, one in September 2018 and the second in February 2019, which, together, account for the entirety of the Newark facility. The value of these subleases is in excess of the Company's remaining costs under the Newark lease and therefore no cease use cost has been recognized.

Effective February 28, 2018, the Company entered into an Office Lease, in Lake Forest, Illinois (Lake Forest Lease) for its new corporate headquarters, where the Company leases approximately 31,000 rentable square feet of space. The initial tenant improvements in the space were completed in August 2018 and the Company began occupying the space at that time. The Lake Forest Lease term is for five years and six months. The Company has the right to renew the term of the Lease for one period of five years, provided that written notice is made to the Landlord no later than twelve months prior to the expiration of the initial term of the Lease.

The Lake Forest Lease initial annual base rent is \$18.00 per rentable square foot and will increase annually by \$0.50 per rentable square foot. The lease is a triple net lease, with the Company required to pay its pro rata share of real estate taxes and operating expenses. The Landlord will make available to the Company a tenant improvement allowance of \$28.00 per square rentable square foot, which the Company may use towards the initial build-out or apply to the payment of rent.

As of December 31, 2018, the aggregate rent payable over the remaining term of the lease agreements was approximately \$6.4 million on the Newark Lease and \$3.0 million on the Lake Forest Lease. Deferred rent was approximately \$1.6 million as of December 31, 2018 and \$1.4 million as of December 31, 2017. As of December 31, 2018, the Company had a liability of \$3.6 million related to the deferred recognition of tenant improvement allowances. Rent expense relating to the Newark and Lake Forest lease agreements was \$0.6 million, \$0.3 million and \$0.6 million for 2018, 2017 and 2016, respectively.

In December 2013, the Company entered into an operating lease agreement with Enterprise FM Trust (Enterprise) for the lease of vehicles to be used by the Company's sales force. The Company began receiving vehicles in the second quarter of 2014, with the lease terms ranging from 18 to 36 months. During the three months ended June 30, 2015, the Company entered into an additional lease with Enterprise, under the existing lease terms. The Company received the additional vehicles in the second half of 2015. As of December 31, 2018, the aggregate rent payable over the remaining term of the vehicle lease agreement was approximately \$0.8 million. Rent expense relating to the lease of cars was \$0.8 million, \$3.2 million and \$3.2 million for 2018, 2017 and 2016, respectively.

Legal Matters

Company v. NUCYNTA and NUCYNTA ER ANDA Filers

Actavis & Alkem: In July 2013, Janssen Pharma filed patent infringement lawsuits in the U.S. District Court for the District of New Jersey (D.N.J.) against Actavis Elizabeth LLC, Actavis Inc. and Actavis LLC (collectively, Actavis), as well as Alkem Laboratories Limited and Ascend Laboratories, LLC (collectively, Alkem). The patent infringement claims against Actavis and Alkem relate to their respective ANDAs seeking approval to market generic versions of NUCYNTA and NUCYNTA ER before the expiration of U.S. Reissue Patent No. 39,593 (the '593 Patent), U.S. Patent No. 7,994,364 (the '364 Patent) and, as to Actavis only, U.S. Patent No. 8,309,060 (the '60 Patent). In December 2013, Janssen Pharma filed an additional complaint in the D.N.J. against Alkem asserting that newly issued U.S. Patent No. 8,536,130 (the '130 Patent) was also infringed by Alkem's ANDA

NOTE 12. COMMITMENTS AND CONTINGENCIES (Continued)

seeking approval to market a generic version of NUCYNTA ER. In August 2014, Janssen Pharma amended the complaint against Alkem to add additional dosage strengths.

Sandoz & Roxane: In October 2013, Janssen Pharma received a Paragraph IV Notice from Sandoz, Inc. (Sandoz) with respect to NUCYNTA related to the '364 Patent, and a Paragraph IV Notice from Roxane Laboratories, Inc. (Roxane) with respect to NUCYNTA related to the '364 and '593 Patents. In response to those notices, Janssen Pharma filed an additional complaint in the D.N.J. against Roxane and Sandoz asserting the '364 Patent against Sandoz and the '364 and '593 Patents against Roxane. In April 2014, Janssen Pharma and Sandoz entered into a joint stipulation of dismissal of the case against Sandoz, based on Sandoz's agreement not to market a generic version of NUCYNTA products prior to the expiration of the asserted patents. In June 2014, in response to a new Paragraph IV Notice from Roxane with respect to NUCYNTA ER, Janssen Pharma filed an additional complaint in the D.N.J. asserting the '364, '593, and '130 Patents against Roxane.

Watson: In July 2014, in response to a Paragraph IV Notice from Watson Laboratories, Inc. (Watson) with respect to the NUCYNTA oral solution product and the '364 and '593 Patents, Janssen Pharma filed a lawsuit in the D.N.J. asserting the '364 and '593 Patents against Watson.

In each of the foregoing actions, the ANDA filers counterclaimed for declaratory relief of non-infringement and patent invalidity. At the time that the actions were commenced, Janssen Pharma was the exclusive U.S. licensee of the patents referred to above. On April 2, 2015, the Company acquired the U.S. rights to NUCYNTA ER and NUCYNTA from Janssen Pharma. As part of the acquisition, the Company became the exclusive U.S. licensee of the patents referred to above. The Company was added as a plaintiff to the pending cases and is actively litigating them.

In September 2015, the Company filed an additional complaint in the D.N.J. asserting the '130 Patent against Actavis. The '130 Patent issued in September 2013 and was timely listed in the Orange Book for NUCYNTA ER, but Actavis did not file a Paragraph IV Notice with respect to this patent. In its new lawsuit, the Company claimed that Actavis would infringe or induce infringement of the '130 Patent if its proposed generic products were approved. In response, Actavis counterclaimed for declaratory relief of non-infringement and patent invalidity, as well as an order requiring the Company to change the corrected use code listed in the Orange Book for the '130 Patent.

In February 2016, Actavis, Actavis UT, Roxane and Alkem each stipulated to infringement of the '593 and '364 patents. On March 9, 2016, a two-week bench trial on the validity of the three asserted patents and infringement of the '130 patent commenced. Closing arguments took place on April 27, 2016. On September 30, 2016, the Court issued its final decision. The Court found that the '593, '364 patent, and '130 patents are all valid and enforceable, that Alkem will induce infringement of the '130 patent, but that Roxane and Actavis will not infringe the '130 patent.

On April 11, 2017, the Court entered final judgment in favor of the Company on the validity and enforceability of all three patents, on infringement of the '593 and '364 Patents by all defendants, and on infringement of the '130 Patent against Alkem. The judgment includes an injunction enjoining all three defendants from engaging in certain activities with regard to tapentadol (the active ingredient in NUCYNTA), and ordering the effective date of any approval of Actavis, Actavis UT, and Roxane's ANDAs, and Alkem's ANDA for NUCYNTA IR to be no earlier than the expiry of the '364 Patent (June 27, 2025), and the effective date of any approval of Alkem's ANDA for NUCYNTA ER to be no earlier than the expiry of the '130 Patent (September 22, 2028). The period of exclusivity with respect to all four defendants may in the future be extended with the award of pediatric exclusivity.

NOTE 12. COMMITMENTS AND CONTINGENCIES (Continued)

Notices of appeal were filed by defendants Alkem and Roxane concerning the validity of the '364 and '130 patents. The Company filed its own cross-appeal with regard to the Court's finding that Roxane and Actavis will not infringe the claims of the '130 Patent. The appeals have been consolidated at the Federal Circuit. Briefing concluded in March 2018 and oral arguments occurred on September 4, 2018. It is estimated that the Federal Circuit will issue a written decision in the first quarter of 2019. The '593 patent is not the subject of any appeals.

Company v. Purdue

The Company sued Purdue Pharma L.P (Purdue) for patent infringement in a lawsuit filed in January 2013 in the U.S. District Court for the District of New Jersey. The lawsuit arose from Purdue's commercialization of reformulated OxyContin® (oxycodone hydrochloride controlled-release) in the U.S. and alleges infringement of U.S. Patent Nos. 6,340,475 (the '475 Patent) and 6,635,280 (the '280 Patent), which expired in September 2016.

On September 28, 2015, the district court stayed the Purdue lawsuit pending the decision of the U.S. Court of Appeals for the Federal Circuit (CAFC) in Purdue's appeal of the PTAB's Final Written Decisions described below. On June 30, 2016, the district court lifted the stay based on the CAFC's opinion and judgment affirming the PTAB's Final Written Decisions confirming the patentability of the patent claims of the '475 and '280 Patents Purdue had challenged. On June 10, 2016, the Company filed a motion for leave to file a second amended Complaint to plead willful infringement. On June 21, 2016, Purdue filed an opposition to the Company's motion for leave to plead willful infringement. On January 31, 2017, the Court granted the Company's motion for leave to plead willful infringement.

On February 1, 2017, the Company filed a Second Amended Complaint pleading willful infringement. On July 10, 2017, the case was reassigned to Judge Wolfson. On February 15, 2017, Purdue answered the Company's Second Amended Complaint and pled counterclaims of non-infringement, invalidity, unenforceability and certain affirmative defenses. On September 26, 2017, the case was reassigned to Judge Martinotti. On December 22, 2017, the Court set the close of expert discovery for March 30, 2018. On January 5, 2018, the Court vacated the January 25, 2018 pretrial conference.

On July 9, 2018, the Court issued an order administratively terminating the case pending the outcome of settlement discussions between the parties. On August 28, 2018, the Company and each of Purdue, The P.F. Laboratories, Inc. a New Jersey corporation, and Purdue Pharmaceuticals L.P., a Delaware limited partnership (collectively, Purdue Companies), entered into a Settlement Agreement. Pursuant to the Settlement Agreement: (i) Purdue Companies paid the Company \$30 million on August 28, 2018 and paid the Company an additional \$32 million on January 30, 2019; (ii) each party covenanted not to sue the other with regard to any alleged infringement of such party's patents or patent rights as a result of the commercialization of the other party's current product portfolio; (iii) each party covenanted not to challenge the other party's patents or patent rights covering such other party's current product portfolio; and (iv) each party agreed to a mutual release of claims relating to any claim or potential claim relating to the other party's current product portfolio.

Securities Class Action Lawsuit and Related Matters

On August 23, 2017, the Company, its current chief executive officer and president, its former chief executive officer and president, and its former chief financial officer were named as defendants in a purported federal securities law class action filed in the United States District Court for the Northern District of California (*Huang v. Depomed et al.*, No. 3:17-cv-4830-JST, N.D. Cal.). The action alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and

NOTE 12. COMMITMENTS AND CONTINGENCIES (Continued)

Rule 10b-5 relating to certain prior disclosures of the Company about its business, compliance, and operational policies and practices concerning the sales and marketing of its opioid products and contends that the conduct supporting the alleged violations affected the value of Company common stock and is seeking damages and other relief. In an amended complaint filed on February 6, 2018, the lead plaintiff (referred to in its pleadings as the Depomed Investor Group), which seeks to represent a class consisting of all purchasers of Company common stock between July 29, 2015 and August 6, 2017, asserted the same claims arising out of the same and similar disclosures against the Company and the same individuals as were involved in the original complaint. The Company and the individuals filed a motion to dismiss the amended complaint on April 9, 2018. The lead plaintiff filed an opposition to the motion on June 8, 2018. The Company and the individuals filed a reply in support of their motion to dismiss on July 23, 2018. Oral arguments took place on December 13, 2018. The Company believes that the action is without merit and intends to contest it vigorously.

In addition, five shareholder derivative actions were filed on behalf of the Company against its officers and directors for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of the federal securities laws. The claims arise out of the same factual allegations as the class action. The first derivative action was filed in the Superior Court of California, Alameda County on September 29, 2017 (*Singh v. Higgins et al.*, RG17877280). The second and third actions were filed in the Northern District of California on November 10, 2017 (*Solak v. Higgins et al.*, No. 3:17-cv-6546-JST) and November 15, 2017 (*Ross v. Fogarty et al.*, No. 3:17-cv-6592- JST). The fourth action was filed in the District of Delaware on December 21, 2018 (*Lutz v. Higgins et al.*, No. 18-2044-CFC). The fifth derivative action was filed in the Superior Court of California, Alameda County on January 28, 2019 (*Youse v. Higgins et al.*, No. HG19004409). On December 7, 2017, the plaintiffs in *Solak v. Higgins, et al.* voluntarily dismissed the first federal derivative action. The *Ross*, *Singh*, and *Lutz* actions were stayed on January 18, 2018, January 23, 2018, and January 11, 2019, respectively, pending the resolution of the motion to dismiss in the securities class action. The parties in the *Singh* and *Youse* actions are seeking to consolidate those cases and stay the consolidated matter pending the resolution of the motion to dismiss. The Company believes that these actions are without merit and intends to contest them vigorously.

Opioid-Related Request and Subpoenas

As a result of the greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers generally by federal, state, and local regulatory and governmental agencies. The Company received a letter from Senator Claire McCaskill (D-MO), the then-Ranking Member on the U.S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information from the Company regarding its historical commercialization of opioid products. The Company voluntarily furnished information responsive to Sen. McCaskill's request. The Company has also received subpoenas or civil investigative demands focused on its historical promotion and sales of Lazanda, NUCYNTA, and NUCYNTA ER from various State Attorneys General seeking documents and information regarding the Company's historical sales and marketing of opioid products. In addition, the State of California Department of Insurance (CDI) has issued a subpoena to the Company seeking information relating to its historical sales and marketing of Lazanda. The CDI subpoena also seeks information on Gralise, a non-opioid product in the Company's portfolio. The Company has received subpoenas from the U.S. Department of Justice (DOJ) seeking documents and information regarding its historical sales and marketing of opioid products. The Company also from time to time receives and complies with subpoenas from governmental authorities related to investigations primarily directed at third parties, including health care practitioners, pursuant to which the Company's records related to

NOTE 12. COMMITMENTS AND CONTINGENCIES (Continued)

agreements with and payments made to those third parties, among other items, are produced. As a general matter, the Company is cooperating with all of the requests from and investigations by the regulators described above.

Multidistrict Opioid Litigation

A number of pharmaceutical manufacturers, distributors and other industry participants have been named in numerous lawsuits around the country brought by various groups of plaintiffs, including city and county governments, hospitals and others. In general, the lawsuits assert claims arising from defendants' manufacturing, distributing, marketing and promoting of FDA-approved opioid drugs. The specific legal theories asserted vary from case to case, but most of the lawsuits include federal and state statutory claims as well as claims arising under state common law. Plaintiffs seek various forms of damages, injunctive and other relief and attorneys' fees and costs.

For such cases filed in or removed to federal court, the Judicial Panel on Multi-District Litigation issued an order in December 2017, establishing a Multi-District Litigation court (MDL Court) in the Northern District of Ohio (In re National Prescription Opiate Litigation, Case No. 1:17-MD-2804). Since that time, more than 1,000 such cases that were originally filed in U.S. District Courts, or removed to federal court from state court, have been transferred to the MDL Court. The Company is currently involved in 19 lawsuits that have been transferred to the MDL Court and one additional federal lawsuit in the Eastern District of Missouri. Plaintiffs may file additional lawsuits in which the Company may be named. Plaintiffs in the federal cases include county and municipal governmental entities, employee benefit plans, health clinics and health insurance providers who assert federal and state statutory claims and state common law claims, such as conspiracy, nuisance, fraud, negligence or deceptive trade practices. In these cases, plaintiffs seek a variety of forms of relief, including actual damages to compensate for alleged past and future costs such as to provide care and services to persons with opioid-related addiction or related conditions, injunctive relief to prohibit alleged deceptive marketing practices and abate an alleged nuisance, establishment of a compensation fund, disgorgement of profits, punitive and statutory treble damages, and attorneys' fees and costs. These lawsuits are in the earliest stages of proceedings, and the Company intends to defend itself vigorously in these matters.

State Opioid Litigation

Related to the cases in the MDL Court noted above, there have been hundreds of similar lawsuits filed in state courts around the country, in which various groups of plaintiffs assert opioid-drug related claims against similar groups of defendants. The Company is currently named in 20 such cases—three filed in Texas, three in Pennsylvania, six in Utah, four in Missouri, two in Nevada and one each in Arizona and Arkansas. Plaintiffs may file additional lawsuits in which the Company may be named. In these cases, plaintiffs are asserting state common law and statutory claims against the defendants similar in nature to the claims asserted in the MDL cases. Plaintiffs are seeking past and future damages, disgorgement of profits, injunctive relief, punitive and statutory treble damages, and attorneys' fees and costs. These lawsuits are likewise in their earliest stages, and the Company intends to defend itself vigorously in these matters.

Insurance Litigation

On January 15, 2019, the Company was named as a defendant in a declaratory judgment action filed by Navigators Specialty Insurance Company (Navigators) in the United States District Court for the Northern District of California (Case No. 3:19-cv-255). Navigators is the Company's primary

NOTE 12. COMMITMENTS AND CONTINGENCIES (Continued)

product liability insurer. Navigators is seeking declaratory judgment that opioid litigation claims noticed by the Company (as further described above under “Multidistrict Opioid Litigation” and “State Opioid Litigation”) are not covered by the Company’s policies with Navigators. The Company filed a response to the complaint on February 28, 2019.

General

The Company cannot reasonably predict the outcome of the legal proceedings described above, nor can the Company estimate the amount of loss, range of loss or other adverse consequence, if any, that may result from these proceedings or the amount of any gain in the event the Company prevails in litigation involving a claim for damages. As such the Company is not currently able to estimate the impact of the above litigation on its financial position or results of operations.

The Company may from time to time become party to actions, claims, suits, investigations or proceedings arising from the ordinary course of its business, including actions with respect to intellectual property claims, breach of contract claims, labor and employment claims and other matters. The Company may also become party to further litigation in federal and state courts relating to opioid drugs. Although actions, claims, suits, investigations and proceedings are inherently uncertain and their results cannot be predicted with certainty, other than the matters set forth above, the Company is not currently involved in any matters that the Company believes may have a material adverse effect on its business, results of operations or financial condition. However, regardless of the outcome, litigation can have an adverse impact on the Company because of associated cost and diversion of management time.

NOTE 13. STOCK-BASED COMPENSATION

The Company uses the Black-Scholes option valuation model to determine the fair value of stock options and employee stock purchase plan (ESPP) shares. The determination of the fair value of stock-based payment awards on the date of grant using an option valuation model is affected by the Company’s stock price as well as assumptions, which include the Company’s expected term of the award, the expected stock price volatility, risk-free interest rate and expected dividends over the expected term of the award. The fair value of restricted stock units equals the market value of the underlying stock on the date of grant.

The Company uses historical option exercise data to estimate the expected term of the options. The Company estimates the volatility of its common stock price by using the historical volatility over the expected term of the options. The Company bases the risk-free interest rate on U.S. Treasury zero-coupon issues with terms similar to the expected term of the options as of the date of grant. The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model.

The Company used the following assumptions to calculate the fair value of option grants for the years ended December 31, 2018, 2017 and 2016.

	2018	2017	2016
Employee and Director Stock Options			
Risk-free interest rate	2.17%	1.65 - 1.93%	0.90 - 1.78%
Expected option term (in years)	4.34	4.24 - 4.30	4.23 - 4.31
Expected stock price volatility	61.94%	51.67 - 59.59%	48.39 - 50.96%

NOTE 13. STOCK-BASED COMPENSATION (Continued)

The Company used the following assumptions to calculate the fair value of stock purchase rights granted under the ESPP for the years ended December 31, 2018, 2017 and 2016:

	<u>2018</u>	<u>2017</u>	<u>2016</u>
Employee Stock Purchase Plan			
Risk-free interest rate	2.05 - 2.50%	1.07 - 1.45%	0.49 - 0.60%
Expected option term (in years)	0.5	0.5	0.5
Expected stock price volatility	56.1 - 58.6%	52.2 - 82.0%	48.1 - 67.5%

The following table presents stock-based compensation expense recognized for stock options, restricted stock units and the ESPP in the Company's Statements of Operations (in thousands):

	<u>2018</u>	<u>2017</u>	<u>2016</u>
Cost of sales	\$ 30	\$ 98	\$ 43
Research and development expense	446	710	496
Selling, general and administrative expense	9,963	12,157	16,633
Restructuring charges	2,146	51	—
Total	<u>\$12,585</u>	<u>\$13,016</u>	<u>\$17,172</u>

The weighted-average grant date fair value of options granted during the years ended December 31, 2018, 2017 and 2016 was \$4.32, \$5.55 and \$6.81, respectively. The weighted-average grant date fair value of stock purchase rights granted under the ESPP during the years ended December 31, 2018, 2017 and 2016 was \$1.73, \$2.97 and \$6.09, respectively. The total intrinsic value of options exercised during the years ended December 31, 2018, 2017 and 2016 was \$0.6 million, \$5.0 million and \$6.6 million, respectively. The total grant date fair value of options that vested during the years ended December 31, 2018, 2017 and 2016 was \$2.3 million, \$4.7 million and \$9.3 million, respectively. At December 31, 2018, the Company had \$14.0 million of total unrecognized compensation expense, related to stock option grants and restricted stock units that will be recognized over an average vesting period of 2 years. Cash received from stock option exercises was \$1.5 million, \$7.0 million and \$6.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. There is no stock-based compensation recorded within inventory in any of the years presented. The recognized tax benefits on total stock-based compensation expense during the years ended December 31, 2018, 2017 and 2016 was \$0.7 million, \$0.4 million and \$0.6 million, respectively.

2004 Equity Incentive Plan

The Company's 2004 Equity Incentive Plan (2004 Plan) was adopted by the Board of Directors and approved by the shareholders in May 2004. The 2004 Plan provides for the grant to employees of the Company, including officers, of incentive stock options, and for the grant of non-statutory stock options to employees, directors and consultants of the Company. The number of shares authorized under the 2004 Plan was 14,450,000 shares and there were no more shares available for future issuance at December 31, 2018.

Generally, the exercise price of all incentive stock options and non-statutory stock options granted under the 2004 Plan must be at least 100% and 85%, respectively, of the fair value of the common stock of the Company on the grant date. The term of incentive and non-statutory stock options may not exceed 10 years from the date of grant. An option shall be exercisable on or after each vesting date in accordance with the terms set forth in the option agreement. The right to exercise an option

NOTE 13. STOCK-BASED COMPENSATION (Continued)

generally vests over four years at the rate of at least 25% by the end of the first year and then ratably in monthly installments over the remaining vesting period of the option.

The following tables summarize the activity for the year ended December 31, 2018 under the 2004 Plan:

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>
Options outstanding at December 31, 2017	1,786,041	\$ 7.62
Options granted	—	—
Options exercised	(277,443)	5.37
Options forfeited	(6,965)	12.69
Options expired	<u>(332,221)</u>	9.56
Options outstanding at December 31, 2018	1,169,412	\$ 7.57
Options vested and expected to vest at December 31, 2018 . . .	1,169,412	\$ 7.57
Options exercisable at December 31, 2018	1,169,412	\$ 7.57

	<u>Weighted-Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Options outstanding at December 31, 2018	1.78	\$29
Options vested and expected to vest at December 31, 2018	1.78	\$29
Options exercisable at December 31, 2018	1.78	\$29

There have been no restricted stock units granted under the 2004 Equity Incentive Plan.

Equity Match Program

On December 6, 2017, the Company Board of Directors approved a one-time incentive program (the Equity Match Program) for the Company’s Chief Executive Officer (the CEO). The Equity Match Program is intended to provide an incentive for the CEO to purchase shares of the Company’s common stock, no par value (the Common Stock), through open-market purchases between December 5, 2017 and February 3, 2018 (the Purchase Period). Under the terms of the Equity Match Program, for each \$100,000 of Common Stock purchased by the CEO during the Purchase Period (up to \$600,000 in total), the Company will grant the CEO an award of restricted stock units (the Matching Units) under the Company’s 2014 Omnibus Incentive Plan having a grant-date value equal to the purchase price of the Common Stock purchased by the CEO (rounded down to the nearest \$100,000). The Matching Units will be granted on the first business day following the earlier of: (i) the CEO’s purchase of a total of \$600,000 of Common Stock, or (ii) the end of the Purchase Period. The Matching Units will vest in full on the third anniversary of the first day during the Purchase Period that the CEO purchased Common Stock in the open market, subject to the CEO’s continued employment through such date. Notwithstanding the foregoing, the Matching Units may vest in full upon a termination without cause or resignation for good reason (including following a change of control of the Company), or upon the CEO’s death or total and permanent disability. As of December 31, 2018, 75,000 shares of the Company Common Stock had been purchased by the CEO at an average price per share of \$8.16 and Matching Units of 73,529 shares were awarded, with a fair value of \$8.16 at the grant date.

NOTE 13. STOCK-BASED COMPENSATION (Continued)

2014 Omnibus Incentive Plan

The Company's 2014 Omnibus Incentive Plan (2014 Plan) was adopted by the Board of Directors and approved by the shareholders in May 2014. The 2014 Plan provides for the grant of stock options, stock appreciation rights, stock awards, cash awards and performance award to the employees, non-employee directors and consultants of the Company. The number of shares authorized under the 2014 Plan is 12,130,000 shares, of which 5,751,303 were available for future issuance at December 31, 2018.

Generally, the exercise price of all incentive stock options and non-statutory stock options granted under the 2014 Plan must be the fair value of the common stock of the Company on the grant date. The term of incentive and non-statutory stock options may not exceed 10 years from the date of grant. An option shall be exercisable on or after each vesting date in accordance with the terms set forth in the option agreement. The right to exercise an option generally vests over four years at the rate of at least 25% by the end of the first year and then ratably in monthly installments over the remaining vesting period of the option.

The following table summarize the activity for the year ended December 31, 2018 under the 2014 Plan:

	<u>Shares</u>	<u>Weighted Average Exercise Price</u>
Options outstanding at December 31, 2017	3,455,769	\$14.24
Options granted	75,304	8.55
Options exercised	—	—
Options forfeited	(1,270,762)	13.20
Options expired	(798,842)	17.83
Options outstanding at December 31, 2018	1,461,469	\$12.90
Options vested and expected to vest at December 31, 2018 . . .	1,461,469	\$12.90
Options exercisable at December 31, 2018	808,141	\$14.30

	<u>Weighted- Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Options outstanding at December 31, 2018	6.75	\$—
Options vested and expected to vest at December 31, 2018	6.75	\$—
Options exercisable at December 31, 2018	6.04	\$—

NOTE 13. STOCK-BASED COMPENSATION (Continued)

Restricted stock units generally vest over three or four years, with 33% or 25% of each award vesting annually, respectively.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (in years)
Non-vested restricted stock units at December 31, 2017	1,166,046	\$10.69	
Granted	1,897,661	6.84	
Vested	(539,898)	9.77	
Forfeited	(585,021)	9.05	
Non-vested restricted stock units at December 31, 2018	1,938,788	\$ 6.94	1.24

The total fair value of restricted stock vested during 2018 was \$3.1 million.

Performance-based Restricted Stock Units

During the twelve months ended December 31, 2018, the Company granted Performance Stock Units (PSUs) with an aggregate target award of 523,187 units and a weighted-average grant-date fair value of \$10.58 per unit. The PSUs vest in annual cliffs over a three year period based on the Relative Total Shareholder Return (TSR) of the Company’s common stock against the Russell 3000 Pharmaceuticals Total Return Index over the period. The ultimate award, which is determined at the end of the three-year cycle, can range from zero to 200% of the target. The recipients of the PSU awards will have voting rights and the right to receive a dividend once the underlying shares have been issued. The grant-date fair value is based upon the Monte Carlo simulation method.

The following table summarizes the PSU activity for the year ended December 31, 2018 under the 2014 Plan (in thousands, except per share data):

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in 000s)
Non-vested performance-based restricted stock units at December 31, 2017	—	\$ —		
Granted	523,187	10.58		
Vested	—	—		
Forfeited	(148,363)	11.68		
Non-vested performance-based restricted stock units at December 31, 2018	374,824	\$10.14	2.09	1,353

As of December 31, 2018, total unrecognized compensation cost related to PSUs was \$2.8 million which is expected to be recognized over the remaining weighted-average vesting period of 2.08 years.

NOTE 14. SHAREHOLDERS' EQUITY

Reincorporation

On August 14, 2018, Depomed reincorporated from California to Delaware (the Reincorporation) and changed its name to Assertio Therapeutics, Inc. To effectuate the Reincorporation, Depomed

NOTE 14. SHAREHOLDERS' EQUITY (Continued)

merged with and into Assertio Therapeutics, Inc., a Delaware corporation and wholly owned subsidiary of Depomed prior to the effective time of the merger, with Assertio continuing as the surviving corporation. Pursuant to the merger, each share of Depomed common stock, no par value, was converted into one share of Assertio common stock, \$0.0001 par value, and all outstanding Depomed equity awards were assumed by Assertio. As a result of the Reincorporation and the related conversion of each share of Depomed-California common stock, no par value, into one share of Assertio-Delaware common stock, \$0.0001 par value, the Company has separated the par value of stock within Common Stock from additional-paid-in-capital on the Company's Consolidated Balance Sheets. The Company has elected to present this impact of the Reincorporation retrospectively. Accordingly, to conform to current year presentation, the Company reclassified \$264.5 million from common stock to additional paid-in capital as of December 31, 2015 on the Company's Consolidated Balance Sheets.

Employee Stock Purchase Plan

In May 2004, the ESPP was approved by the shareholders. The ESPP is qualified under Section 423 of the Internal Revenue Code. The ESPP is designed to allow eligible employees to purchase shares of the Company's common stock through periodic payroll deductions. The price of the common stock purchased under the ESPP must be equal to at least 85% of the lower of the fair market value of the common stock on the commencement date of each offering period or the specified purchase date. The number of shares authorized for issuance under the ESPP as of December 31, 2018 was 3,000,000, of which 302,549 shares were available for future issuance.

In 2018, the Company sold 106,500 shares of its common stock under the ESPP. The shares were purchased at a weighted-average purchase price of \$4.95 with proceeds of approximately \$0.5 million. In 2017, the Company sold 261,569 shares of its common stock under the ESPP. The shares were purchased at a weighted-average purchase price of \$7.49 with proceeds of approximately \$2.0 million.

Option Exercises

Employees exercised options to purchase 278,000 shares of the Company's common stock with net proceeds to the Company of approximately \$1.5 million during 2018. Employees exercised options to purchase 1,000,892 shares of the Company's common stock with net proceeds to the Company of approximately \$7.0 million during 2017.

NOTE 15. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted net income (loss) per share is calculated by dividing the net income by the weighted-average number of shares of common stock outstanding during the period, plus potentially dilutive common shares, consisting of stock options and convertible debt. The Company uses the treasury-stock method to compute diluted earnings per share with respect to its stock options and equivalents. The Company uses the if-converted method to compute diluted earnings per share with respect to its convertible debt. For purposes of this calculation, options to purchase stock are considered to be potential common shares and are only

NOTE 15. NET INCOME (LOSS) PER SHARE (Continued)

included in the calculation of diluted net income (loss) per share when their effect is dilutive. Basic and diluted earnings per common share are calculated as follows:

(in thousands, except for per share amounts)	<u>2018</u>	<u>2017</u>	<u>2016</u>
Basic and diluted net income (loss) per share			
Net income (loss)	\$36,908	\$(102,496)	\$(88,720)
Denominator	63,794	62,702	61,297
Basic net income (loss) per share	<u>\$ 0.58</u>	<u>\$ (1.63)</u>	<u>\$ (1.45)</u>
Diluted net income (loss) per share			
Numerator:			
Net income (loss)	\$36,908	\$(102,496)	\$(88,720)
Denominator:			
Denominator for basic income (loss) per share	63,794	62,702	61,297
Add effect of diluted securities:			
Stock options and equivalents	414	—	—
Denominator for diluted income (loss) per share	<u>\$64,208</u>	<u>\$ 62,702</u>	<u>\$ 61,297</u>
Diluted net income (loss) per share	<u>\$ 0.57</u>	<u>\$ (1.63)</u>	<u>\$ (1.45)</u>

The following table sets forth outstanding potential shares of common stock that are not included in the computation of diluted net income (loss) per share because, to do so would be anti-dilutive:

(in thousands)	<u>2018</u>	<u>2017</u>	<u>2016</u>
Convertible debt	17,931	17,931	17,931
Stock options and equivalents	3,701	5,618	3,371
Total potentially dilutive common shares	<u>21,632</u>	<u>23,549</u>	<u>21,302</u>

NOTE 16. ACQUISITIONS AND DISPOSITIONS

On November 7, 2017, the Company entered into an agreement with Slán Medicinal Holdings Limited (Slán) under which it (i) acquired from Slán certain rights to market the specialty drug, long-acting cosyntropin in the United States and (ii) divested to Slán all of its rights to Lazanda® (fentanyl) nasal spray CII. The term of the License Agreement for long-acting cosyntropin runs from November 7, 2017, through the end of the 10-year period following the first commercial sale of an approved product (Licensed Product), but the Company may terminate the License Agreement if the FDA determines that a Licensed Product is not approvable in the U.S. Under the terms of the Agreement, Slán is responsible for clinical and regulatory expenses associated with long-acting cosyntropin prior to its first approval by the U.S. Food and Drug Administration. Upon approval, the Company will be responsible for marketing and selling long-acting cosyntropin for the first seven years following the first commercial sale of a Licensed Product in the U.S., and Slán will be responsible for selling the Licensed Product during the remaining three years of the 10-year period.

NOTE 16. ACQUISITIONS AND DISPOSITIONS (Continued)

The acquisition of exclusive rights to market long-acting cosyntropin in the United States was treated as an asset acquisition under the applicable guidance contained with U.S. GAAP. The fair value of the license to market long-acting cosyntropin was estimated to be approximately \$24.9 million which, in accordance with the applicable accounting rules, was recorded as “acquired in process research and development” in the accompanying consolidated statements of operations as long-acting cosyntropin is still under development and the rights the Company acquired were deemed to have no alternative future use.

As consideration for this acquisition, the Company provided the seller all of the rights and obligations, as defined under the arrangement, associated with Lazanda and together with \$5.0 million in cash to Slán. The divestiture of Lazanda was treated as a disposition of a business for accounting purposes and resulted in a gain of approximately \$17.1 million which was recorded as “gain on divestiture of Lazanda” in the accompanying consolidated statements of operations. The Company determined that the divestiture of Lazanda does not qualify for reporting as discontinued operations as the divestiture does not constitute on its own a strategic shift that will have a major effect on the Company’s operations and financial results.

NOTE 17. INCOME TAXES

The (benefit) provision for income taxes consists of the following (in thousands):

	<u>2018</u>	<u>2017</u>	<u>2016</u>
Current:			
Federal	\$ 896	\$ 384	\$ 1,087
State	171	(1,813)	140
	<u>\$1,067</u>	<u>\$(1,429)</u>	<u>\$ 1,227</u>
Deferred:			
Federal	\$ —	\$ —	\$16,291
State	—	—	6,700
	<u>—</u>	<u>—</u>	<u>22,991</u>
Total (benefit) provision for income taxes	<u>\$1,067</u>	<u>\$(1,429)</u>	<u>\$24,218</u>

A reconciliation of income taxes at the statutory federal income tax rate to the actual tax rate included in the statements of operations is as follows (in thousands):

	<u>2018</u>	<u>2017</u>	<u>2016</u>
Tax at federal statutory rate	\$ 7,975	\$(36,374)	\$(22,580)
State tax, net of federal benefit	192	71	(748)
Research credit	(41)	(41)	(902)
Stock based compensation	1,259	159	1,435
Non-deductible meals and entertainment	223	973	955
Non-deductible other expense	308	6,508	1,426
Change in valuation allowance	(9,233)	1,326	44,632
Uncertain tax provisions	384	(1,611)	—
Tax rate changes	—	27,560	—
Total	<u>\$ 1,067</u>	<u>\$(1,429)</u>	<u>\$ 24,218</u>

NOTE 17. INCOME TAXES (Continued)

During 2018, the Company recorded income tax expense of approximately \$1.1 million principally due to the increase in book income from Purdue litigation settlement.

During 2017, the Company recognized a tax benefit of approximately \$1.4 million principally due to release of liability and accrued interest and penalties associated with uncertain tax

During 2016, the Company recorded income tax expense of approximately \$24.2 million principally due to the recording of a full valuation allowance against its deferred tax assets.

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act (the Tax Act). The Tax Act includes significant changes to the U.S. corporate income tax system including, but not limited to, a federal corporate rate reduction from 35% to 21% and limitations on the deductibility of interest expense and executive compensation. In order to calculate the effects of the new corporate tax rate on our deferred tax balances, ASC 740 *Income Taxes* (ASC 740) required the re-measurement of our deferred tax balances as of the enactment date of the Tax Act, based on the rates at which the balances were expected to reverse in the future. Due to the Company's full valuation allowance position, there is no change to the presentation of the deferred tax balances on the financial statements, except for the re-measurement of these deferred tax balances in the income tax footnote. The re-measurement resulted in a one-time reduction in federal & state deferred tax assets of approximately \$25.5 million, which was fully offset by a corresponding change to the Company's valuation allowance. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (SAB 118), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. As of December 31, 2018, we completed our accounting for all tax effects related to the Tax Act, and there were no material adjustments recorded during the year to the previously recorded provisional amounts reflected in our 2017 financial statements.

As of December 31, 2018, the Company had net operating loss carry forwards for federal income tax purposes of approximately \$4.9 million, which begin to expire in 2021. Net operating loss carryforwards for state income tax purposes were approximately \$89.7 million, which begin to expire in 2018. The Company had federal and California state research and development credit carryforwards of \$0.0 million and \$2.6 million, respectively. The California state research and development credit has no expiration.

Utilization of the Company's net operating loss and credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

NOTE 17. INCOME TAXES (Continued)

Deferred income taxes reflect the temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	<u>2018</u>	<u>2017</u>
Deferred tax assets:		
Net operating losses	\$ 6,618	\$ 16,391
Tax credit carryforwards	1,096	1,860
Intangibles	33,604	38,509
Stock-based compensation	2,286	1,505
Reserves and other accruals not currently deductible	<u>10,706</u>	<u>12,094</u>
Total deferred tax assets	54,310	70,359
Valuation allowance for deferred tax assets	<u>(41,905)</u>	<u>(54,224)</u>
	\$ 12,405	\$ 16,135
Deferred tax liabilities		
Convertible debt	\$(12,213)	\$(16,135)
Fixed Assets	<u>(192)</u>	<u>—</u>
Net deferred tax asset (liability)	<u>—</u>	<u>—</u>

In 2018, the Company recorded a valuation allowance of \$41.9 million to offset, in full, the benefit related to its net deferred tax assets as of December 31, 2018 because realization of the future benefits is uncertain. The Company reviewed both positive evidence such as, but not limited to, the projected availability of future taxable income and negative evidence such as the history of cumulative losses in recent years. The Company will continue to assess the realizability of its deferred tax assets on a quarterly basis, and assess whether an additional reserve or a release of the valuation allowance is required in future periods.

The valuation allowance decreased by \$12.3 million, increased by \$9.0 million, and increased by \$44.6 million during the years ended December 31, 2018, 2017 and 2016 respectively.

The Company files income tax returns in the United States federal jurisdiction and in various states, and the tax returns filed for the years 1997 through 2017 and the applicable statutes of limitation have not expired with respect to those returns. Because of net operating losses and unutilized R&D credits, substantially all of the Company's tax years remain open to examination.

Interest and penalties, if any, related to unrecognized tax benefits would be recognized as income tax expense by the Company. At December 31, 2018, the Company had approximately \$1.4 million of accrued interest and penalties associated with any unrecognized tax benefits.

NOTE 17. INCOME TAXES (Continued)

The following table summarizes the activity related to the Company's unrecognized tax benefits for the three years ended December 31, 2018 (in thousands):

Unrecognized tax benefits—January 1, 2016	\$ 5,686
Gross increases—current year tax positions	240
Gross increases—prior year tax positions	8,761
Unrecognized tax benefits—December 31, 2016	14,687
Gross increases—current year tax positions	3,423
Gross decreases—prior year tax positions	(966)
Unrecognized tax benefits—December 31, 2017	17,144
Gross increases—current year tax positions	262
Gross decreases—prior year tax positions	(1,342)
Unrecognized tax benefits—December 31, 2018	<u>\$16,064</u>

The total amount of unrecognized tax benefit that would affect the effective tax rate is approximately \$16.1 million as of December 31, 2018 and \$17.1 million as of December 31, 2017. The Company has recorded an other asset of \$5.3 million related to tax benefits that would be realized in 2018 if all uncertain tax positions were assessed.

The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for items that arise in the ordinary course of business.

NOTE 18. SUBSEQUENT EVENTS*Amended Senior Note Agreement*

In January 2019, the Company entered into a Fourth Amendment to Note Purchase Agreement (the "Amendment") with respect to the Note Purchase Agreement, dated as of March 12, 2015, among the Company, the other credit parties party thereto, the purchasers party thereto and Deerfield. Pursuant to the Amendment, the minimum EBITDA covenant was replaced with a senior secured debt leverage ratio covenant and a minimum net sales covenant, the prepayment premium was adjusted to be 3% of the principal amount of notes prepaid on or prior to April 14, 2020 and 1% of the principal amount of notes prepaid thereafter, flexibility to sell certain royalty assets and/or modify the terms thereof was added, certain definitions were amended and certain other amendments were made. The Company paid a \$3.2 million upfront non-refundable amendment fee.

NOTE 19. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables set forth certain unaudited quarterly financial data for each of the eight quarters beginning with the quarter ended March 31, 2017 through the quarter ended December 31, 2018 (in thousands). This quarterly financial data is unaudited, but has been prepared on the same basis as the annual financial statements and, in the opinion of management, reflects all adjustments, consisting only of normal recurring adjustments necessary for a fair representation of the information

NOTE 19. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED) (Continued)

for the periods presented. Operating results for any quarter are not necessarily indicative of results for any future period.

(in thousands)	2018 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Product sales	\$ 44,354	\$ 26,838	\$29,435	\$ 29,339
Total revenues	128,404	63,274	77,493	42,599
Gross margin on product sales	32,310	24,085	26,460	28,635
(Loss) income from operations	51,338	(4,225)	9,628	(13,082)
Net income (loss)	33,824	(21,048)	48,270	(24,138)
Basic net loss per share	\$ 0.53	\$ (0.33)	\$ 0.76	\$ (0.38)
Diluted net loss per share	\$ 0.48	\$ (0.33)	\$ 0.65	\$ (0.38)

(in thousands)	2017 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Product sales	\$ 90,285	\$100,232	\$ 95,204	\$ 94,159
Total revenues	90,447	100,457	95,413	94,407
Gross margin on product sales	72,511	80,507	77,808	76,455
Loss from operations	(6,665)	(4,068)	1,238	(32,685)
Net loss	(26,741)	(26,659)	(15,992)	(33,104)
Basic net loss per share	\$ (0.43)	\$ (0.43)	\$ (0.25)	\$ (0.52)
Diluted net loss per share	\$ (0.43)	\$ (0.43)	\$ (0.25)	\$ (0.52)

SCHEDULE II: VALUATION AND QUALIFYING ACCOUNTS

(in thousands)

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Additions</u>		<u>Deductions(1)</u>	<u>Balance at End of Year</u>
		<u>Charged as a Reduction to Revenue</u>	<u>Change in Deferred Revenue</u>		
Sales & return allowances, discounts, chargebacks and rebates:					
Year ended December 31, 2018	\$137,328	\$122,481	\$—	\$(183,408)	\$ 76,401
Year ended December 31, 2017	\$133,646	\$363,260	\$—	\$(359,578)	\$137,328
Year ended December 31, 2016	\$122,516	\$339,094	\$—	\$(327,964)	\$133,646

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Additions</u>		<u>Deductions(1)</u>	<u>Balance at End of Year</u>
		<u>Charged as a Reduction to Revenue</u>	<u>Change in Deferred Revenue</u>		
Deferred tax asset valuation allowance:					
Year ended December 31, 2018(4)	\$54,224	\$ —	\$—	\$(12,319)	\$41,905
Year ended December 31, 2017(3)	\$45,206	\$ 9,018	\$—	\$ —	\$54,224
Year ended December 31, 2016(2)	\$ 573	\$44,633	\$—	\$ —	\$45,206

- (1) Deductions to sales discounts and allowances relate to discounts or allowances actually taken or paid.
- (2) The Company recorded a valuation allowance of \$44.6 million during 2016.
- (3) The Company recorded a valuation allowance of \$9.0 million during 2017.
- (4) The Company reversed a valuation allowance of \$12.3 million during 2018.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer, principal financial officer and principal accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on this evaluation, our principal executive officer, our principal financial officer and principal accounting officer concluded that our disclosure controls and procedures were effective as of December 31, 2018 to ensure that information to be disclosed by us in this Annual Report on Form 10-K was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-K.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer, principal financial officer and principal accounting officer, as appropriate, to allow for timely decisions regarding required disclosure.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer, principal financial officer and principal accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2018. Ernst & Young LLP, our independent registered public accounting firm, has attested to and issued a report on the effectiveness of our internal control over financial reporting, which is included herein.

(c) Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2018, there were no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Assertio Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Assertio Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2018, 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, Assertio Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, 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 Assertio Therapeutics, Inc. as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) and our report dated March 11, 2019 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 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

Chicago, Illinois

March 11, 2019

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated herein by reference to the information set forth under the headings “Board of Directors and Director Nominees,” “Executive Officers,” “Corporate Governance—Code of Ethics,” “Corporate Governance—Board and Board Committees,” “Corporate Governance—Director Nominations” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our 2019 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2019 Annual Meeting of Stockholders (the 2019 Proxy Statement). The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of our 2018 fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to the information set forth under the headings “Corporate Governance—Compensation Committee Interlocks and Insider Participation,” “Compensation Committee Report” and “Executive Compensation” in our 2019 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information required by this Item 12 is incorporated herein by reference to the information set forth under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance under Equity Compensation Plans” in our 2019 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated herein by reference to the information set forth under the headings “Certain Relationships and Related Transactions” and “Corporate Governance—Board and Board Committees—Board Independence” in our 2019 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to the information set forth under the headings “Audit Related Matters—Fees Paid to Independent Registered Public Accounting Firm” and “Audit Related Matters—Policy on Pre-Approval of Audit and Permissible Non-Audit Services” in our 2019 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements listed in the accompanying Index to Financial Statements included in “Item 8. Financial Statements and Supplementary Data.”

(2) **Financial Statement Schedules**

The following financial statement schedule included in “Item 8. Financial Statements and Supplementary Data”: Schedule II: Valuation and Qualifying Accounts

(3) **Exhibits:**

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger, dated August 10, 2018, by and between Depomed Inc., a California corporation and Assertio Therapeutics, Inc., a Delaware corporation (incorporated by reference to Exhibit 2.1 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
3.1	Certificate of Merger effective August 14, 2018 at 11:59 p.m. Eastern (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
3.2	Certificate of Incorporation of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
3.3	Bylaws of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
3.4	Specimen Common Stock Certificate of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 3.4 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
4.1	Senior Indenture dated as of September 9, 2014 between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on September 9, 2014)
4.2	First Supplemental Indenture dated as of September 9, 2014 between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee, supplementing the Senior Indenture dated as of September 9, 2014 (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed on September 9, 2014)
4.3	Second Supplemental Indenture, dated August 14, 2018, by and between Assertio Therapeutics, Inc., a Delaware corporation, and the Bank of New York Melon Trust Company, N.A. as Trustee (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
10.1*	Form of Indemnification Agreement of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
10.2*	Form of Amended and Restated Management Continuity Agreement of Assertio Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K12B filed on August 15, 2018)
10.3*	Amended and Restated 2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.5 to the Company’s Quarterly Report on Form 10-Q filed on November 9, 2018)
10.4*	Second Amended and Restated 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Company’s Quarterly Report on Form 10-Q filed on November 9, 2018)

Exhibit Number	Description of Document
10.5*	Amended and Restated 2014 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2018)
10.6*	Form of Equity Award Documents under Amended and Restated 2014 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2018)
10.7*	Form of Equity Award Documents for Inducement Grants (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2018)
10.8*	Amended and Restated Annual Bonus Plan, as adopted on May 17, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 22, 2017)
10.9*	Non-Employee Director Compensation and Grant Policy (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2018)
10.10*	Transition and Consulting Agreement dated December 8, 2017 by and between the Company and Matthew M. Gosling (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed on March 1, 2018)
10.11*	Transition and Consulting Agreement dated December 8, 2017 by and between the Company and August J. Moretti (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed on March 1, 2018)
10.12*	Offer Letter dated March 28, 2017 between the Company and Arthur J. Higgins (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2017)
10.13*	Offer Letter dated October 17, 2017 by and between the Company and Santosh J. Vetticaden, M.D., PH.D. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2017)
10.14*	Offer Letter dated June 1, 2018, between the Company and Phillip B. Donenberg (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed August 8, 2018)
†10.15	Commercial Manufacturing Agreement dated June 1, 2011 between the Company and Patheon Puerto Rico, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 7, 2011)
†10.16	Commercialization Agreement dated August 22, 2011 between the Company and Santarus, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 7, 2011)
10.17	Asset Purchase Agreement dated June 21, 2012 between the Company and Xanodyne Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 3, 2012)
†10.18	Asset Purchase Agreement, dated December 17, 2013 between the Company and Nautilus Neurosciences, Inc. (incorporated by reference to Exhibit 10.51 to the Company's Annual Report on Form 10-K filed on March 17, 2014)
†10.19	Asset Purchase Agreement dated January 15, 2015 between the Company and Janssen Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K filed on February 26, 2015)

Exhibit Number	Description of Document
†10.20	Assignment and Consent Agreement dated January 13, 2015 between the Company and Grunenthal GmbH related to the License Agreement (U.S.) dated January 13, 2015 between Grunenthal GmbH and Janssen Research and Development (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q/A filed on December 18, 2015)
†10.21	Transitional Supply Agreement dated April 2, 2015 among the Company and Janssen Pharmaceuticals, Inc. and Janssen Ortho LLC (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q/A filed on December 18, 2015)
†10.22	Supply Agreement dated April 2, 2015 between the Company and Normaco, Inc. (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q/A filed on December 18, 2015)
10.23	Drug Product Manufacturing Services Agreement dated June 6, 2017 by and between the Company and Halo Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2017)
†10.24	Commercialization Agreement dated December 4, 2017 by and among the Company Collegium Pharmaceutical, Inc. and Collegium NF, LLC (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed March 1, 2018)
†10.25	Consent Agreement dated as of November 30, 2017 by and between the Company and Grunenthal GmbH related to the License Agreement (U.S.) dated January 13, 2015 between Grunenthal GmbH and Janssen Research and Development (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K filed March 1, 2018)
10.26	Amendment dated January 9, 2018 to Commercialization Agreement by and among the Company Collegium Pharmaceutical, Inc. and Collegium NF, LLC (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed March 1, 2018)
10.27	Amendment No. 2, to Commercialization Agreement, dated as of August 29, 2018, by and among the Company, Collegium Pharmaceutical, Inc. and Collegium NF, LLC (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2018)
10.28	Amendment No. 3 to Commercialization Agreement, dated November 8, 2018, by and among Assertio Therapeutics, Inc., Collegium Pharmaceutical, Inc., and Collegium NF, LLC. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 8, 2018)
†10.29	Note Purchase Agreement dated March 12, 2015 among the Company and Deerfield Private Design Fund III, L.P., Deerfield Partners, L.P., Deerfield International Master Fund, L.P., Deerfield Special Situations Fund, L.P., Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and BioPharma Secured Investments III Holdings Cayman LP, Inteligo Bank Ltd. And Phemus Corporation and Deerfield Design Fund III, L.P., as collateral agent (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q/A filed on December 18, 2015)
†10.30	Pledge and Security Agreement dated April 2, 2015 between the Company and Deerfield Private Design Fund III, L.P., a collateral agent (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q/A filed on December 18, 2015)

Exhibit Number	Description of Document
†10.31	Consent and First Amendment to Note Purchase Agreement dated December 29, 2015 between the Company, Deerfield Private Design Fund III, L.P. and the parties thereto (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on February 26, 2016)
10.32	Waiver and Second Amendment to Note Purchase Agreement dated December 4, 2017 by and among the company, the purchases thereto and Deerfield Private Design Fund III, L.P., as collateral agent (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on December 14, 2017)
10.33	Waiver, Consent and Third Amendment to Note Purchase Agreement and Partial Release of Security Interest, dated August 2, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 2, 2018)
10.34	Consent to Note Purchase Agreement and Assumption Agreement dated August 14, 2018. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K12B filed on August 15, 2018)
10.35	Consent, dated November 8, 2018, by and among Assertio Therapeutics, Inc., certain purchasers and Deerfield Private Design Fund III, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 8, 2018)
10.36	Fourth Amendment to Note Purchase Agreement, dated January 8, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 9, 2019)
10.37	Agreement dated October 17, 2016 among the Company and Starboard Value LP and certain of its affiliates (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 19, 2016)
10.38	Cooperation and Support Agreement dated March 28, 2017 by and among the Company, Starboard Value LP and certain of its affiliates (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 29, 2017)
†10.39	Royalty Purchase and Sale Agreement dated October 18, 2013, among the Company, Depo DR Sub, LLC and PDL BioPharma, Inc. (incorporated by reference to Exhibit 10.50 to the Company's Annual Report on Form 10-K filed on March 17, 2014)
10.40	Amendment No. 1 to Royalty Purchase and Sale Agreement and Bill of Sale, dated August 2, 2018, by and among Depomed, Inc., Depo DR Sub, LLC, and PDL Investment Holdings, LLC (as assignee of PDL BioPharma, Inc.) (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed August 8, 2018)
10.41	Settlement Agreement, dated as of August 28, 2018, by and among the Company, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2018)
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on signature page hereto)
31.1	Certification pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act
31.2	Certification pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act
32.1**	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350

Exhibit Number	Description of Document
32.2**	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

† Confidential treatment granted

* Compensatory Plan or Arrangement

** Furnished Herewith

ITEM 16. FORM 10-K SUMMARY

None.

<hr/> Heather L. Mason	Director	March 11, 2019
<hr/> /s/ WILLIAM T. MCKEE William T. McKee	Director	March 11, 2019
<hr/> /s/ PETER D. STAPLE Peter D. Staple	Director	March 11, 2019
<hr/> /s/ JAMES L. TYREE James L. Tyree	Director	March 11, 2019

SUBSIDIARIES OF THE REGISTRANT

<u>Name of Subsidiary</u>	<u>State of Jurisdiction or Organization</u>
Depo DR Sub, LLC	Delaware
Depo NF Sub, LLC	Delaware
Depomed Bermuda Ltd	Bermuda

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- 1) Registration Statements (Forms S-3 No. 333-53486, No. 333-66688, No. 333-86542, No. 333-104956, No. 333-197433 and No. 333-223420) and related Prospectuses of Assertio Therapeutics, Inc.,
- 2) Registration Statements (Forms S-8 No. 333-116697, No. 333-145291, No. 333-156538, No. 333-167015, No. 333-181710, No. 333-196263, No. 333-211642, No. 333-211643, No. 333-224924, and No. 333-228290) pertaining to the 2004 Equity Incentive Plan, the Second and Amended and Restated 2004 Employee Stock Purchase Plan, the Amended and Restated 2014 Omnibus Incentive Plan of Assertio Therapeutics, Inc. and the Assertio Therapeutics, Inc. Inducement Award Program.

of our reports dated March 11, 2019, with respect to the consolidated financial statements and schedule of Assertio Therapeutics, Inc., and the effectiveness of internal control over financial reporting of Assertio Therapeutics, Inc., included in this Annual Report (Form 10-K) of Assertio Therapeutics, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Chicago, Illinois
March 11, 2019

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER

I, Arthur J. Higgins, certify that:

1. I have reviewed this Annual Report on Form 10-K of Assertio Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2019

By: /s/ ARTHUR J. HIGGINS

Arthur J. Higgins
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER

I, Daniel A. Peisert, certify that:

1. I have reviewed this Annual Report on Form 10-K of Assertio Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2019

By: /s/ DANIEL A. PEISERT

Daniel A. Peisert
*Senior Vice President and Chief Financial Officer
(Principal Financial Officer)*

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

In connection with the Annual Report on Form 10-K of Assertio Therapeutics, Inc. (the “Company”) for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Arthur J. Higgins, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2019

/s/ ARTHUR J. HIGGINS

Arthur J. Higgins
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Annual Report on Form 10-K of Assertio Therapeutics, Inc. (the “Company”) for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Daniel A. Peisert, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2019

/s/ DANIEL A. PEISERT

Daniel A. Peisert
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)