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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

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

**For the year ended December 31, 2020**

**OR**

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

**For the transition period from to**

**Commission File Number 001-37372**

# Collegium Pharmaceutical, Inc.

(Exact name of registrant as specified in its charter)

| **Virginia** | **03-0416362** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |
| **100 Technology Center Drive**<br>**Stoughton, MA** | **02072** |
| (Address of principal executive offices) | (Zip Code) |

**(781) 713-3699**

(Registrant's telephone number, including area code)

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

| Title of each class | Trading Symbol(s) | Name of exchange on which registered: |
|---|---|---|
| Common stock, par value $0.001 per share | COLL | The NASDAQ Global Select Market |

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $598.6 million, based on the closing price of the registrant's common stock on The NASDAQ Global Select Market on June 30, 2020 of $17.50 per share. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

As of January 31, 2021, there were 34,756,311 shares of the registrant's common stock, par value, $0.001 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2020, are incorporated by reference in Part II and Part III of this Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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**Forward-Looking Statements**

Statements made in this Annual Report on Form 10-K that are not statements of historical or current facts, such as those under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our current expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. These statements may be preceded by, followed by or include the words "aim," "anticipate," "believe," "estimate," "expect," "forecast," "intend," "outlook," "plan," "potential," "project," "projection," "seek," "may," "could," "would," "should," "can," "can have," "likely," the negatives thereof and other words and terms of similar meaning.

Forward-looking statements are inherently subject to risks, uncertainties and assumptions; they are not guarantees of performance. You should not place undue reliance on these statements. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that our assumptions made in connection with the forward-looking statements are reasonable, we cannot assure you that the assumptions and expectations will prove to be correct.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our ability to commercialize and grow sales of our products, particularly in light of current global challenges stemming from the COVID-19 pandemic;
- our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products and any product candidates, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts with favorable terms for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P.;
- the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and to manufacture adequate quantities of commercially salable inventory and to maintain our supply chain in the face of global challenges, such as the COVID-19 pandemic;
- our ability to effectively manage our relationships with licensors and to commercialize products that we in-license from third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our operations and business development;
- our ability to comply with the terms of our outstanding indebtedness;
- regulatory developments in the United States;
- our ability to obtain and maintain sufficient intellectual property protection for our products and any product candidates;
- our ability to comply with stringent government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency ("DEA") compliance;
- the loss of key commercial, scientific or management personnel;
- our customer concentration, which may adversely affect our financial condition and results of operations;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading "Risk Factors" in this Annual Report on Form 10-K.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Annual Report on Form 10-K (including the exhibits hereto) might not occur. We undertake no obligation, and specifically decline any obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

These and other risks are described under the heading "Risk Factors" in this Annual Report on Form 10-K. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.

# PART I

## Item 1. Business

### Overview

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our portfolio includes Xtampza ER, an abuse-deterrent, extended-release, oral formulation of oxycodone and Nucynta ER and Nucynta IR (collectively, the "Nucynta Products"), which are extended-release ("ER") and immediate-release ("IR") formulations of tapentadol. Xtampza ER was approved by the U.S. Food and Drug Administration ("FDA") in April 2016 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. We commercially launched Xtampza ER in June 2016.

Nucynta ER 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 in adults, and for which alternate treatment options are inadequate. Nucynta IR is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. We initially licensed the right to commercialize the Nucynta Products in the United States through a Commercialization Agreement with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio") entered into in December 2017 (the "Nucynta Commercialization Agreement") and began marketing the Nucynta Products in February 2018. On February 13, 2020, we closed our acquisition of certain assets related to the Nucynta Products, including the right to commercialize the Nucynta Products in the United States and certain regulatory and supply chain assets (the "Nucynta Acquisition"), from Assertio for an aggregate purchase price of $375.0 million, subject to certain adjustments as set forth in the Asset Purchase Agreement, dated as of February 6, 2020, between us and Assertio (the "Nucynta Purchase Agreement").

For the fiscal year ended December 31, 2020, we generated $310.0 million in net revenues, comprised of $128.0 million from sales of Xtampza ER and $182.0 million from sales of the Nucynta Products.

The COVID-19 pandemic has severely impacted global economic activity, and federal and state governments, as well as numerous foreign countries, have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. The travel restrictions and "social distancing" recommendations resulting from the spread of COVID-19, as well as the closure or limited operations of many physicians' offices, have impacted our sales professionals' ability to travel to and meet with healthcare providers in person. As of the date of the filing of this Annual Report on Form 10-K, the COVID-19 pandemic and actions taken to contain it have impacted revenue (due to fewer new patients beginning therapy with our products and the pandemic's adverse impact on our ability to promote products) and decreased certain operating expenses, including travel, marketing and expenses associated with participation in congresses that have been postponed. We believe that the disruptions caused by COVID-19 will continue in the near term, and there remains substantial uncertainty as to when such disruptions will cease (or ease).

### Pain, Pain Management and Opioid Abuse in the United States

#### *Acute and Chronic Pain*

Pain can be classified along many different variables, including severity, duration and etiology. There are two broad categories of pain based on duration: acute pain, or pain that is self-limited and generally requires treatment for no more than up to a few weeks, and chronic pain, or pain that lasts beyond the healing of an injury or that persists longer than 3-6 months. According to a 2019 U.S. Centers for Disease Control and Prevention ("CDC") report, it is estimated that chronic pain affects at least 40 million U.S. adults annually, with at least 14 million of those adults experiencing high impact chronic pain, defined as chronic pain that interferes with daily life or work activities most days or every day. Acute pain is even more prevalent and can occur after an injury, burn, trauma or surgery.

Chronic pain leads to over $560 billion in healthcare and productivity costs annually, according to a 2011 report from the Institute of Medicine. In addition, studies suggest that healthcare costs for people suffering from chronic pain are higher, and often substantially higher, than for those without chronic pain.

***The Role of Prescription Opioids in the Treatment of Pain***

Prescription opioids continue to serve as important tools in the treatment of acute and chronic pain where alternative treatments have been inadequate. Prescription opioids are available in immediate-release formulations as well as in extended-release formulations, which incorporate a time-release mechanism designed to deliver steady amounts of opioid, typically over 12 to 24 hours. Extended-release opioids are designed to offer more convenient dosing with a longer period of consistent blood levels of the active drug as compared to immediate-release formulations.

In 2020, there were approximately 157.1 million prescriptions for opioids written in the United States, representing an 8% decline from 2019 levels and including approximately 3.2 million prescriptions for branded extended-release opioids, approximately 13.1 million prescriptions for generic extended-release opioids, and greater than 140.8 million prescriptions for immediate-release opioids. After marked increases in opioid prescriptions from 2000 to 2015, prescriptions have decreased each year since 2015, correlated with rising awareness of the extent and impact of the opioid crisis. Prescription levels for 2020 represent a return to levels similar to these seen in the year 2000, when 143.8 million prescriptions for opioid were written in the United States, including 11.4 million prescriptions for extended-release opioids and 132.3 million prescriptions for immediate-release opioids

Increasingly, practitioners and regulators are focusing on multidisciplinary, multimodal approaches to pain management, including exercise, physical therapy and psychotherapy, and opioid and non-opioid medications. Recognizing the role that opioid therapy continues to play in effective management of moderate to severe pain in appropriate patients, these groups are advocating for best practices that support appropriate opioid prescribing practices that may help mitigate the risks of abuse, addiction and other adverse events to patients.

***Prescription Opioid Abuse in the United States***

Prescription opioids of all kinds, including both immediate-release and extended-release formulations, are subject to manipulation, misuse, and abuse. Besides their accepted uses for analgesia, opioids produce a general sense of well-being or euphoria by reducing tension, anxiety, and aggression. These effects contribute to the attractiveness of opioids for abuse and, indeed, the CDC has described abuse of prescription drugs in the United States as a vast and deadly epidemic. The beginning of the opioid overdose epidemic in the late 1990s was marked by a rise in prescription opioid overdose deaths. For a variety of reasons, heroin use began increasing in the mid-2000s, and had surpassed prescription opioids as a cause of opioid-related overdose by 2016, reaching a rate of 4.9 per 100,000 persons in 2018. Meanwhile, the predominant opioid cause of death in 2018 involved synthetic opioids other than methadone. While opioid-involved overdose deaths declined slightly in 2018 (in contrast to the sharp increases during 2014 to 2017), the number of drug overdose deaths was still four times higher in 2018 than in 1999. Moreover, and despite the decrease in prescription opioid utilization, the rate of opioid-involved overdose deaths rose slightly again in 2019 (from 20.7 per 100,000 to 21.6), and there are early indications that widespread social isolation, coupled with reduced access to harm reduction services, has been correlated with a substantial upswing in such deaths beginning in early 2020.

The opioid epidemic has, in addition to its death toll, imposed significant burdens on the U.S. healthcare system. In 2016, there were an estimated 91,840 hospitalizations and 197,970 emergency department visits for opioid-related poisonings in the United States. A nonprofit group that studies the health economy recently estimated that the opioid epidemic has cost the United States more than a trillion dollars since 2001, based on CDC mortality data through June 2017. The greatest financial cost of the epidemic, according to the report, is in lost earnings and productivity losses to employers.

Despite the reduction in opioid prescriptions in recent years and the heightened awareness of the risks associated with opioid use, abuse of prescription opioids, including extended-release formulations, continues to be a major public health issue. In 2019, an estimated 10.1million, or 3.7% of persons aged 12 and older, reported opioid misuse in the prior year.

Extended-release opioids may be especially attractive to people who abuse opioids because, if the extended release mechanism can be defeated through tampering, many extended-release products quickly deliver a relatively large amount of active pharmaceutical ingredient (an effect known as “dose dumping”). By manipulating these products, therefore, people who abuse opioids achieve a more intense euphoria as a result of rapid increases in the blood concentration of the active pharmaceutical ingredient.

In response to issues surrounding abuse of prescription opioids, pharmaceutical companies have developed novel, abuse-deterrent formulation strategies. Abuse-deterrent formulations, including the DETERx platform that is incorporated in Xtampza ER, target the known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject, for the specific opioid drug substance. The FDA has encouraged the development of prescription opioids with abuse-deterrent formulations to help combat the opioid crisis, and expanding access to abuse deterrent formulations is part of the FDA's comprehensive Opioids Action Plan. These technologies, however, do not eliminate the possibility of misuse and abuse. Moreover, no abuse deterrence technology, including DETERx, is able to deter the most common form of abuse—swallowing a number of intact capsules or tablets to achieve a feeling of euphoria.

***Legislative and Regulatory Actions***

In response to widespread prescription opioid abuse, the U.S. government and a number of state legislatures have in recent years enacted new legislation and regulations intended to fight the opioid epidemic. At the federal level (in addition to the DEA and FDA efforts discussed elsewhere in this Annual Report on Form 10-K), in 2016 the CDC issued prescribing guidelines intended to reduce opioid-related harms by encouraging primary care physicians to limit the amount of morphine milligram equivalents (MMEs) that they prescribe for chronic pain patients.

While much, if not most, of the state level efforts have focused primarily on increasing people's access to substance abuse treatment and harm reduction measures, some initiatives more directly impact manufacturers and distributors of prescription opioid products; these laws include requirements that manufacturers fund statewide drug take-back programs or pay opioid-specific taxes or "impact fees" and laws that limit the amount of opioid products that a physician may prescribe. Recent years have also seen a variety of proposed and enacted laws and regulations at the federal, state and local level intended to reduce, or limit increases in, pharmaceutical prices, including particularly prescription drug price disclosure laws. Other jurisdictions may enact similar or novel measures intended to reduce or constrain the growth of pharmaceutical spending or otherwise impose policy measures (either opioid-specific or applicable to the pharmaceutical industry as a whole) that could increase our operating costs associated with compliance.

**The Collegium Portfolio**

Our mission is to be the leader in responsible pain management. We have leveraged our research and development efforts as well as licensing relationships with third parties, to develop a portfolio of meaningfully differentiated products for use in the treatment of moderate to severe pain.

***Xtampza ER***

In April 2016, the FDA approved our New Drug Application ("NDA") for Xtampza ER (extended-release oxycodone) 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. The approved labeling for Xtampza ER includes human abuse potential studies, as well as data supporting the administration of the product as a sprinkle or through feeding tubes. In June 2016, we launched Xtampza ER in the United States. Xtampza ER is formulated using our novel abuse-deterrent technology platform, DETERx, which provides extended-release delivery, while also providing barriers to common methods of abuse and misuse (e.g., crushing, chewing, heating and injecting). This technology combines an active opioid ingredient with a fatty acid and waxes to form microspheres that are filled into a capsule. These wax-based microspheres are designed to resist particle size reduction and dose dumping when subjected to physical and chemical manipulation. Xtampza ER's label indicates a dosing regimen of one capsule every 12 hours and it must be taken with food.

Xtampza ER, OxyContin from Purdue, and the authorized generic version of OxyContin (which is identical to the branded version) are the only extended-release oxycodone products marketed in the United States as of January 2021. In 2020, the extended-release oxycodone (OER) market generated approximately $1.4 billion in gross U.S. sales and there were approximately 2.4 million prescriptions written. OxyContin is the largest selling extended-release oxycodone (and largest-selling branded extended-release opioid) in the United States by dollars and prescription volume, with approximately $1.0 billion in U.S. gross sales and approximately 1.9 million prescriptions written in 2020. Relative to 2019, dollars generated by sales for OxyContin and its authorized generic forms written in the United States in 2020 declined 17%, with a 20% decline prescription volume. In 2020, approximately 566,000 prescriptions for Xtampza ER were written.

Xtampza ER and OxyContin (along with its authorized generic) feature the same active pharmaceutical ingredient and feature abuse-deterrent technologies – though the abuse deterrent technologies are designed differently. In November 2017, we announced FDA approval of a Supplemental New Drug Application ("sNDA") for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate-release). In the study, Xtampza ER maintained its extended-release pharmacokinetic profile when crushed, while OxyContin showed a rapid release of oxycodone when crushed with common household tools; crushed OxyContin was bioequivalent to crushed oxycodone IR. The sNDA also added results from an oral human abuse potential study and an oral abuse deterrent claim to the label, making Xtampza ER the only single-agent extended-release oxycodone with oral, intranasal, and intravenous abuse-deterrent labeling.

We believe Xtampza ER is well-positioned to capture a significant share of extended-release oxycodone market.

**Nucynta ER and Nucynta IR**

Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment, and for which alternate treatment options are inadequate. Nucynta ER is also the only extended-release opioid approved by the FDA for management of the neuropathic pain associated with diabetic peripheral neuropathy. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. Nucynta ER and Nucynta IR are the only tapentadol-based products marketed in the United States and the drug substance is patent-protected.

Nucynta ER's label includes data from separate clinical trials that demonstrate its efficacy in improving pain intensity for patients suffering from chronic low back pain and neuropathic pain associated with diabetic peripheral neuropathy. Nucynta IR's label includes data from a clinical trial that demonstrates its efficacy in improving pain intensity for post-surgical acute pain.

In December 2017, we entered into the Nucynta Commercialization Agreement, pursuant to which Assertio agreed to grant us a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization of such products in the United States. On January 9, 2018, we amended the Nucynta Commercialization Agreement and consummated the transactions contemplated thereby. On February 13, 2020, we closed the Nucynta Acquisition.

We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and we began commercial promotion of the Nucynta Products in February 2018. The Nucynta Commercialization Agreement initially required us to pay guaranteed minimum royalty of $135.0 million per year through December 2021, as well as a variable royalty based on annual net sales over $233.0 million and a variable royalty of 14% on net sales for ultimate payment to Grünenthal Gmbh. On November 8, 2018, we amended certain terms of the Nucynta Commercialization Agreement, which eliminated the $135.0 million guaranteed minimum annual royalties and adjusted the royalty structure such that beginning on January 1, 2019, our obligation to make royalty payments to Assertio became conditional solely upon net sales. Upon the closing of the Nucynta Acquisition and the termination of the Nucynta Commercialization Agreement (except for certain sections that survive in accordance with the Nucynta Purchase Agreement), we assumed all commercialization responsibilities, including sales and marketing, for the Nucynta Products, through the assumption of a license from Grünenthal Gmbh (the "Grünenthal License"). Our prior royalty obligation to Assertio ceased and our only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal Gmbh under the Grünenthal License.

**Manufacturing of Our Products**

***Overview***

Xtampza ER is manufactured using a proprietary process. This process is reproducible, scalable and cost-efficient, and we believe that the microsphere formulation — and the related manufacturing process — is unique in the extended-release opioid market. To date, we have produced Xtampza ER through a contract manufacturing organization, Patheon, a subsidiary of Thermo Fisher Scientific, Inc. Our microsphere production is currently conducted in an area of the manufacturing plant that is shared with other clients. We have completed the build-out of a dedicated manufacturing suite within the same Patheon site and will be transitioning production to the new suite. Patheon has an established

record of manufacturing FDA-approved products in the United States, including products containing controlled substances. We own all of the intellectual property, including know-how and specialized manufacturing equipment, necessary to be able to qualify the manufacturing equipment currently located at Patheon's facility as an alternative location (and with an alternative vendor) if necessary.

Pursuant to the Nucynta Commercialization Agreement, Assertio was historically responsible for manufacturing and delivering to us the Nucynta Products for commercialization in the United States. As part of our partnership with Assertio, we participated in a Joint Manufacturing Steering Committee with our counterparts at Assertio, through which we took part in decisions regarding the commercial manufacturing of the Nucynta Products. Effective upon the closing of the Nucynta Acquisition, we assumed responsibility for manufacturing the Nucynta Products for commercialization in the United States. Nucynta ER is produced at a Janssen facility in Puerto Rico pursuant to a supply agreement that we assumed from Assertio in connection with the Nucynta Acquisition. At the time of closing of the Nucynta Acquisition, Assertio had initiated a technology transfer to enable manufacturing of Nucynta ER at Patheon in Cincinnati, Ohio; we have assumed responsibility for completing such technology transfer in connection with the Nucynta Acquisition. Nucynta IR is produced at a contract manufacturing organization, Cambrex, pursuant to a manufacturing and supply agreement that we assumed from Assertio in connection with the Nucynta Acquisition.

***Drug Substances***

The active pharmaceutical ingredient used to formulate Xtampza ER is oxycodone base, which presents as myristate salt in the Xtampza ER formulation. We currently procure this active pharmaceutical ingredient pursuant to a supply agreement with a single U.S.-based manufacturer. We are aware of other suppliers who we would expect to be able to satisfy our commercial orders.

The active pharmaceutical ingredient used in the Nucynta Products is tapentadol, which is supplied by a single U.S.-based manufacturer.

Oxycodone base and tapentadol are classified as narcotic controlled substances under U.S. federal law. Xtampza ER and the Nucynta Products are classified by the DEA as Schedule II controlled substances, meaning that they have a high potential for abuse and dependence but are recognized as having an accepted medical use. Consequently, the manufacturing, shipping, dispensing and storing of our products are subject to a high degree of regulation, as described in more detail under the caption "— Governmental Regulation — DEA and Opioid Regulation."

**Marketing and Commercialization**

We commercialize Xtampza ER and the Nucynta Products in the United States with a dedicated field sales force, consisting of approximately 145 sales representatives and managers, to call on the approximately 11,000 health care professionals who write approximately 65% of the branded extended-release opioid prescriptions in the United States, with a primary focus on pain specialists. In addition, we employ medical science liaisons who engage in peer-to-peer medical science education with respect to pain and opioid pain therapy and respond to clinician inquiries about Xtampza ER and the Nucynta Products. We also employ a market-access team to support our formulary approval and payor contracting.

Our marketing strategy focuses on increasing awareness of the differentiated features of Xtampza ER and the Nucynta Products. As an integral part of educating clinicians regarding the properties and differentiated profiles of our products, our sales force is trained to share information relating to significant risks associated with prescription opioids, including risks relating to addiction, abuse and misuse.

We primarily sell our products to wholesalers that, in turn, distribute our products to retail outlets (such as drug store and supermarket chains and independent pharmacies), managed health care organizations and government agencies. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers. Three of our customers comprised 10% or more of our revenue during the year ended December 31, 2020. These customers comprised 34%, 31% and 31% of revenue, respectively.

**Intellectual Property**

The protection of patents, designs, trademarks and other proprietary rights that we own or license is critical to our success and competitive position. Xtampza ER is protected by nineteen issued patents in the United States (which cover both the abuse-deterrent technology and methods of using it to treat patients), one granted and two pending applications in the European Patent Office, two issued patents in Canada, and one issued patent in each of Japan and Australia. Finally, we have six patent applications pending in the United States, one pending patent application in each of Canada and Japan, and one pending PCT application. Our issued U.S. patents are projected to expire in 2023, 2025, 2030, and 2036 and our pending patent applications in the United States, if issued, would be projected to expire in 2023, 2030, and 2036. In addition, we use a unique and proprietary process to manufacture our products that requires significant know how, which we currently protect as trade secrets.

We have concluded that some of our technology is best protected as proprietary know-how, rather than through obtaining patents. Except for licenses from Grünenthal GmbH to commercialize the Nucynta Products in the United States and its territories, our technology and products are not in-licensed from any third party, and we own all of the rights to Xtampza ER. We believe we have freedom to operate in the United States and other countries, but there can be no assurance that other companies, known and unknown, will not attempt to assert their intellectual property against us.

We also rely on trademarks and trade designs to develop and maintain our competitive position. We have received trademark registration for Collegium Pharmaceutical, Inc., DETERx, and Xtampza ER in the United States, and acquired trademarks associated with the Nucynta Products in connection with the Nucynta Acquisition.

Our business depends upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and, in some cases, requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

**Competition**

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. Most of the existing and potential competitors have significantly more financial and other resources than we do. We believe the key competitive factors that will affect the commercial success of our products include the therapeutic efficacy, convenience of dosing and distribution and, in the case of Xtampza ER, the degree of abuse deterrence of competing products, as well as their safety, cost and tolerability profiles.

***Xtampza ER***

Currently, the only extended-release opioid drugs on the market that have an abuse-deterrent product label, in addition to Xtampza ER, are OxyContin and Hysingla®, both from Purdue. Hysingla is a once a day hydrocodone product.

Xtampza ER may also face competition from commercially available generic and branded extended-release and long-acting opioid drugs other than oxycodone, including morphine sulfate, fentanyl, hydromorphone, oxymorphone and methadone, as well as opioids that are currently in clinical development, including a generic version of Xtampza ER for which Teva submitted an Abbreviated New Drug Application ("ANDA") to the FDA. Pursuant to a settlement we reached with Teva in September 2020, we agreed to grant Teva a license to market its generic version of Xtampza ER in the United States beginning on or after September 2, 2033 (subject to FDA approval and acceleration under certain circumstances). As a result of the settlement, Teva agreed to a consent judgment confirming that its proposed generic products infringe upon our asserted patents and that those patents are valid and enforceable with respect to Teva's proposed generic products. For more information regarding the settlement, please refer to Note 11, *Commitments and Contingencies*.

Xtampza ER competes against all extended-release opioids, including Purdue's OxyContin and its authorized generics. Although Purdue lists 19 patents for OxyContin in the Orange Book, of which 10 list expiration dates between 2027 and 2030, it is possible that generic forms of OxyContin could become available sooner, in which case Xtampza ER would compete with any such generic oxycodone extended-release products, in addition to all other extended-release opioids and their respective generics.

***The Nucynta Products***

Nucynta ER competes primarily against other long-acting opioid medications, including: OxyContin; Butrans; Belbuca; and Hysingla. Nucynta ER may also face competition from commercially available generic and branded extended-release and long-acting opioid drugs including oxycodone, morphine sulfate, fentanyl, hydromorphone, oxymorphone and methadone.

Nucynta IR competes primarily against short-acting opioids used for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. There are numerous such medicines, including: generic hydrocodone acetaminophen; generic oxycodone; generic oxycodone acetaminophen; and generic tramadol.

**Government Regulation**

***FDA Approval Process***

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act and other federal and state statutes and regulations govern the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of the product from the market, injunctions, fines, civil penalties, and criminal prosecution. Failure to meet FDA requirements for approval would also result in a medication not being approved for marketing.

The process of developing a pharmaceutical product and obtaining FDA approval to market the medication in the United States typically involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's good laboratory practices ("GLP"), regulation;
- submission to the FDA of an Investigational New Drug Application ("IND") for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices ("GCP") to establish the safety and efficacy of the proposed drug product for each indication for which FDA approval is sought;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations;
- submission to the FDA of an NDA or, in the case of a generic drug, an ANDA;
- satisfactory completion of a review by an FDA advisory committee, if convened; and
- FDA review and approval of the NDA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry,

manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or subjects under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, including GCP, an international standard meant to protect the rights, safety and wellbeing of subjects and to define the roles of clinical trial sponsors, administrators, and monitors; and (ii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and any effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined.

- Phase 1: The drug is initially introduced into healthy human subjects or patients, and is tested to assess safety, dose tolerance, absorption, metabolism, PK, pharmacological actions, side effects associated with increasing doses, and, in some cases, early evidence of effectiveness.
- Phase 2: The drug is typically tested in a limited patient population to begin to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common AEs and safety risks. Multiple Phase 2 trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.
- Phase 3: If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials (often called “pivotal trials”) are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of subjects, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the clinical trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible. Sponsors of clinical trials generally must register and report key parameters of certain clinical trials at the NIH-maintained website ClinicalTrials.gov.

For products designed to deter abuse, FDA guidance regarding studies and clinical trials dictates what types of studies should be conducted to demonstrate abuse-deterrence, how those studies and clinical trials will be evaluated, and what product labeling claims may be approved based on the results of those studies and clinical trials. There are four categories of abuse-deterrence studies and clinical trials: Categories 1, 2 and 3 consist of pre-marketing studies and clinical trials designed to evaluate a product candidate’s potentially abuse-deterrent properties under controlled conditions, while Category 4, post-marketing clinical trials and studies, assesses the real-world impact of abuse-deterrent formulations. The final guidance also provides examples of product label claims that may be made based on the results of the corresponding studies and clinical trials.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing. Pursuant to agreements reached during reauthorization of the Prescription Drug User Fee Act (“PDUFA”), the FDA has a goal of acting on most original NDAs within six months or ten months of the application submission or filing date, depending on the nature of the drug. The FDA has a number of programs intended to help expedite testing, review, and approval of drug candidates that meet certain eligibility criteria. The FDA may refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

If the FDA’s evaluations of the NDA and of the sponsor’s manufacturing facilities are favorable, the FDA will issue an approval letter, and the sponsor may begin marketing the drug for the approved indications, subject to any post-approval requirements, described further below. If the FDA determines it cannot approve the NDA in its current form, it will issue a complete response letter indicating that the application will not be approved in its current form. The complete response

letter usually describes the specific deficiencies that the FDA identified in the application and may require additional clinical or other data or impose other conditions that must be met in order to obtain approval of the NDA. After receiving a complete response letter, the applicant may resubmit the application addressing all deficiencies in the letter or withdraw the application. Addressing the deficiencies noted by the FDA can be costly and can result in significant delays prior to approval. Moreover, even if the applicant believes it has addressed the deficiencies, it is possible that approval may not ultimately be obtained.

Where a sponsor wishes to expand the originally approved prescribing information, such as by adding a new indication, it must submit and obtain approval of an sNDA. Changes to an indication generally require additional clinical studies, which can be time-consuming and require the expenditure of substantial additional resources. Under PDUFA, the target timeframe for the review of an sNDA to add a new clinical indication is six or ten months from the receipt date, depending on whether or not the sNDA has priority review. As with an NDA, if the FDA determines that it cannot approve an sNDA in its current form, it will issue a complete response letter as discussed above.

***REMS***

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), either as a condition of the approval of an NDA or after approval to ensure that the benefits of a drug outweigh its risks. If the FDA determines a REMS is necessary for a new drug, the drug sponsor must submit a proposed REMS plan as part of its NDA prior to approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits continue to outweigh its risks. A REMS can include medication guides, communication plans for healthcare professionals, and Elements To Assure Safe Use ("ETASU"). In addition, the REMS must include a timetable for periodically assessing the strategy, at a minimum, at 18 months, three years, and seven years after the REMS approval. The requirement for a REMS can materially affect the potential market and profitability of a drug.

In July 2012, the FDA approved a class-wide REMS for extended-release and long-acting opioid products. Extended-release formulations of oxycodone, morphine, hydrocodone and hydromorphone, for example, are required to have a REMS. Manufacturers subject to this class-wide REMS must work together to implement the REMS as part of a single shared system to reduce the burden of the REMS on the healthcare system. The central component of the extended-release/long acting opioid REMS program is an education program for prescribers and patients. Specifically, the REMS includes a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of ETASU. These ETASU include training for healthcare professionals who prescribe the drug; information provided to prescribers that they can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers about the existence of the REMS and the strong recommendation that they complete the available training. Prescriber training required to be offered as part of the REMS is conducted by accredited, independent continuing education providers, without cost to healthcare professionals, under unrestricted grants funded by the opioid analgesic manufacturers. Moreover, REMS assessments must be submitted on an annual basis to assess the extent to which the ETASU are meeting the goals of the REMS and whether the goals or elements should be modified.

In September 2018, and pursuant to its Opioids Action Plan, the FDA approved the final class-wide REMS, which includes several measures to facilitate communication of the risks associated with opioid pain medications to patients and health care professionals and, for the first time, applies to immediate-release and extended-release/long-acting opioid analgesics intended for use in an outpatient setting. The REMS requires that training be made available to health care providers who are involved in the management of patients with pain (including nurses and pharmacists) and requires that the education cover broad information about appropriate pain management, including alternatives to opioids for the treatment of pain. In connection with the 2018 REMS, the FDA also approved new product labeling containing information about the health care provider education available through the 2018 REMS.

***Advertising and Promotion***

The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, guidance and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and efficacy that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and therefore not described in

the drug's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the U.S. Department of Justice, or the Office of the Inspector General of the HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

***Post-Approval Requirements***

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion restrictions.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require, in addition to REMS discussed above, post-market testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration subjects entities to periodic announced or unannounced inspections by the FDA or these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Regulatory authorities may withdraw product approvals, request product recalls, or take other punitive action if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, warrant them. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for such a risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

***The Hatch-Waxman Amendments***

*Orange Book Listing*

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active pharmaceutical ingredient in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or efficacy of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to make certain certifications to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than make certifications concerning a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the

FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

For further detail regarding our litigation with Teva with respect to Teva's ANDA relating to Xtampza ER, refer to "Item 3. Legal Proceedings".

*Exclusivity*

Upon approval of an NDA for a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA, discussed in more detail below, that relies on the FDA's findings regarding that drug. A sponsor may obtain a three-year period of exclusivity for a change to an approved drug, such as the addition of a new indication to the labeling or a new formulation, if the supplement includes reports of new clinical trials (other than bioavailability clinical trials) essential to the approval of the supplement.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. No ANDA application will receive final approval before any applicable non patent exclusivity listed in the Orange Book for the referenced product has expired.

*Section 505(b)(2) NDAs*

A Section 505(b)(2) NDA is a special type of NDA often used by applicants seeking approval for new or improved formulations or new uses of previously approved active moieties. Under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, in lieu of developing all of the information normally required for approval of an NDA, an applicant may rely, in part, on data developed by another party and for which the applicant has not obtained a right of reference. Most commonly, 505(b)(2) applicants rely on the FDA's findings of safety and efficacy in a prior approval of a similar product (although they may also rely on information in published literature). A 505(b)(2) application that references a prior approval may seek approve for some or all of the referenced product's labeled indications and/or for a different indication not included in the referenced product's label.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's findings of safety and effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired; until any non-patent exclusivity listed in the Orange Book for the referenced product has expired; and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. In the interim period, the FDA may grant tentative approval. Tentative approval indicates that the FDA has determined that the applicant meets the standards for approval as of the date that the tentative approval is granted. Final regulatory approval can only be granted if the FDA is assured that there is no new information that would affect final regulatory approval. As with traditional NDAs, a Section 505(b)(2) NDA may be eligible for three-year marketing exclusivity, assuming the NDA includes reports of new clinical trials (other than bioavailability clinical trials) essential to the approval of the NDA. For further detail regarding our litigation with Purdue regarding our Section 505(b)(2) NDA for Xtampza ER, refer to "Item 3. Legal Proceedings".

***DEA and Opioid Regulation***

Our products are regulated as "controlled substances" as defined in the Controlled Substances Act ("CSA"), which establishes registration, security, recordkeeping, reporting, storage, distribution, importation, exportation and other requirements administered by the DEA.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. 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.

Xtampza ER and the Nucynta Products are listed by the DEA as a Schedule II controlled substance under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of our products is subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting. Also, distribution and dispensing of these drugs are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, presented to a pharmacist and may not be refilled without a new prescription.

Annual DEA registration is required for any facility that manufactures, distributes, dispenses, imports or exports any 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.

In addition, a DEA quota system, which was amended in 2018 to require sponsors to strengthen controls over diversion of controlled substances, controls and limits the availability and production of controlled substances in Schedule I or II. In November 2017, the DEA reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the U.S. in calendar year 2018 by 20%. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. The DEA proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, oxymorphone), by an average of 28%. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. If finalized, the proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. In April 2020 in response to the COVID-19 pandemic, the DEA adjusted the established 2020 aggregate production quotas and assessment of annual needs for select Schedule II substances. The DEA took this action to ensure that the country has an adequate and uninterrupted supply of these substances during the public health emergency.

Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because Xtampza ER and the Nucynta Products are regulated as a Schedule II controlled substances, they are subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much active opioid ingredients, such as oxycodone and tapentadol, may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount of opioids that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including oxycodone base for use in manufacturing Xtampza ER. In addition, we and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure tapentadol for use in manufacturing the Nucynta Products. 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 also requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring system includes well-defined due diligence, "know your customer" efforts and order monitoring.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances. We and our contract manufacturers are subject to state regulation on distribution of these products.

Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use. In 2016, the Comprehensive Addiction and Recovery Act ("CARA"), was enacted to address the national epidemics of prescription opioid abuse and heroin use. CARA expands the availability of naloxone for law enforcement and other first responders, forms an interagency task force to develop best practices for pain management with opioid medications and provides resources to improve state monitoring of opioids. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"), which was signed into law in November 2018, includes a number of measures directed towards regulation and improvement of treatment for substance use-disorder and increased coverage by CMS of medically-assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries.

***Healthcare Fraud and Abuse Laws and Compliance Requirements***

We are subject to federal, state and local laws targeting fraud and abuse in the healthcare industry, violations of which can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to us as both a manufacturer and a supplier of products and they also apply to hospitals, physicians and other potential purchasers of our products. The applicable federal fraud and abuse laws apply to products or services reimbursed by federal healthcare programs. Some states, however, have applicable fraud and abuse laws that apply more broadly to include products or services reimbursed by private payors.

The federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) prohibits knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, coupons, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Under the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b, a person or entity need not have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of 42 U.S.C. § 1320a-7b, constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute and implementing regulations provide for certain exceptions for "safe harbors" for certain discounting, rebating or personal services arrangements, among other things. However, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult. Violations of the federal Anti-Kickback Statute can result in significant criminal fines, exclusion from participation in Medicare and Medicaid and follow-on civil litigation, among other things, for both entities and individuals.

Other federal healthcare fraud-related laws also provide criminal liability for violations. The Criminal Healthcare Fraud statute, 18 U.S.C. § 1347 prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers. Federal criminal law at 18 U.S.C. § 1001, among other sections, prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The civil False Claims Act and similar state laws impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. The Federal Physician Payments Sunshine Act and similar state laws impose reporting requirements for various types of payments to physicians and teaching hospitals. Failure to comply with required reporting requirements under these laws could subject manufacturers and others to substantial civil money penalties. In addition, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or

misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations and litigation by certain government entities regarding our marketing of opioid products.

***Third-Party Payor Coverage and Reimbursement***

The commercial success of Xtampza ER and the Nucynta Products will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments. In addition, some third-party payors also require preapproval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who prescribe such therapies.

The cost of pharmaceuticals and devices continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative reforms.

While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for Xtampza ER, the Nucynta Products and any other products we may seek to commercialize, and to operate profitably.

***Healthcare Reform***

In the United States, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. The Medicare Modernization Act imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

In March 2010, the Affordable Care Act was enacted, which significantly changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;

- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a licensure framework for follow-on biologic products;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- establishment of a Center for Medicare Innovation at CMS in January 2011 to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court which heard oral arguments in the case on November 10, 2020. A ruling is expected in 2021.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Joint Select Committee on Deficit Reduction (created under the Budget Control Act of 2011) did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, triggering automatic reductions to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2030 unless additional action is taken by Congress (although they have been suspended by the Coronavirus Aid, Relief and Economic Security, or CARES, Act, until March 31, 2021).

The American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

In December 2017, the Tax Cuts and Jobs Act ("TCJA") repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years, and is likely to lead to increases in insurance premiums. It is uncertain how or whether this legislation may affect our customers and, accordingly, our financial operations.

***Other Regulatory Requirements***

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

***Employees and Human Capital Resources***

Investing in, developing, and maintaining human capital is critical to our success. As of December 31, 2020, we had a total of 234 full-time employees. We emphasize a number of measures and objectives in managing our human capital assets, including, among others, employee safety and wellness; talent acquisition and retention; employee engagement,

development, and training; diversity and inclusion; and compensation and pay equity. None of our employees are represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the community in which we operate, and which comply with government regulations. This includes us allowing our employees to work from home, while implementing additional safety measures for employees who chose to work on-site.

***Executive Officers of the Company***

The following table lists the positions, names and ages of our executive officers as of February 25, 2021:

| Name | Age | Position(s) |
|---|---|---|
| Joseph Ciaffoni | 49 | Director, President and Chief Executive Officer |
| Alison Fleming | 46 | Executive Vice President and Chief Technical Officer |
| Paul Brannelly | 48 | Executive Vice President and Chief Financial Officer |
| Scott Dreyer | 48 | Executive Vice President and Chief Commercial Officer |
| Shirley Kuhlmann | 37 | Executive Vice President and General Counsel |
| Richard Malamut | 61 | Executive Vice President and Chief Medical Officer |

***Executive Officers***

***Joseph Ciaffoni, Director, President and Chief Executive Officer.*** Mr. Ciaffoni has served as our President and Chief Executive Officer since July 2018, and prior to that, served as our Executive Vice President and Chief Operating Officer since May 2017. Prior to joining us, Mr. Ciaffoni served as President, U.S. Branded Pharmaceuticals of Endo International plc, a specialty pharmaceutical company, from August 2016 to December 2016. Before that, from April 2012 to August 2016, Mr. Ciaffoni held various positions of increasing responsibility at Biogen Idec, including Senior Vice President, Global Specialty Medicines Group, Senior Vice President, U.S. Commercial and Vice President, U.S. Neurology Field Operations and Marketing. Prior to joining Biogen Idec, Mr. Ciaffoni was Executive Vice President and Chief Operating Officer of Shionogi Inc. and President of Shionogi Pharmaceuticals from July 2008 to October 2010. Mr. Ciaffoni also previously served as Vice President, Sales for Schering-Plough (now Merck) from May 2004 to June 2008, where he was responsible for the cholesterol franchise, and has held several commercial leadership roles at Sanofi-Synthelabo (now Sanofi) from January 2002 to April 2004 and Novartis from January 1994 to December 2001. Mr. Ciaffoni received a B.A. in Communications in 1993 and an M.B.A. in 2000, both from Rutgers, The State University of New Jersey.

***Alison Fleming, Ph.D., Chief Technical Officer.*** Dr. Fleming has served as our Executive Vice President and Chief Technical Officer since January 2017. Prior to being our Chief Technical Officer, Dr. Fleming led our development team

as our Vice President, Product Development since October 2002. Prior to joining us, Dr. Fleming's academic research focused on implantable drug delivery systems for cancer therapy. Dr. Fleming is an inventor on several U.S. patents and pending patent applications, and has authored numerous scientific publications and poster presentations in the field of novel drug delivery systems and abuse-deterrent opioid formulations. Dr. Fleming graduated from the University of Massachusetts, Amherst in 1997 with a B.S. in Chemical Engineering and received a Ph.D. in Chemical and Biomolecular Engineering from Cornell University in 2002.

***Paul Brannelly, Executive Vice President and Chief Financial Officer.*** Mr. Brannelly has served as our Executive Vice President and Chief Financial Officer since February 2015. Prior to joining us, Mr. Brannelly served as Senior Vice President, Finance and Administration, and Treasurer of Karyopharm Therapeutics Inc., a biopharmaceutical company, from June 2013 to August 2014. From August 2014 to November 2014, Mr. Brannelly served as a consultant to Karyopharm. Prior to joining Karyopharm, Mr. Brannelly served as Vice President, Finance, Treasurer and Secretary at Verastem, Inc. from August 2010 to May 2013. From January 2010 to September 2011, Mr. Brannelly held the position of Chief Financial Officer at the Longwood Fund, a venture capital firm aimed at investing in, managing and building healthcare companies, where he set up the financial and operational infrastructure following the closing of its first fund and eventually served as Chief Financial Officer of its two startup companies, Verastem and OvaScience, Inc. From November 2005 to September 2009, he served as Vice President, Finance at Sirtris Pharmaceuticals, Inc., a biopharmaceutical company which GlaxoSmithKline plc purchased for $720 million in 2008. Mr. Brannelly started his biopharmaceutical career at Dyax Corporation from September 1999 to May 2002, and subsequently moved on to positions of increasing responsibility at CombinatoRx Inc. from May 2002 to November 2005, including as Vice President, Finance and Treasurer, where he led the initial public offering process. Mr. Brannelly graduated from the University of Massachusetts at Amherst with a B.B.A. in Accounting in 1995.

***Scott Dreyer, Executive Vice President and Chief Commercial Officer.*** Mr. Dreyer has served as our Executive Vice President and Chief Commercial Officer since August 2018, and joined us in January 2018 as Senior Vice President, Sales, Marketing and Training. Prior to joining us, Mr. Dreyer served as the Senior Vice President, Sales, Marketing and Commercial Operations at The Medicines Company, a biopharmaceutical company, from September 2016 to December 2017; Vice President and Chief Marketing Officer – US at Biogen from June 2014 to September 2016; and Vice President, Business Development at Publicis Touchpoint Solutions, a healthcare commercialization company, from October 2013 to June 2014. Mr. Dreyer began his career in the pharmaceutical industry at Merck & Co., where he held roles of increasing responsibility from 1994 to 2013, including Vice President of Hospital and Oncology Sales from 2011 to 2012, and Vice President of Primary Care Sales from 2012 until 2013. Mr. Dreyer holds a B.S. in Biology from Messiah College in 1994.

***Shirley Kuhlmann, Executive Vice President and General Counsel***. Ms. Kuhlmann has served as our Executive Vice President and General Counsel since March 2018. Prior to joining us, Ms. Kuhlmann was a corporate and securities attorney at Pepper Hamilton LLP from September 2007 until March 2018. At Pepper Hamilton, where she was made a partner effective January 2017, Ms. Kuhlmann advised private and public companies on a range of commercial and transactional matters, including financings, corporate governance and disclosure matters, and mergers and acquisitions and other business combination transactions. Ms. Kuhlmann holds a B.A. in Economics/Political Science from Columbia University in 2004 and a J.D. from Emory University School of Law in 2007.

***Richard Malamut, M.D., Executive Vice President and Chief Medical Officer.*** Dr. Malamut has served as our Chief Medical Officer since April 2019. Prior to joining us, Dr. Malamut served as Chief Medical Officer, Head of Research and Development and Senior Vice President at Braeburn Pharmaceuticals from June 2018 to January 2019; Chief Medical Officer at Avanir Pharmaceuticals from November 2016 to June 2018; and Senior Vice President of Global Clinical Development at Teva Pharmaceuticals Industries Ltd from March 2013 to November 2016. Dr. Malamut also previously held roles of increasing responsibility at Bristol-Myers Squibb and AstraZeneca focusing on early clinical development and translational medicine in neurology and analgesia. Dr. Malamut holds a medical degree from Hahnemann University in June 1985 and a B.S. in Biology from Trinity College in May 1981. Dr. Malamut worked as a board-certified academic and clinical neurologist for 17 years and has more than 50 publications in the fields of pain medicine, neuromuscular disease, autonomic disease and neurodegenerative disease.

***Our Corporate Information***

We are headquartered in Stoughton, Massachusetts and our common stock trades on the NASDAQ Global Select Market ("NASDAQ") under the trading symbol "COLL."

Our predecessor was incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. and in October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In July 2014, we reincorporated in the Commonwealth of Virginia pursuant to a merger whereby Collegium Pharmaceutical, Inc., a Delaware corporation, merged with and into Collegium Pharmaceutical, Inc., a Virginia corporation, with the Virginia corporation surviving the merger.

***Available Information***

We maintain a website at www.collegiumpharma.com. We make available, free of charge on our website, our Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission ("SEC"). We also make available, free of charge on our website, the reports filed with the SEC by our officers, directors and 10% shareholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The SEC also maintains a website, at www.sec.gov, that contains reports, proxy and information statements and other information regarding us and other issuers that file electronically. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this Form 10-K.

**Item 1A. Risk Factors.**

***Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as all other information included in this Annual Report on Form 10-K, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and investors could lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.***

**Risks Related to Our Financial Position and Capital Needs**

***Our ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products and product candidates that we may develop or acquire in the future. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.***

Our ability to maintain profitability depends upon our ability to realize the full commercial potential of our products and to commercialize successfully any other products and product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from our current or future products depends on a number of factors, including our ability to:

- realize a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- sustain a commercial organization capable of sales, marketing and distribution for the products we sell;
- obtain coverage and adequate reimbursement from third parties, including government payors; and
- comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers, and to our products specifically, including FDA post-marketing requirements.

If we fail to maintain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

As of December 31, 2020, we had a federal net operating loss ("NOL") carryforward of approximately $226.8 million and state NOL carryovers of approximately $170.3 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state NOL carryforwards begin to expire in 2030. We also had U.S. federal tax credits of approximately $4.6 million, and state tax credits of approximately $1.2 million. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended. As of December 31, 2020, and December 31, 2019, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

***We have outstanding indebtedness in the form of our 2.625% Convertible Senior Notes and our Loan Agreement with BioPharma, which may adversely affect our business, financial condition and results of operations.***

In February 2020, in connection with the Nucynta Acquisition, we incurred (i) $143.8 million in principal amount of indebtedness in the form of 2.625% Convertible Senior Notes due in 2026 (the "Convertible Notes") and (ii) $200.0 million in secured indebtedness pursuant to our Loan Agreement with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (as amended from time to time, the "Loan Agreement"). We may also incur additional indebtedness to meet future financing needs. Our existing and future levels of indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;

- limiting our ability to obtain additional financing;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing shareholders as a result of issuing shares of our common stock upon conversion of the convertible notes;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than we are or have better access to capital;
- increasing our vulnerability to downturns in our business, our industry or the economy in general, including any such downturn related to the impact of the COVID-19 pandemic.

Holders of our Convertible Notes will have the right to require us to repurchase our Convertible Notes for cash following a fundamental change, or to pay any cash amounts due upon conversion of our Convertible Notes. Further, our noteholders, subject to a limited exception described in the notes, may require us to repurchase their notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the notes or pay the cash amounts due upon conversion. Applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the notes or pay the cash amounts due upon conversion. Additionally, our Loan Agreement contains certain covenants and obligations applicable to us, including, without limitation, covenants that require us and our subsidiaries to maintain $200 million in annual net sales and covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business.

Failure to comply with covenants in the indenture governing the Convertible Notes or in the Loan Agreement would constitute an event of default under these instruments, notwithstanding our ability to meet our debt service obligations. Our failure to repurchase notes or to pay the cash amounts due upon conversion when required will constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. In such event, we may not have sufficient funds to satisfy all amounts due under our other indebtedness (including the Loan Agreement) and the notes. The Loan Agreement includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement. If we fail to comply with such covenants and terms, we may be in default and the maturity of the related debt could be accelerated and become immediately due and payable. In addition, because our assets are pledged as a security under the Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets are subject to the risk of foreclosure by our lenders. Moroever, a default on indebtedness under the Loan Agreement could result in a default under the terms of the indenture governing our Convertible Notes. There is no guarantee that we would be able to satisfy our obligations if any of our indebtedness is accelerated.

**Risks Related to our Products**

***If we cannot continue successfully commercializing Xtampza ER or the Nucynta Products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.***

To date, we have invested substantial resources in the development of Xtampza ER, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products. Our business and future success are substantially dependent on our ability to continue successfully commercializing these products.

Our ability to continue successfully commercializing Xtampza ER and the Nucynta Products will depend on many factors, including but not limited to:

- our ability to manufacture commercial quantities of Xtampza ER at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to execute sales and marketing strategies successfully and continually;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of our products;

- the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments with similar indications;
- our ability to defend successfully any challenges to our intellectual property or suits asserting patent infringement relating to our products;
- the availability and quality of coverage and adequate reimbursement for our products;
- a continued acceptable safety profile of our products; and
- our ability to comply with applicable legal and regulatory requirements, including any additional manufacturing or packaging requirements that may become applicable to certain opioid products.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to continue successfully commercializing or to generate sufficient revenue from our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

***Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling of Xtampza ER and our ability to market Xtampza ER successfully may be adversely affected.***

Xtampza ER was approved with label language describing abuse-deterrent properties of the formulation with respect to the nasal and IV routes of abuse, consistent with Guidance for Industry, "Abuse-Deterrent Opioids- Evaluation and Labeling." In November 2017, the FDA approved an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

The FDA can require changes to the product labeling for Xtampza ER or the Nucynta Products at any time which can impact our ability to generate product sales. In particular, if the FDA determines that our post-marketing data for Xtampza ER does not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrates a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims, which would have a material adverse effect on our ability to continue successfully commercializing Xtampza ER.

***Xtampza ER and the Nucynta Products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products.***

The FDA has imposed a class-wide REMS on all IR, ER and long acting ("LA") opioid drug products (known as the Opioid Analgesic REMS). The FDA continually evaluates whether the REMS program is meeting its goal of ensuring that the benefit of these drugs continue to outweigh their risks, and whether the goals or elements of the program should be modified. If the FDA determines that additional measures are necessary, the modification of the Opioid Analgesic REMS to impose additional or more burdensome requirements could increase the costs associated with marketing our products and/or reduce the willingness of healthcare providers to prescribe our products, both which would have a material adverse effect on our ability to continue successfully commercializing, or to generate sufficient revenue from, our products.

***We could fail to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations.***

Xtampza ER has FDA-approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA approved product labeling includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of Xtampza ER.

***Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza ER and the Nucynta Products, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.***

Advertising and promotion of any pharmaceutical product marketed in the United States, including Xtampza ER and the Nucynta Products, is heavily scrutinized by, among others, the FDA, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

Engaging in off-label promotion of our products could also subject us to false claims liability under federal and state statutes, and other litigation and/or investigations, which could lead to civil and criminal penalties and fines, and could also require us to enter into agreements that materially restrict the manner in which we promote or distribute our drug products.

In addition, after product approval, subsequent discovery of serious and unanticipated adverse events associated with the product; the emergence of other problems with the product, manufacturer or facility; or our failure to make required regulatory submissions may result in adverse regulatory actions, including withdrawal of the product from the market or the requirement to add or strengthen label warnings about the product. The failure to obtain or maintain requisite governmental approvals or the imposition of additional or stronger warnings could delay or preclude us from further developing, marketing or realizing the full commercial potential of our products.

**Risks Related to Intellectual Property**

***Unfavorable outcomes in intellectual property litigation could result in costly litigation and potentially limit our ability to commercialize our products.***

Our commercial success depends upon our ability to commercialize products without infringing the intellectual property rights of others. Our current or future products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations.
Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States, or litigation against our collaborators may be costly and time consuming and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation, including our pending litigation with Purdue, could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products.

***If we are unable to obtain or maintain intellectual property rights for our technologies, products or any future product candidates which we may develop, we may lose valuable assets or be unable to compete effectively in our market.***

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which

offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking.

***We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets.***

We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope.
This litigation is expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States may be less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor, or those with whom they communicate, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed or independently developed, our competitive position would be harmed.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected.

**Risks Related to the Commercialization of Our Products**

***If we are unable to utilize our own sales and marketing capabilities successfully or enter into strategic alliances with marketing collaborators, we may not continue to be successful in commercializing our products and may be unable to generate sufficient product revenue.***

Our commercial organization continues to evolve, and in light of its short history and limited track record, we cannot guarantee that we will continue to be successful in marketing our products. In addition, we compete with other pharmaceutical and biotechnology companies with extensive and well-funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not remain profitable. Factors that may inhibit our efforts to continue successfully commercializing our products in the United States include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to reach adequate numbers of physicians who may prescribe our products; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

If we are not successful in retaining sales and marketing personnel or in maintaining our sales and marketing infrastructure or if we do not preserve strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty in continuing to commercialize our products.

Additionally, our sales, marketing and distribution capabilities may be hindered as a result of the COVID-19 outbreak. In response to the outbreak and the resulting mandatory closure of non-essential businesses and imposition of "social distancing" measures recommended by U.S. public health officials, our sales personnel have transitioned partly or entirely to remote work. The safety and well-being of our employees is our highest priority and we expect to maintain mitigating measures until such time as mandated closures are lifted and public health officials change their recommendations, and we have, and will continue to, equip our personnel with the tools and resources needed to effectively continue their sales and marketing efforts in a manner that complies with all relevant regulations, whether in person or from a remote setting. We face the risk, however, that limitations on activities within the healthcare sector and on economic activity generally will impede our ability to continue successfully commercializing our products. The travel restrictions and "social distancing" recommendations resulting from the spread of COVID-19 have impacted our sales professionals' ability to travel to and meet with customers in person. The outbreak has also prompted healthcare providers to limit our and our wholesalers' and distributors' access to physicians and other key healthcare personnel, which may inhibit our and our customers' ability to meet existing, or generate new, demand for our products. If we are unable to successfully commercialize our products during the COVID-19 outbreak, our ability to generate sufficient product revenue may be adversely affected.

***If the medical community, patients, and healthcare payors do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.***

Physicians and others in the medical community, patients, and healthcare payors may not accept and use our products. Acceptance and use of our products will depend on a number of factors including:

- approved indications, warnings and precautions language that may be less desirable than competitive products;
- perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our products;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology;
- the availability of competitive products;
- the pricing and cost-effectiveness of our products relative to competing products;
- the potential and perceived advantages of our products over alternative treatments;
- the convenience and ease of administration to patients of our products;
- actual and perceived availability and quality of coverage and reimbursement for our products from government or other third-party payors;
- any negative publicity related to our products or negative or positive publicity related to our competitors' products;
- the prevalence and severity of adverse side effects;
- policy initiatives by FDA, HHS, or other federal or state agencies regarding opioids;

- our ability to comply with the Opioid Analgesic REMS; and
- the effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If our products fail to have an adequate level of acceptance by the medical community, patients, or healthcare payors, we will not be able to generate sufficient revenue to remain profitable. Since we expect to rely on sales generated by Xtampza ER and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza ER or the Nucynta Products to maintain market acceptance would harm our business prospects.

***Our products contain, and our future product candidates may contain, controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies.***

Our products contain, and our future product candidates may contain, controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as Schedule II controlled substances under the CSA and regulations of the DEA. A number of states also independently regulate these drugs, including oxycodone and tapentadol, as controlled substances.

We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. In light of the COVID-19 public health emergency, the DEA now allows the issuance of a prescription for a controlled substance after examination of a patient through telemedicine technology as an in-person examination may not be possible.

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. For more information, see "Business—Government Regulation—DEA and Opioid Regulation." We may not be able to obtain sufficient quantities of these controlled substances in order to meet commercial demand. If commercial demand for Xtampza ER, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active pharmaceutical ingredient (in the case of Xtampza ER, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

Failure to obtain and maintain required registrations or to comply with any applicable regulations could delay or preclude us from developing and commercializing our products that contain controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our products containing controlled substances.

***Current and future legislation may increase the difficulty and cost for us to continue to commercialize our products and may reduce the prices we are able to obtain for our products.***

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could prevent or delay marketing approval of future product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell our products for which we obtain marketing approval. For example, several states, including New York, have recently imposed taxes or fees on the sale of opioids. Other states could impose similar taxes or fees, and such laws and proposals can vary in the tax and fee amounts imposed and the means of calculation. Liabilities for taxes or assessments under any such laws could have an adverse impact on our results of operations.

California and several other states have enacted legislation related to prescription drug pricing transparency and it is

unclear the effect this legislation will have on our business. Laws intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing of our products may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may subject us to more stringent product labeling and post-marketing testing and other requirements.

***Our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain.***

The regulations that govern marketing approvals, pricing and reimbursement for new drug products can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products.

Our ability to commercialize any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels and tiers of preference based on the perceived value and innovation of a given product. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications and establishing administrative hurdles that incentivize use of generic and/or lower cost products first. Increasingly, third-party payors are requiring that drug companies provide them with discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third-party payors may seek discounts and rebates in order to offer or maintain access for our products. We cannot be sure that high-quality coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to expand and maintain coverage and profitable reimbursement rates from both government-funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to continue to commercialize our products and affect the prices we may obtain.***

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act, and the Affordable Care Act has also been subject to challenges in the courts. See "Business—Government Regulation —Healthcare Reform."

Further changes to and under the Affordable Care Act remain possible, although the new Biden administration has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue and maintain profitability.

***Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory and enforcement efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business.***

Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to commercialize our products.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of people who abuse drugs to discover previously unknown ways to abuse opioid drugs, including Xtampza ER and the Nucynta Products; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for our products, decrease the revenues we are able to generate from their sale and adversely impact external investor perceptions of our business. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third party payers may not be willing to pay a premium for abuse-deterrent formulations of opioid.

Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use, including the Comprehensive Addiction and Recovery Act and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. These laws are described in more detail under the caption "Business— Governmental Regulation — DEA and Opioid Regulation."

***If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline.***

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. In November 2017, FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to

demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In the second half of 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent opioid formulations, including one guidance specifically relating to Xtampza ER, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

**Risks Related to Our Dependence on Third Parties**

***If the third-party manufacturers of Xtampza ER or the Nucynta Products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated facility at our third-party manufacturer's site for the manufacturing of Xtampza ER, our costs may be higher than expected and could have a material adverse effect on our business.***

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility and do not have the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our products. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as other vendors to formulate, test, supply, store and distribute our products and we control only certain aspects of their activities.

In 2020, we completed the build-out of a dedicated manufacturing suite at a site operated by our contract manufacturing organization, Patheon, part of Thermo Fisher Scientific. This dedicated facility requires the maintenance of regulatory approvals and other costs, all of which we will need to absorb. We cannot guarantee that we will be able to leverage the dedicated manufacturing suite in a profitable manner. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations.

Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional cost, to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and the future manufacturer of Nucynta ER, exposes us to the following risks, any of which could impact commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products including the ongoing COVID-19 pandemic, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.
- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and/or deliver the dedicated facility according to the currently agreed timeline.
- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products, before we may use the alternative manufacturer to produce commercial supplies.
- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully.
- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture our products could adversely affect our ability to continue to commercialize the product, which could in turn adversely affect our results of operations and financial condition. Certain components of Xtampza ER are naturally derived products, for which we rely on sole suppliers. The inability of any of our raw material suppliers to provide components

that meet our specifications and requirements could adversely impact our ability to manufacture our product. Furthermore, the quota procurement process limits the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to execute a business strategy that builds appreciable safety stock of finished drug product.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that our products to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Any stock out, or failure to obtain sufficient supplies of any of our products, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture each of our products, could adversely affect our ability to commercialize such products, which could in turn adversely affect our results of operations and financial condition.

***Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of our products, any production problems with our supplier could have a material adverse effect on us.***

We presently depend upon a single supplier for the active pharmaceutical ingredient for Xtampza ER (oxycodone base) and the Nucynta Products (tapentadol), and we contract with this supplier for commercial supply to manufacture our products. Further, and effective January 2021, our sole supplier also supplies our primary competitor in the extended-release oxycodone space, Purdue. Although we have identified an alternate source for oxycodone base for Xtampza ER, it would be time-consuming and costly to qualify this source. Any changes that our supplier makes to the respective drug substance raw materials, intermediates, or manufacturing processes would introduce technical and regulatory risks to our downstream drug product supply. If our supplier were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of disruptions in personnel or the global supply chain resulting from the COVID-19 outbreak), we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

***Manufacturing issues may arise that could increase product and regulatory approval costs, delay commercialization or limit commercial supply.***

In our current commercial manufacturing operations, and as we scale up manufacturing of our products and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials, obtain regulatory approval for commercial marketing and build commercial supplies. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply.

***We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors, that loss may materially adversely affect our financial condition and results of operations.***

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented 34%, 31% and 31% of our product shipments for the year ended December 31, 2020. Our loss of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases, a significant disruption to transportation infrastructure or other means of distribution of our products, including as a result of the ongoing COVID-19 outbreak, could have a material adverse effect on our business, results of operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot guarantee that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

***Our products could be subject to post-marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control.***

Our products are subject to a comprehensive regulatory scheme, including post-marketing requirements ("PMRs") to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium ("OPC"). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our products. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

***We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect.***

We have relied upon and plan to continue to rely upon contract research organizations ("CROs") to monitor and manage data for any non-clinical and clinical programs that we may conduct, including the OPC PMR studies discussed above. We rely on these parties for execution of our non-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing the activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our products would have an adverse impact on our commercial efforts.

**Risks Related to Our Business and Strategy**

***Our business may be adversely affected by the COVID-19 pandemic.***

COVID-19 has sickened millions of people across the world and, in March 2020, the World Health Organization declared COVID-19 a pandemic. Federal, state and city governments have taken significant measures to curtail the spread of the coronavirus that causes COVID-19, including issuing "shelter in place" or similar orders, closing non-essential businesses and imposing severe travel restrictions. The outbreak and any preventative or protective actions that we, our manufacturers, suppliers, licensors and other collaborators or governmental authorities may take with respect to the COVID-19 pandemic has disrupted and may continue to disrupt our business and the U.S. and global economies as a whole. The COVID-19 pandemic poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to a substantial percentage of personnel contracting the virus or due to shutdowns that have been or may be requested or mandated by governmental authorities. The full extent to which the COVID-19 pandemic will affect the U.S. and global economies is unknown.

The COVID-19 pandemic has, and will likely continue to have, a substantial impact on the delivery of healthcare services in the United States. Healthcare providers have reduced staffing and limited access for non-patients, including our sales professionals. In addition, as discussed above, travel restrictions due to COVID-19 have impacted our sales

professionals' ability to travel to customers, which has had, and will continue to have, a negative impact on our sales and the market penetration of our products. Moreover, the spread of COVID-19 has had, and may continue to have, an impact on the number of patients seeking and receiving treatment for conditions that might otherwise result in the prescription of our products, as patients increasingly make efforts to avoid or postpone seeking non-essential medical care and hospitals cancel elective surgeries due to the COVID-19 pandemic. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations.

The extent to which the COVID-19 pandemic continues to impact our results of operation will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, the rate and manner in which it spreads, the duration of the pandemic, travel restrictions imposed by the United States and other countries, business closures or business disruption in the United States and other countries, a reduction in time spent out of home and the actions taken throughout the world, including in our markets, to contain COVID-19 or treat its impact. These actions could have a material adverse impact on our business, financial condition and results of operations, and we will continue to monitor the effects of the COVID-19 pandemic closely.

***Litigation or regulatory action regarding opioid medications could negatively affect our business.***

Beginning in 2018, lawsuits alleging damages related to opioids have been filed naming us as a defendant along with other manufacturers of prescription opioid medications. These lawsuits, filed in multiple jurisdictions, are brought by various local governments as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States. These lawsuits generally contend that we have engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. Plaintiffs seek a variety of remedies, including abatement, restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. In some of the lawsuits, the plaintiffs have alleged joint and several liability among the defendants, meaning that any given defendant may be found liable for the activities of other defendants. None of the complaints specify the exact amount of damages at issue. These cases are generally in early stages of litigation.

In addition, certain governmental and regulatory agencies are focused on the abuse of opioid medications, a concern we share, and we have received Civil Investigative Demands or subpoenas from four state attorneys general investigating our sales and marketing of opioids and seeking documents relating to the manufacture, marketing and sale of opioid medications. We are cooperating fully in these investigations. Managing litigation and responding to governmental investigations is costly and may involve a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve injunctive relief or substantial monetary penalties, either or both of which could have a material adverse effect on our reputation, business, results of operations and cash flows.

***We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do.***

The competition in the pain and opioid market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our products compete with oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Actavis, BioDelivery Sciences, Endo, Mallinckrodt, Purdue, Teva, and others. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do.

Our competitors have developed or may be in the process of developing technologies that are, or in the future may be, the basis for competitive products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings. The widespread acceptance of currently available therapies with which our products compete may limit market acceptance of our products. Oral medications, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic pain, are widely accepted in the medical community and have a long history of use. These

treatments will compete with our products and the established use of these competitive products may limit the potential for our products to receive widespread acceptance.

***Commercial sales of our products, and clinical trials of our products and any future product candidates, may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.***

We currently carry product liability insurance. Product liability claims may be brought against us by patients; clinical trial participants; healthcare providers; or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may cause us to incur significant costs to defend the litigation.

***Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.***

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products and any product candidates for which we may obtain marketing approval.
Even though we do not and will not control referrals of healthcare services or bill Medicare, Medicaid or other third-party payors directly, we may provide reimbursement guidance and support regarding our products to our customers and patients. Federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action by government authorities. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

***We or the third parties upon whom we depend may be adversely affected by natural disasters and/or health epidemics, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemic (such as the ongoing COVID-19 pandemic) or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it might become difficult or, in certain cases, impossible for us to continue our business, and any disruption could last for a substantial period of time.

The disaster recovery and business continuity plans we have in place, and the technology that we may rely upon to implement such plans, may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition and results of operation.

**Risks Related to Our Common Stock**

***The price of our common stock may be volatile and you may lose all or part of your investment.***

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors described in these Risk Factors, some of which are beyond our control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad

market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks, or any of a broad range of other risks discussed in this report, could have a material adverse effect on the market price of our common stock.

***We are subject to anti-takeover provisions in our second amended and restated articles of incorporation and amended and restated bylaws and under Virginia law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our shareholders.***

Certain provisions of Virginia law, the state in which we are incorporated, and our second amended and restated articles of incorporation and amended and restated bylaws could hamper a third party's acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders to remove our Board of Directors or management or elect new directors to our Board of Directors.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to report our financial condition, results of operations or cash flows accurately, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. If we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. Further, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to capital markets.

***Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. Moreover, the exercise of options and warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock.***

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

As of December 31, 2020, there were outstanding options to purchase an aggregate of 3,860,481 shares of our common stock at a weighted average exercise price of $17.78 per share, of which options to purchase 2,373,097 shares of our common stock were then exercisable. In addition, as of December 31, 2020, we had an outstanding warrant to purchase 1,041,667 shares of our common stock at an exercise price of $19.20 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

Our corporate headquarters are located in Stoughton, Massachusetts, where we lease 50,678 square feet of office and laboratory space. We use this facility for research and development, commercial and general and administrative purposes. The corporate headquarters lease expires in July 2029 and the lease term may be extended for two additional five-year terms at our election.

We believe that our existing facilities are adequate for our current and expected future needs. We may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe that appropriate alternative space is readily available on commercially reasonable terms.

**Item 3. Legal Proceedings**

Discussion of legal matters is incorporated by reference from Note 11 to the Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K.

**Item 4. Mine Safety Disclosures**

Not applicable.

**PART II**

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

**Market Information**

Our common stock is publicly traded on the NASDAQ Global Select Market under the symbol "COLL" since May 7, 2015. Prior to May 7, 2015, there was no public trading market for our common stock.

**Holders**

As of January 31, 2021, there were 24 holders of record of our common stock. The number of holders of record does not include beneficial owners whose shares are held by nominees in street name.

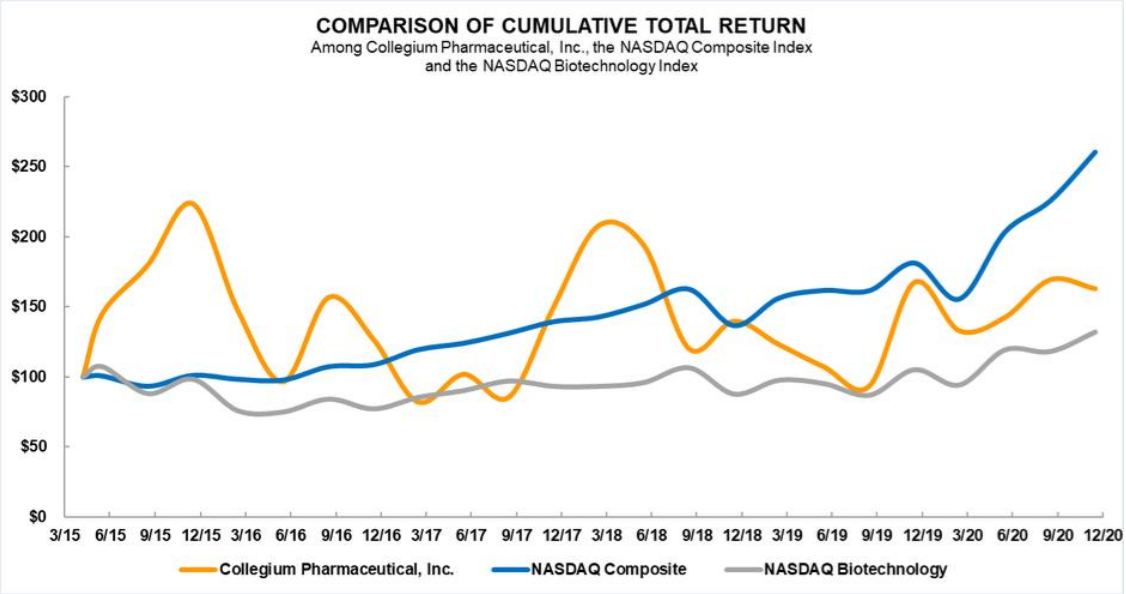
**Dividends**

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future.

**Stock Performance Graph**

The following graph shows a comparison from May 7, 2015, the date on which our common stock first began trading on the NASDAQ Global Select Market, of the total cumulative shareholder return on an assumed investment of $100.00 in cash in our common stock as compared to the same investment in the NASDAQ Composite Index and the NASDAQ Biotechnology Index, all through December 31, 2020. Such returns are based on historical results and are not intended to

suggest future performance. Data for the NASDAQ Composite Index and NASDAQ Biotechnology Index assume reinvestment of dividends, however no dividends have been declared on our common stock to date.




| $100 investment in stock or index | May 7, 2015 | December 31, 2019 | December 31, 2020 |
|---|---|---|---|
| Collegium Pharmaceutical, Inc. (COLL) | $ 100.00 | $ 167.45 | $ 162.98 |
| NASDAQ Composite Index (IXIC) | $ 100.00 | $ 181.43 | $ 260.60 |
| NASDAQ Biotechnology Index (NBI) | $ 100.00 | $ 105.13 | $ 132.14 |

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

**Recent Sales of Unregistered Securities**

There were no unregistered sales of equity securities during the period covered by this Form 10-K.

**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

The following table sets forth purchases of our common stock for the three months ended December 31, 2020:

| Period | (a) Total number of shares purchased [1] | (b) Average Price Paid per Share | (c) Total number of shares purchased as part of publicly announced plans or programs | (d) Maximum number of shares that may yet be purchased under the plans or programs |
|---|---|---|---|---|
| October 1, 2020 through October 31, 2020 | — | $ — | — | — |
| November 1, 2020 through November 30, 2020 | 4,672 | $ 18.49 | — | — |
| December 1, 2020 through December 31, 2020 | — | $ — | — | — |
| **Total** | 4,672 | $ 18.49 | — | — |

(1) All of the shares were transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock units during the period.

**Item 6. Selected Financial Data**

Not applicable.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K. The following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Form 10-K, including those set forth under "Forward-looking Statements" and "Risk Factors", as revised and supplemented by those risks described from time to time in other reports which we file with the SEC.

**Overview**

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our portfolio includes Xtampza ER, an abuse-deterrent, extended-release, oral formulation of oxycodone, and Nucynta ER and Nucynta IR (collectively, the "Nucynta Products"), which are extended-release ("ER") and immediate-release ("IR") formulations of tapentadol.

Xtampza ER was approved by the FDA in April 2016 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. We commercially launched Xtampza ER in June 2016.

Nucynta ER 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 in adults, and for which alternate treatment options are inadequate. Nucynta IR is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. We initially licensed the right to commercialize the Nucynta Products in the United States through a Commercialization Agreement with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio") entered into in December 2017 (the "Nucynta Commercialization Agreement"). On February 6, 2020, we entered into an Asset Purchase Agreement with Assertio (the "Nucynta Purchase Agreement"), pursuant to which we agreed to acquire from Assertio certain assets related to the Nucynta Products (the "Nucynta Acquisition"), including the license from Grünenthal GmbH ("Grünenthal"), for an aggregate purchase price of $375.0 million. On February 13, 2020, we closed the Nucynta

Acquisition in accordance with the Nucynta Purchase Agreement. Upon closing, the Nucynta Commercialization Agreement was effectively terminated. Our prior royalty obligation to Assertio ceased and our only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

For the fiscal year ended December 31, 2020, we generated $310.0 million in net revenues, comprised of $128.0 million from sales of Xtampza ER and $182.0 million from sales of the Nucynta Products.

***Outlook***

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. We are promoting Xtampza ER to approximately 11,000 health care professionals who write approximately 65% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 145 sales representatives and managers. We are promoting the Nucynta Products to the same health care professionals to whom we promote Xtampza ER, leveraging our existing sales organization. We have historically paid royalties to Assertio on all revenues from the sale of Nucynta Products based on certain net sales thresholds. Upon the closing of the Nucynta Acquisition and the termination of the Nucynta Commercialization Agreement (except for certain sections that survive in accordance with the Nucynta Purchase Agreement) in February 2020, our prior royalty obligation to Assertio ceased and our only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

We were historically not profitable and incurred net losses in each year since inception until 2020. We generated net income of $26.8 million in the year ended December 31, 2020 and incurred a net loss of $22.7 million in the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $333.1 million. Substantially all of our net losses resulted from costs incurred in connection with selling, general and administrative costs associated with our operations and research and development programs.

We believe that our cash and cash equivalents at December 31, 2020, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

In December 2019, a novel strain of coronavirus began infecting people in China; since then, the disease caused by that virus, COVID-19, has sickened millions of people across the world and in March 2020, the World Health Organization declared COVID-19 a pandemic. The pandemic has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. As of the date of the filing of this Annual Report on Form 10-K, we expect the COVID-19 pandemic and actions taken to contain it to impact our revenue (due to fewer new patients beginning therapy with our products and adverse impact on our ability to promote our products due to closure or limited operations of many physicians' offices) and have decreased certain operating expenses, including travel, marketing and expenses associated with participation in congresses that have been postponed. We believe that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease (or ease).

**Financial Operations Overview**

***Product Revenues***

Product revenue through the year ended December 31, 2020 has been generated from product sales of Xtampza ER and the Nucynta Products. In accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, product sales are recorded upon delivery of products to customers, net of a provision for estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns.

***Cost of Product Revenues***

Cost of product revenues include amortization of the intangible asset acquired in connection with the Nucynta Acquisition and the prior Nucynta Commercialization Agreement ("Nucynta Intangible Asset"), royalty expense, the cost of active pharmaceutical ingredient, the cost of producing finished goods that correspond with revenue for the reporting period, as well as certain period costs related to freight, packaging, stability and quality testing. Please refer to

Note 4, *License Agreements*, and Note 9, *Intangible Assets*, for further detail around the Nucynta Intangible Asset and royalty expense.

***Research and Development Expenses***

Research and development expenses consist of costs associated with our research and development activities for our products. These costs are expensed as incurred and include compensation and employee-related costs, including stock-based compensation; costs associated with conducting our clinical and non-clinical activities, including clinical and non-clinical trials that we conduct for post-marketing requirements; and costs for laboratory supplies, depreciation of lab equipment, and other expenses including allocated expenses for rent and maintenance of facilities.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation and travel expenses for our employees in executive, finance, sales and marketing and administrative functions. Other selling, general and administrative expenses include facility-related costs and professional fees for directors, accounting and legal services, and expenses associated with obtaining and maintaining patents. As we continue to invest in the commercialization of our products, we expect our selling, general and administrative expenses to be substantial for the foreseeable future.

***Interest Expense***

Interest expense consists primarily of cash and non-cash interest costs related to the term notes and convertible notes issued in connection with the Nucynta Acquisition. Historically, interest expense has also related to the Nucynta Commercialization Agreement and cash interest costs from the Loan and Security Agreement with Silicon Valley Bank ("SVB").

***Interest Income***

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

***Provision for Income Taxes***

Provision for income taxes consists of state income tax for certain states that enacted changes in tax laws that prevent us from using our state-level NOLs to offset taxable income in 2020. We did not record income tax expense in 2019 due to the utilization of federal and state NOLs carried forward to offset taxable income.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. Estimates include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of our products, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets and tax valuation allowances. We base our estimates and assumptions on historical experience when available and on various factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements appearing elsewhere in this on Form 10-K, we believe the following accounting policies to be most critical to the significant judgments and estimates used in the preparation of our consolidated financial statements.

***Revenue Recognition***

Our accounting policy for revenue recognition will have a substantial impact on reported results and relies on certain estimates. Estimates are based on historical experience, current conditions and various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amounts of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions.

*Product Revenue*

Our only source of revenue to date has been generated by sales of our products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients ("end users"). For the year ended December 31, 2020, in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), revenue for product sales is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. This generally occurs upon delivery; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns are reasonably determinable. Therefore, product sales are recorded upon delivery net of estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, as well as estimated product returns.

Prior to the adoption of ASC 606 on January 1, 2018, we recognized revenue in accordance with ASC Topic 605, *Revenue Recognition* ("legacy GAAP"), or when there was persuasive evidence of an arrangement; when title and risk of loss had passed to the customer; when estimated provisions for chargebacks, rebates, sales incentives and allowances, distribution service fees, and returns were reasonably determinable; and when collectability was reasonably assured. The satisfaction of these criteria generally occurred upon delivery of products to customers, or the sell-in method of revenue recognition under legacy GAAP. In addition, we recognized the transaction price net of estimated chargebacks, rebates, sales incentives and allowance. Given that timing of recognition for product sales under legacy GAAP and ASC 606 occurred on the delivery of products to customers and there were no differences in transaction price under legacy GAAP and ASC 606, the adoption of Topic 606 did not have a material impact on our consolidated financial position, results of operations, equity or cash flows for the year ended December 31, 2018.

*Sales Deductions*

Sales deductions consist primarily of provisions for (1) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (2) product returns, including return estimates for both the Nucynta Products and Xtampza ER; and (3) trade allowances and chargebacks, including fees for distribution service fees, prompt pay discounts, and chargebacks. We estimate the amount of variable consideration that should be included in revenue under the expected value method for all sales deductions other than trade allowances, which are estimated under the most likely amount method. These provisions reflect our best estimates of the amount of revenue to which we are entitled based on the terms of our contracts.

Provisions for rebates and incentives are based on the estimated amount of rebates and incentives to be claimed on the related sales from the period. As our rebates and incentives are based on products dispensed to patients, we are required to estimate the expected value of claims at the time of product delivery to distributors. Given that distributors sell the product to pharmacies, which in turn dispense the product to patients, claims can be submitted significantly after the related sales are recognized. Our estimates of these claims are based on the historical experience of existing or similar programs, including current contractual and statutory requirements, specific known market events and trends, industry data, and estimated distribution channel inventory levels. Accruals and related reserves required for rebates and incentives are adjusted as new information becomes available, including actual claims. If actual results vary, we may need to adjust these estimates, which could have an effect on revenue and earnings in the period of the adjustment.

Provisions for product returns are based on product-level historical trends, as well as relevant market events and other factors. For the Nucynta Products, estimates of product returns are primarily based on historical trends as the Nucynta Products have been commercially sold for a number of years. For Xtampza ER, since the product has only been commercially sold since June 2016, estimates of product returns are based on a combination of historical returns processed to date, taking into consideration the expiration date of product upon delivery to customers, as well as

forecasted customer buying patterns, shipment and prescription trends, channel inventory levels, and other specifically known market events and trends.

Provisions for trade allowances and chargebacks are primarily based on customer-level contractual terms. Accruals and related reserves are adjusted as new information becomes available, which generally consists of actual trade allowances and chargebacks processed relating to sales recognized in the period.

***Intangible Assets***

We record the fair value of finite-lived intangible assets as of the transaction date. Intangible assets are then amortized over their estimated useful lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. We test intangible assets for potential impairment whenever triggering events or circumstances present an indication of impairment. If the sum of expected undiscounted future cash flows of the intangible assets is less than the carrying amount of such assets, the intangible assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows.

As of December 31, 2020, our only intangible asset is related to the Nucynta Intangible Asset.

**Results of Operations**

In this section, we discuss the results of our operations for the year ended December 31, 2020 compared to the year ended December 31, 2019. For a discussion of the year ended December 31, 2019 compared to the year ended December 31, 2018, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019.

***Comparison of the Years Ended December 31, 2020 and 2019***

The following table summarizes the results of our operations for the years ended December 31, 2020 and 2019:

| | Years ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Product revenues, net | $ 310,016 | $ 296,701 |
| Cost of product revenues | | |
| Cost of product revenues (excluding intangible asset amortization) | 69,500 | 178,908 |
| Intangible asset amortization | 60,680 | 14,752 |
| Total cost of products revenues | 130,180 | 193,660 |
| Gross profit | 179,836 | 103,041 |
| Operating expenses | | |
| Research and development | 9,772 | 10,340 |
| Selling, general and administrative | 113,832 | 116,449 |
| Total operating expenses | 123,604 | 126,789 |
| Income (loss) from operations | 56,232 | (23,748) |
| Interest expense | (28,882) | (909) |
| Interest income | 232 | 1,935 |
| Income (loss) before income taxes | 27,582 | (22,722) |
| Provision for income taxes | 830 | — |
| Net income (loss) | $ 26,752 | $ (22,722) |

***Comparison of the Years Ended December 31, 2020 and 2019***

Product revenues, net were $310.0 million for the year ended December 31, 2020 (“2020”), compared to $296.7 million for the year ended December 31, 2019 (“2019”). The $13.3 million increase related to an increase in revenue for Xtampza ER of $23.0 million, offset by a decrease in revenue for the Nucynta Products of $9.7 million. For 2020, Xtampza ER revenue was $128.0 million, compared to $105.0 million for 2019. The increase in revenue for Xtampza ER was primarily related to an increase in sales volume due to increasing demand. For 2020, Nucynta IR and ER

revenue was $116.3 million and $65.7 million, respectively, compared to $117.7 million and $74.0 million, respectively, for 2019. The decrease in revenue for the Nucynta Products was primarily related to lower sales volume, partially offset by an increase in price.

Cost of product revenues (excluding intangible asset amortization) was $69.5 million for 2020, compared to $178.9 million for 2019. The $109.4 million decrease was primarily related to a decrease in royalty expense for the Nucynta Products. In 2019, we recognized $118.6 million in sales-based royalty expense due to Assertio under the terms of the Nucynta Commercialization Agreement, representing a full year of royalty expense compared to $14.2 million in 2020, when our sales-based royalty obligations to Assertio ceased upon closing of the Nucynta Acquisition on February 13, 2020.

Intangible asset amortization was $60.7 million for 2020, compared to $14.8 million for 2019. The $45.9 million increase was primarily related to the Nucynta Acquisition, in which $367.1 million of consideration was allocated to the existing intangible asset as incremental cost in 2020. The intangible asset is being amortized on a straight-line basis over its estimated useful life of approximately six years.

Research and development expenses were $9.8 million for 2020, compared to $10.3 million for 2019. The $568,000 decrease was primarily related to a decrease in trial related costs.

Selling, general and administrative expenses were $113.8 million for 2020, compared to $116.4 million for 2019. The $2.6 million decrease was primarily related to:

- a decrease in sales, marketing and consulting costs of $4.1 million, primarily due to lower costs incurred in 2020 to support the ongoing commercialization of our products;
- a decrease in travel, trainings, conferences, and meetings of $3.6 million, primarily due to the restrictions imposed in response to the COVID-19 outbreak;
- a decrease in audit, legal, and other professional fees of $2.7 million, primarily due to lower litigation costs; partially offset by
- an increase in other fees of $2.6 million, primarily due to certain states recently enacting excise taxes on the sale of opioids;
- an increase in salaries, wages and benefits of $1.9 million, primarily due to stock-based compensation expense, wage increases and incentive compensation expense;
- an increase in fees and permits, including fees associated with our pariticpation in the opioid PMR consoritum, of $1.2 million;
- an increase in insurance of $917,000, primarily due to higher premiums;
- an increase in subscriptions, licenses and support of $648,000;
- an increase in rent expense of $436,000, primarily related to higher expenses with vehicle leases for our field-based employees.

Interest expense was $28.9 million for 2020, compared to $909,000 for 2019. The $28.0 million increase was primarily due to interest expense recognized in 2020 associated with the term notes and convertible notes issued in connection with the Nucynta Acquisition.

Interest income was $232,000 for 2020, compared to $1.9 million for 2019. The $1.7 million decrease was primarily due to lower interest rates earned on money market funds.

Provision for income taxes was $830,000 for 2020, compared to none for 2019. The increase was primarily due to state income tax expense as, in 2020, certain states enacted changes in tax laws that prevent us from using our state-level NOLs to offset taxable income. In addition, we continue to generate more taxable income from sales of our products in states in which we do not have sufficient state-level NOLs to fully offset state taxable income. We did not record income tax expense in 2019 due to the utilization of federal and state NOLs carried forward to offset taxable income.

**Liquidity and Capital Resources**

**Sources of liquidity**

We have incurred net losses and negative cash flows from operations since inception until 2020. Historically, we have funded our operations primarily through the private placements of our preferred stock and convertible notes, public

offerings of common stock and convertible notes, and commercial bank debt. As of December 31, 2020, we had $174.1 million in cash and cash equivalents.

***Borrowing Arrangements and Equity Offerings***

The following transactions represent the material changes in borrowing arrangements and equity offerings that were previously disclosed in our most recent Annual Report.

*Pharmakon Term Notes*

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, we, together with our subsidiary, Collegium Securities Corporation, entered into the Loan Agreement with BioPharma Credit PLC, as collateral agent and lender; and BioPharma Credit Investments V (Master) LP, as lender. The Loan Agreement provides for a $200.0 million secured term loan (the "term notes"), the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The term notes will mature on the calendar quarter end immediately following the 48-month anniversary of the closing of the Nucynta Acquisition, and is guaranteed by our material domestic subsidiaries and is also secured by substantially all of our material domestic assets. The term notes will bear interest at a rate based upon LIBOR (subject to a LIBOR floor of 2.0%), plus a margin of 7.5% per annum. We are required to repay the term notes by making equal quarterly payments.

The Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, covenants that require us to maintain $200.0 million in annual net sales and covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business. Failure to comply with these covenants would constitute an event of default under the Loan Agreement, notwithstanding our ability to meet its debt service obligations. The Loan Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement. As of December 31, 2020, the Company was in compliance with all of its covenants.

*2026 Convertible Notes*

On February 13, 2020, in connection with the execution of the Nucynta Purchase Agreement, we issued 2.625% convertible senior notes due 2026 (the "convertible notes"), in the aggregate principal amount of $143.8 million, in a public offering registered under the Securities Act of 1933, as amended. The proceeds were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The convertible notes are senior, unsecured obligations and will accrue interest at a rate of 2.625% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate is 34.2618 shares of common stock per $1,000 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price will be subject to adjustment upon the occurrence of certain events.

*Silicon Valley Bank Term Loan Facility*

From August 2012 until January 2020, we maintained a term loan facility with Silicon Valley Bank, which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan, we had a term loan facility in an amount of $11.5 million, which replaced our previously existing term loan facility. The proceeds were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the previously existing term loan. In January 2020, in anticipation of consummation of the Nucynta Acquisition and related financing activities, we repaid all of our outstanding indebtedness under the amended term loan.

**Cash flows**

In this section, we discuss cash flows for the year ended December 31, 2020 compared to the year ended December 31, 2019. For a discussion of the year ended December 31, 2019 compared to the year ended December 31, 2018, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019.

| | Years ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Net cash provided by operating activities | $ 93,942 | $ 27,783 |
| Net cash used in investing activities | (373,772) | (6,438) |
| Net cash provided by (used in) financing activities | 286,474 | 2,041 |
| Net increase in cash, cash equivalents and restricted cash | $ 6,644 | $ 23,386 |

*Operating activities.* Cash provided by operating activities was $93.9 million in 2020, compared to cash provided by operating activities of $27.8 million in 2019. The $66.1 million increase in cash provided by operating activities was primarily due to higher net income as adjusted for non-cash adjustments related to the Nucynta Acquisition, which resulted in higher intangible asset amortization and higher non-cash interest expense from the term notes and convertible notes. These increases were partially offset by decreases in working capital accounts.

*Investing activities.* Cash used in investing activities was $373.8 million in 2020, compared to cash provided by investing activities of $6.4 million in 2019. The $367.4 million increase in cash used in investing activities was primarily related to the Nucynta Acquisition. The remaining change is primarily related to the timing of purchases of property, plant, and equipment primarily for the dedicated production suite at our contract manufacturing organization.

*Financing activities.* Cash provided by financing activities was $286.5 million in 2020, compared to cash provided by financing activities of $2.0 million in 2019. The $284.5 million increase in cash provided by financing activities was primarily related to net proceeds from the term notes of $192.1 million and issuance of the convertible notes of $138.3 million, both of which were issued in 2020. This increase was partially offset by term note repayments of $37.5 million and the SVB term loan repayment of $11.5 million. The remaining change is primarily related to changes in proceeds from the issuance of shares under our employee stock purchase plan and proceeds from exercises of stock options, offset by payments made for employee restricted stock tax withholdings.

**Funding requirements**

We believe that our cash and cash equivalents at December 31, 2020, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, we are subject to all the risks common to the commercialization and development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Certain economic or strategic considerations may cause us to seek additional cash through private or public debt or equity offerings. Such funds may not be available when needed, or, we may not be able to obtain funding on favorable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast that our financial resources will be adequate to support our operations is a forward-looking statement and

involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the generation of reasonable levels of revenue from products sales;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products;
- the cost of patent infringement litigation, including our litigation with Purdue, relating to Xtampza ER and the Nucynta Products, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- the timing and costs associated with manufacturing our products, for commercial sale and clinical trials
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

**Contractual Obligations**

The following table summarizes our contractual obligations as of December 31, 2020 that will affect our future liquidity:

| | Total | Less than 1 year | 1 - 3 years | 3 - 5 years | More than 5 years |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| Operating lease obligations [1] | $ 12,352 | $ 1,287 | $ 2,688 | $ 2,840 | $ 5,537 |
| Term notes, including interest | 189,878 | 63,834 | 113,247 | 12,797 | — |
| Convertible senior notes, including interest | 164,504 | 3,773 | 7,546 | 7,546 | 145,639 |
| Purchase obligations [2] | 6,000 | 3,000 | 3,000 | — | — |
| Total | $ 372,734 | $ 71,894 | $ 126,481 | $ 23,183 | $ 151,176 |

[1] Operating lease obligations represent future minimum lease payments under our non-cancelable operating lease in effect as of December 31, 2020, primarily reflecting remaining lease payments for space at our current headquarters in Stoughton, Massachusetts.

[2] Purchase obligations represent the minimum purchase obligations of up to $3.0 million per year with our contract manufacturer as of December 31, 2020. The disclosed amounts represent the maximum amount that could be payable under the minimum purchase obligations.

We also have employment agreements with executive officers that would require us to make severance payments to them if we terminate their employment without cause or the executives resign for good cause. These payments are contingent upon the occurrence of various future events, and the amounts payable under these provisions depend upon the level of compensation at the time of termination of employment, are therefore not calculable at this time.

**Non-GAAP Financial Measures**

To supplement our financial results presented on a GAAP basis, we have included information about non-GAAP adjusted income and adjusted EBITDA. We use these non-GAAP financial measures to understand, manage and evaluate the Company as we believe they represent the performance of our core business. Because these non-GAAP financial measures are important internal measures for the Company, we believe that the presentation of these non-GAAP financial measures provides analysts, investors, lenders and other third parties insight into management's view and assessment of the Company's ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliation, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing the Company's performance and results from period to period. We report these non-GAAP financial measures to portray the results of our major operations prior to considering certain income statement elements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

*Non-GAAP Adjusted Income*

Non-GAAP adjusted income is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) adjusted to exclude stock-based compensation expense, amortization expense, non-cash interest expense, certain royalty costs recognized in connection with the Nucynta Commercialization Agreement and the provision for income taxes. Non-GAAP adjusted income as used by us may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

| | Three months ended December 31, | | Year ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| GAAP net income (loss) | $ 6,958 | $ (2,201) | $ 26,752 | $ (22,722) |
| Non-GAAP adjustments: | | | | |
| Stock-based compensation expense(1) | 6,210 | 3,966 | 21,910 | 16,528 |
| Intangible asset amortization(2) | 16,795 | 3,688 | 60,680 | 14,752 |
| Non-cash interest expense(3) | 2,545 | — | 8,972 | — |
| Nucynta royalty adjustment (4) | — | — | 14,216 | — |
| Provision for income taxes (5) | 304 | — | 830 | — |
| Total non-GAAP adjustments | $ 25,854 | $ 7,654 | $ 106,608 | $ 31,280 |
| Non-GAAP adjusted income | $ 32,812 | $ 5,453 | $ 133,360 | $ 8,558 |

(1) Represents stock-based compensation expense associated with our stock option, restricted stock unit and performance stock unit grants and our employee share purchase plan.
(2) Represents amortization expense from the Nucynta Intangible Asset.
(3) Represents non-cash interest expense recognized related to the accretion of debt discount and amortization of debt issuance costs.
(4) Represents non-recurring adjustment for royalty expense recognized in 2020 prior to the closing of the Nucynta Asset Purchase Agreement in February 2020. The royalty expense was included as a reduction to the base purchase price for the Nucynta Asset Purchase Agreement and, upon closing, the Company was discharged of any unpaid royalties due to Assertio.
(5) Represents current provision for estimated income taxes.

*Adjusted EBITDA*

Adjusted EBITDA represents GAAP net income (loss) adjusted to exclude interest expense, interest income, income tax expense, depreciation, amortization, and stock-based compensation. Adjusted EBITDA as used by us may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income (loss), which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude stock-based compensation expense from adjusted EBITDA although (a) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect provision for income taxes or the cash requirements to pay taxes; and

- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments.

| | Three months ended December 31, | | Year ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| GAAP net income (loss) | $ 6,958 | $ (2,201) | $ 26,752 | $ (22,722) |
| Adjustments: | | | | |
| Interest expense | 7,737 | 211 | 28,882 | 909 |
| Interest income | (3) | (383) | (232) | (1,935) |
| Provision for income taxes | 304 | — | 830 | — |
| Depreciation | 281 | 196 | 870 | 731 |
| Amortization | 16,795 | 3,688 | 60,680 | 14,752 |
| Stock-based compensation expense | 6,210 | 3,966 | 21,910 | 16,528 |
| Total adjustments | $ 31,324 | $ 7,678 | $ 112,940 | $ 30,985 |
| Adjusted EBITDA | $ 38,282 | $ 5,477 | $ 139,692 | $ 8,263 |

| | First Quarter 2020 | Second Quarter 2020 | Third Quarter 2020 | Fourth Quarter 2020 |
|---|---|---|---|---|
| GAAP net income | $ 450 | $ 8,058 | $ 11,286 | $ 6,958 |
| Adjustments: | | | | |
| Interest expense | 4,823 | 8,259 | 8,063 | 7,737 |
| Interest income | (212) | (14) | (3) | (3) |
| Provision for income taxes | — | 246 | 280 | 304 |
| Depreciation | 198 | 196 | 195 | 281 |
| Amortization | 10,295 | 16,795 | 16,795 | 16,795 |
| Stock-based compensation expense | 4,951 | 5,584 | 5,165 | 6,210 |
| Total adjustments | $ 20,055 | $ 31,066 | $ 30,495 | $ 31,324 |
| Adjusted EBITDA | $ 20,505 | $ 39,124 | $ 41,781 | $ 38,282 |

| | First Quarter 2019 | Second Quarter 2019 | Third Quarter 2019 | Fourth Quarter 2019 |
|---|---|---|---|---|
| GAAP net loss | $ (9,700) | $ (4,712) | $ (6,109) | $ (2,201) |
| Adjustments: | | | | |
| Interest expense | 234 | 236 | 228 | 211 |
| Interest income | (526) | (532) | (494) | (383) |
| Depreciation | 184 | 171 | 180 | 196 |
| Amortization | 3,688 | 3,688 | 3,688 | 3,688 |
| Stock-based compensation expense | 4,263 | 4,162 | 4,137 | 3,966 |
| Total adjustments | $ 7,843 | $ 7,725 | $ 7,739 | $ 7,678 |
| Adjusted EBITDA | $ (1,857) | $ 3,013 | $ 1,630 | $ 5,477 |

**Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements during the periods presented, as defined under SEC rules.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risks**

We are exposed to market risk related to changes in interest rates. As of December 31, 2020, we had cash and cash equivalents consisting of cash and money market funds of $174.1 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our money market funds are short-term highly liquid investments. Due to the short-term duration and the low risk profile of

our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

**Item 8. Consolidated Financial Statements and Supplementary Data**

Our consolidated financial statements, together with the reports of our independent registered public accounting firms, begin on page F-1 of this Form 10-K.

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

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020.

**Management’s Report on Internal Control Over Financial Reporting**

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Also, projections of any evaluation of effectiveness of internal control over financial reporting 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 policies or procedures may deteriorate. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as

such term is defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled “Internal Control—Integrated Framework (2013)” published by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2020, the end of our most recent fiscal year.

**Changes in Internal Control Over Financial Reporting**

As required by Rule 13a-15(d) of the Exchange Act, our management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer did not identify any change in our internal control over financial reporting during the fiscal quarter ended December 31, 2020 that has materially affected, or is 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 Collegium Pharmaceutical, Inc.

**Opinion on Internal Control over Financial Reporting**

We have audited the internal control over financial reporting of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company") as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.
We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2020, of the Company and our report dated February 25, 2021, expressed an unqualified opinion on those financial statements.

**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/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2021

**Item 9B. Other Information**

Not applicable.

**PART III**

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

Other than the information regarding our executive officers provided in Part I of this report under the heading "Business—Executive Officers of the Registrant," the information required to be furnished pursuant to this item is incorporated herein by reference to our definitive proxy statement for the 2021 Annual Meeting of the Shareholders.

Our Board of Directors has adopted a Code of Ethics applicable to all of our employees, executive officers and directors. The Code of Ethics is available on our website at www.collegiumpharma.com. Our Board of Directors is responsible for overseeing compliance with the Code of Ethics, and our Board of Directors or an appropriate committee thereof must approve any waivers of the Code of Ethics for employees, executive officers or directors. Disclosure regarding any amendments to the Code of Ethics, or any waivers of its requirements, will be made on our website.

**Item 11. Executive Compensation**

The information required by this Item 11 is incorporated herein by reference from our definitive proxy statement for the 2021 Annual Meeting of Shareholders.

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

The information required by this Item 12 is incorporated herein by reference from our definitive proxy statement for the 2021 Annual Meeting of Shareholders.

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

The information required by this Item 13 is incorporated herein by reference from our definitive proxy statement for the 2021 Annual Meeting of Shareholders.

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

The information required by this Item 14 is incorporated herein by reference from our definitive proxy statement for the 2021 Annual Meeting of Shareholders.

**PART IV**

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

**Consolidated Financial Statements**

See Part II, Item 8 for the Consolidated Financial Statements required to be included in this Form 10-K.

**Consolidated Financial Statement Schedules**

All financial statement schedules are omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

**Exhibits**

| Exhibit Number | Exhibit Description |
|---|---|
| 2.1† | Agreement and Plan of Merger, dated July 10, 2014, by and between Collegium Pharmaceutical, Inc., a Delaware corporation, and Collegium Pharmaceutical, Inc., a Virginia corporation.(1) |
| 3.1† | Third Amended and Restated Articles of Incorporation of Collegium Pharmaceutical, Inc.(14) |
| 3.2† | Amended and Restated Bylaws of Collegium Pharmaceutical, Inc.(4) |
| 4.1† | Warrant to Purchase Stock, dated November 8, 2018, issued by Collegium Pharmaceutical, Inc. to Assertio Therapeutics, Inc.(9) |
| 4.2† | Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.(12) |
| 4.3† | First Supplemental Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.(12) |
| 4.4† | Form of certificate representing the 2.625% Convertible Senior Notes due 2026 (included as Exhibit A to Exhibit 4.3)(12) |
| 4.5 | Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed herewith). |
| 10.1† | Office Lease agreement by and between Campanelli-Trigate 100 TCD Stoughton, LLC, and Collegium Pharmaceutical, Inc as of March 23, 2018.(6) |
| 10.2+† | 2015 Employee Stock Purchase Plan.(2) |
| 10.3+† | Performance Bonus Plan.(3) |
| 10.4(a)+† | Amended and Restated 2014 Stock Incentive Plan.(2) |
| 10.4(b)+† | Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.(2) |
| 10.4(c)+† | Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.(2) |
| 10.4(d)+† | Form of Restricted Stock Award Agreement under the Amended and Restated 2014 Stock Incentive Plan.(2) |
| 10.4(e)+† | Form of Performance Share Unit Agreement under the Amended and Restated 2014 Stock Incentive Plan.(10) |
| 10.5† | Form of Indemnification Agreement.(3) |
| 10.6+† | Amended & Restated Employment Agreement, dated December 28, 2020, by and between Paul Brannelly and Collegium Pharmaceutical, Inc.(16) |
| 10.7+† | Amended & Restated Employment Agreement, dated December 27, 2020, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.(16) |
| 10.8+† | Amended & Restated Employment Agreement, dated December 27, 2020, by and between Shirley Kuhlmann and Collegium Pharmaceutical, Inc.(16) |
| 10.9+† | Letter Agreement dated June 4, 2018, by and between Collegium Pharmaceutical, Inc. and Michael T. Heffernan.(7) |
| 10.10+† | Amended & Restated Employment Agreement, dated December 27, 2020, by and between Collegium Pharmaceutical, Inc. and Scott Dreyer.(16) |
| 10.11+† | Amended & Restated Employment Agreement, effective as of December 27, 2020, by and between Richard Malamut, M.D. and Collegium Pharmaceutical, Inc.(16) |
| 10.12+† | Amended & Restated Employment Agreement, effective as of December 29, 2020, by and between Alison Fleming, Ph.D. and Collegium Pharmaceutical, Inc.(16) |
| 10.13*† | Commercialization Agreement, by and among, Assertio, Inc., Collegium Pharmaceutical, Inc. and Collegium NF, LLC, dated as of December 4, 2017.(5) |
| 10.14† | Amendment dated January 9, 2018 to Commercialization Agreement by and among Assertio, Inc. and Collegium Pharmaceutical, Inc. and Collegium NF, LLC.(5) |
| 10.15† | Amendment No. 2 to Commercialization Agreement, dated August 29, 2018, by and among Collegium Pharmaceutical, Inc., Collegium NF, LLC, and Assertio Therapeutics, Inc.(8) |
| 10.16† | Amendment No. 3 to Commercialization Agreement, dated November 8, 2018, by and among Collegium Pharmaceutical, Inc., Collegium NF, LLC, and Assertio Therapeutics, Inc.(9) |

| | |
|---|---|
| 10.17† | Purchase Agreement, dated as of February 6, 2020, by and between Collegium Pharmaceutical, Inc. and Assertio Therapeutics, Inc.(11) |
| 10.18† | Loan Agreement, dated as of February 6, 2020, by and among the Company, its subsidiaries, BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender.(11) |
| 10.19† | First Amendment to Loan Agreement, dated as of February 24, 2020, by and among the Company, its subsidiaries, BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender.(13) |
| 10.20† | Second Amendment to Loan Agreement, dated as of May 27, 2020, by and among the Company, Collegium Securities Corporation, BioPharma Credit PLC, as collateral agent, BPCR Limited Partnership, as lender, and BioPharma Credit Investments V (Master) LP, as lender.(14) |
| 10.21† | License Agreement (U.S.), dated as of January 13, 2015, by and among Grünenthal GmbH, Janssen Research & Development, LLC, Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc.(13) |
| 10.22† | Consent Agreement, dated January 30, 2020, by and among Grünenthal GmbH, Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc.(13) |
| 10.23† | Settlement Agreement, dated September 29, 2020, by and among Collegium Pharmaceutical, Inc. and Teva Pharmaceuticals USA, Inc.(15) |
| 21.1 | Subsidiaries of Collegium Pharmaceutical, Inc. |
| 23.1 | Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm. |
| 31.1 | Certifying Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certifying Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certifying Statement of the Chief Executive Officer pursuant to Section 1350 of Title 18 of the United States Code. |
| 32.2 | Certifying Statement of the Chief Financial Officer pursuant to Section 1350 of Title 18 of the United States Code. |
| 101 | The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL: (i) Consolidated Balance Sheets as of December 31, 2020, 2019, (ii) Consolidated Statements of Operations for the years ended December 31, 2020, 2019 and 2018, (iii) Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2020, 2019 and 2018, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

†Previously filed.

+Indicates management contract or compensatory plan.

* Certain portions of the exhibits that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the Commission upon request.

(1) Previously filed as an exhibit to the registrant’s Registration Statement on Form S-1 (File No. 333-203208) filed with the Commission on April 2, 2015.

(2) Previously filed as an exhibit to the registrant’s Registration Statement on Form S-8 (File No. 333-207744) filed with the Commission on November 2, 2015.

(3) Previously filed as an exhibit to the registrant’s Registration Statement on Form S-1/A (File No. 333-203208) filed with the Commission on April 27, 2015.

(4) Previously filed as an exhibit to the registrant’s Current Report on Form 8-K filed with the Commission on December 4, 2017.

(5) Previously filed as an exhibit to the registrant’s Annual Report on Form 10-K filed with the Commission on March 7, 2018.

(6) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018 filed with the Commission on May 9, 2018.

(7) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on June 4, 2018.

(8) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 filed with the Commission on November 8, 2018.

(9) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on November 8, 2018.

(10) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019 filed with the Commission on May 8, 2019.

(11) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on February 10, 2020.

(12) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on February 13, 2020.

(13) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 filed with the Commission on May 7, 2020.

(14) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020 filed with the Commission on August 5, 2020.

(15) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on September 30, 2020.

(16) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on December 30, 2020.

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

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

COLLEGIUM PHARMACEUTICAL, INC.

By: /s/ Joseph Ciaffoni.
Joseph Ciaffoni
Chief Executive Officer

| Signature | Title | Date |
|---|---|---|
| /s/ Joseph Ciaffoni<br>Joseph Ciaffoni | President and Chief Executive Officer (Principal Executive Officer) and Director | February 25, 2021 |
| /s/ Paul Brannelly<br>Paul Brannelly | Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | February 25, 2021 |
| /s/ Michael T. Heffernan, R.Ph.<br>Michael T. Heffernan, R.Ph. | Chairman of the Board | February 25, 2021 |
| /s/ Rita Balice-Gordon, Ph.D.<br>Rita Balice-Gordon, Ph.D. | Director | February 25, 2021 |
| /s/ Garen G. Bohlin<br>Garen G. Bohlin | Director | February 25, 2021 |
| /s/ John A. Fallon, M.D.<br>John A. Fallon, M.D. | Director | February 25, 2021 |
| /s/ John G. Freund, M.D.<br>John G. Freund, M.D. | Director | February 25, 2021 |
| /s/ Gwen Melincoff<br>Gwen Melincoff | Director | February 25, 2021 |
| /s/ Gino Santini<br>Gino Santini | Director | February 25, 2021 |
| /s/ Theodore R. Schroeder<br>Theodore R. Schroeder | Director | February 25, 2021 |

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated

**COLLEGIUM PHARMACEUTICAL, INC.**
**Index to Consolidated Financial Statements**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the shareholders and the Board of Directors of Collegium Pharmaceutical, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

We have also 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, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2021, expressed an unqualified opinion on the Company's internal control over financial reporting.

**Basis for Opinion**

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

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

**Critical Audit Matter**

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

***Revenue Sales Deductions – Xtampza ER Product Return Reserves — Refer to Note 3 to the financial statements***

*Critical Audit Matter Description*

Revenue is stated net of certain sales deductions, including provisions for product returns. Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company’s consolidated balance sheets.

Estimating the provision for product returns of Xtampza ER, a product that was first shipped in 2016, requires significant judgment by management. Management’s model for estimating returns is based on historical returns, while also considering levels of inventory in the channel, purchasing, shipment and prescription trends, production dates and expiration dates. Given the limited history of production lots of Xtampza ER, for which the right of return has been terminated or lapsed, coupled with the level of estimation uncertainty involved, our audit in this area required a high degree of auditor judgment and an increased extent of effort.

*How the Critical Audit Matter Was Addressed in the Audit*

Our audit procedures related to the Revenue Sales Deductions – Xtampza ER Product Return Reserves included the following, among others:

- We tested the effectiveness of controls over the calculation of the provision for product return, including Management's controls over product return and product revenue data.
- We evaluated the Company's methodology and significant assumptions made in developing the provision for product return, including testing the completeness and accuracy of the underlying data used by management that serves as the basis for their product return estimates.
- We tested the mathematical accuracy of management's calculation of the provision for product return.
- We tested the reasonableness of management's provision for product return by comparing the assumptions used in the projections to external market sources, information produced by the entity and corroboration with management outside of accounting and finance.
- We evaluated management's ability to accurately forecast product returns activity by performing a retrospective review, comparing prior period product return estimates to actual returns processed in the subsequent year to identify potential bias or unanticipated trends in the determination of product return reserves.
- We developed independent estimates of the provision for product returns using historical sales and returns activity, product dating and expiration dates and independent estimates of product inventory in the channel and compared our estimates to management's estimates.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2021

We have served as the Company's auditor since 2016.

**COLLEGIUM PHARMACEUTICAL, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share and per share data)**

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 174,116 | $ 170,019 |
| Accounts receivable | 83,320 | 72,953 |
| Inventory | 15,614 | 9,643 |
| Prepaid expenses and other current assets | 4,838 | 3,105 |
| Total current assets | 277,888 | 255,720 |
| Property and equipment, net | 18,988 | 11,854 |
| Operating lease assets | 8,391 | 9,047 |
| Intangible asset, net | 335,904 | 29,503 |
| Restricted cash | 2,547 | — |
| Other noncurrent assets | 123 | 178 |
| Total assets | $ 643,841 | $ 306,302 |
| **Liabilities and shareholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 10,016 | $ 6,247 |
| Accrued expenses | 24,656 | 33,480 |
| Accrued rebates, returns and discounts | 156,554 | 157,549 |
| Current portion of term notes payable | 47,495 | 3,833 |
| Current portion of operating lease liabilities | 730 | 656 |
| Total current liabilities | 239,451 | 201,765 |
| Term notes payable, net of current portion | 110,019 | 7,667 |
| Convertible senior notes | 99,575 | — |
| Operating lease liabilities, net of current portion | 8,765 | 9,438 |
| Total liabilities | 457,810 | 218,870 |
| Commitments and contingencies (see Note 11) | | |
| Shareholders’ equity: | | |
| Preferred stock, $0.001 par value; authorized shares - 5,000,000 at December 31, 2020 and December 31, 2019; issued and outstanding shares - none at December 31, 2020 and December 31, 2019 | — | — |
| Common stock, $0.001 par value; authorized shares - 100,000,000 at December 31, 2020 and December 31, 2019; issued and outstanding shares - 34,612,054 at December 31, 2020 and 33,678,840 at December 31, 2019 | 35 | 34 |
| Additional paid-in capital | 519,143 | 447,297 |
| Accumulated deficit | (333,147) | (359,899) |
| Total shareholders’ equity | 186,031 | 87,432 |
| Total liabilities and shareholders’ equity | $ 643,841 | $ 306,302 |

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

**COLLEGIUM PHARMACEUTICAL, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(In thousands, except share and per share data)**

| | Years ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Product revenues, net | $ 310,016 | $ 296,701 | $ 280,413 |
| Cost of product revenues | | | |
| Cost of product revenues (excluding intangible asset amortization) | 69,500 | 178,908 | 55,843 |
| Intangible asset amortization | 60,680 | 14,752 | 109,834 |
| Total cost of products revenues | 130,180 | 193,660 | 165,677 |
| Gross profit | 179,836 | 103,041 | 114,736 |
| Operating expenses | | | |
| Research and development | 9,772 | 10,340 | 8,661 |
| Selling, general and administrative | 113,832 | 116,449 | 126,760 |
| Total operating expenses | 123,604 | 126,789 | 135,421 |
| Income (loss) from operations | 56,232 | (23,748) | (20,685) |
| Interest expense | (28,882) | (909) | (20,130) |
| Interest income | 232 | 1,935 | 1,687 |
| Income (loss) before income taxes | 27,582 | (22,722) | (39,128) |
| Provision for income taxes | 830 | — | — |
| Net income (loss) | $ 26,752 | $ (22,722) | $ (39,128) |
| | | | |
| Earnings (loss) per share — basic | $ 0.78 | $ (0.68) | $ (1.19) |
| Weighted-average shares — basic | 34,407,959 | 33,453,844 | 32,953,808 |
| | | | |
| Earnings (loss) per share — diluted | $ 0.76 | $ (0.68) | $ (1.19) |
| Weighted-average shares — diluted | 35,151,353 | 33,453,844 | 32,953,808 |

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

**COLLEGIUM PHARMACEUTICAL, INC.**
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**
**(In thousands, except share data)**

| | Common Stock | | Additional Paid-In | Accumulated | Total Shareholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Equity |
| Balance at December 31, 2017 | 32,770,678 | $ 33 | $ 402,096 | $ (298,049) | $ 104,080 |
| Exercise of common stock options | 349,777 | — | 4,255 | — | 4,255 |
| Issuance for employee stock purchase plan | 86,929 | — | 1,117 | — | 1,117 |
| Vesting of RSUs | 85,119 | — | — | — | — |
| Shares withheld for employee taxes upon vesting of RSUs | (26,874) | — | (560) | — | (560) |
| Stock-based compensation | — | — | 13,778 | — | 13,778 |
| Issuance of warrant | — | — | 8,043 | — | 8,043 |
| Net loss | — | — | — | (39,128) | (39,128) |
| Balance at December 31, 2018 | 33,265,629 | $ 33 | $ 428,729 | $ (337,177) | $ 91,585 |
| Exercise of common stock options | 201,308 | — | 2,046 | — | 2,046 |
| Issuance for employee stock purchase plan | 74,142 | 1 | 816 | — | 817 |
| Vesting of RSUs | 196,139 | — | — | — | — |
| Shares withheld for employee taxes upon vesting of RSUs | (58,378) | — | (822) | — | (822) |
| Stock-based compensation | — | — | 16,528 | — | 16,528 |
| Net loss | — | — | — | (22,722) | (22,722) |
| Balance at December 31, 2019 | 33,678,840 | $ 34 | $ 447,297 | $ (359,899) | $ 87,432 |
| Exercise of common stock options | 637,924 | 1 | 6,656 | — | 6,657 |
| Issuance for employee stock purchase plan | 67,512 | — | 758 | — | 758 |
| Vesting of RSUs | 335,524 | — | — | — | — |
| Shares withheld for employee taxes upon vesting of RSUs | (107,746) | — | (2,255) | — | (2,255) |
| Stock-based compensation | — | — | 21,910 | — | 21,910 |
| Equity component of 2020 Convertible Notes, net of issuance costs of $1,773 | — | — | 44,777 | — | 44,777 |
| Net income | — | — | — | 26,752 | 26,752 |
| Balance at December 31, 2020 | 34,612,054 | $ 35 | $ 519,143 | $ (333,147) | $ 186,031 |

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

**COLLEGIUM PHARMACEUTICAL, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | Years ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| **Operating activities** | | | |
| Net income (loss) | $ 26,752 | $ (22,722) | $ (39,128) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | | |
| Amortization expense | 60,680 | 14,752 | 109,834 |
| Depreciation expense | 870 | 731 | 1,074 |
| Stock-based compensation expense | 21,910 | 16,528 | 13,778 |
| Non-cash lease expense | 57 | 313 | — |
| Non-cash interest expense for amortization of debt discount and issuance costs | 8,972 | — | — |
| Non-cash interest expense for Nucynta asset acquisition | — | — | 19,281 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (10,367) | 4,993 | (68,231) |
| Inventory | (8,270) | (1,826) | 219 |
| Prepaid expenses and other assets | (1,598) | 2,037 | (166) |
| Accounts payable | 3,769 | (5,903) | 6,465 |
| Accrued expenses | (7,838) | 6,056 | 18,995 |
| Accrued rebates, returns and discounts | (995) | 12,766 | 106,593 |
| Operating lease assets and liabilities | — | 734 | — |
| Other long-term liabilities | — | (676) | 676 |
| Net cash provided by operating activities | 93,942 | 27,783 | 169,390 |
| **Investing activities** | | | |
| Purchase of intangible asset | (368,226) | — | (18,877) |
| Purchases of property and equipment | (5,546) | (6,438) | (5,477) |
| Net cash used in investing activities | (373,772) | (6,438) | (24,354) |
| **Financing activities** | | | |
| Proceeds from issuances of common stock from employee stock purchase plans | 758 | 817 | 1,117 |
| Proceeds from the exercise of stock options | 6,577 | 2,046 | 4,255 |
| Payments made for employee restricted stock tax withholdings | (2,255) | (822) | (560) |
| Proceeds from issuance of term note, net of issuance costs of $2,456 | 192,117 | — | — |
| Proceeds from convertible senior notes, net of issuance costs of $5,473 | 138,277 | — | — |
| Repayment of term notes | (37,500) | — | — |
| Repayment of term loan | (11,500) | — | — |
| Proceeds from issuance of common stock from public offerings, net of issuance costs of $-, $- and $30, respectively | — | — | (30) |
| Proceeds from term loan amendment, net of repayment of amended term loan | — | — | 10,021 |
| Repayment of asset acquisition obligations | — | — | (132,000) |
| Net cash provided by (used in) financing activities | 286,474 | 2,041 | (117,197) |
| | | | |
| Net increase in cash, cash equivalents and restricted cash | 6,644 | 23,386 | 27,839 |
| Cash, cash equivalents and restricted cash at beginning of period | 170,019 | 146,633 | 118,794 |
| Cash, cash equivalents and restricted cash at end of period | $ 176,663 | $ 170,019 | $ 146,633 |
| | | | |
| Reconciliation of cash, cash equivalents and restricted cash to the Consolidated Balance Sheets: | | | |
| Cash and cash equivalents | 174,116 | 170,019 | 146,633 |
| Restricted cash | 2,547 | — | — |
| Total cash, cash equivalents and restricted cash | $ 176,663 | 170,019 | 146,633 |
| | | | |
| **Supplemental disclosure of cash flow information** | | | |
| Cash paid for offering costs | $ — | $ — | $ 30 |
| Cash paid for interest | $ 18,967 | $ 709 | $ 582 |
| Cash paid for income taxes | $ 483 | $ — | $ — |
| | | | |
| **Supplemental disclosure of non-cash activities** | | | |
| Acquisition of property and equipment in accounts payable and accrued expenses | $ 293 | $ 134 | $ 3,261 |
| Accrued royalties discharged upon closing of asset acquisition | $ 1,145 | — | — |
| Inventory used in the construction and installation of property and equipment | $ 2,299 | — | — |
| Receivable from stock option exercises in other current assets | $ 80 | $ — | $ — |
| Operating lease assets assumed | $ — | $ 9,957 | $ — |
| Operating lease liabilities assumed | $ — | $ 10,691 | $ — |
| Liabilities assumed from Nucynta asset acquisition included in accrued rebates, returns and discounts | $ — | $ — | $ 22,406 |
| Liabilities assumed from Nucynta asset acquisition included as a reduction to accounts receivable | $ — | $ — | $ 254 |
| Warrant issued in connection with Nucynta asset acquisition | $ — | $ — | $ 8,043 |

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

**COLLEGIUM PHARMACEUTICAL, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(in thousands, except share and per share data)**

## 1. NATURE OF BUSINESS

### Organization

Collegium Pharmaceutical, Inc. (the "Company") was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Stoughton, Massachusetts. The Company is a specialty pharmaceutical company committed to being the leader in responsible pain management. The Company's first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the United States Food and Drug Administration (the "FDA") approved the Company's new drug application ("NDA") for Xtampza ER 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. In June 2016, the Company announced the commercial launch of Xtampza ER.

The Company's product portfolio also includes Nucynta ER and Nucynta IR (the "Nucynta Products"). In December 2017, the Company entered into a Commercialization Agreement (the "Nucynta Commercialization Agreement") with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio"), pursuant to which the Company acquired the right to commercialize the Nucynta Products in the United States. The Company began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. Nucynta ER is an extended-release formulation 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 in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

On February 6, 2020, the Company entered into an Asset Purchase Agreement with Assertio (the "Nucynta Purchase Agreement"), pursuant to which the Company agreed to acquire from Assertio certain assets related to the Nucynta Products (the "Nucynta Acquisition"), including the license from Grünenthal GmbH ("Grünenthal"), for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments as described in the Nucynta Purchase Agreement. On February 13, 2020, the Company closed the Nucynta Acquisition in accordance with the Nucynta Purchase Agreement. Upon closing, the Nucynta Commercialization Agreement was effectively terminated. Following the closing, the Company's prior royalty obligation to Assertio ceased and the Company's only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

In December 2019, a novel strain of coronavirus began infecting people in China; since then, the disease caused by virus, COVID-19, has sickened millions of people across the world and in March 2020, the World Health Organization declared COVID-19 a pandemic. The pandemic has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. The travel restrictions and "social distancing" recommendations resulting from the spread of COVID-19 have impacted the Company's sales professionals' ability to travel to and meet with healthcare providers in person. The Company periodically reviews its accounting estimates in light of changes in circumstances, facts and experience. As of the date of the filing of this Annual Report on Form 10-K, the COVID-19 pandemic and actions taken to contain it have impacted revenue (due to fewer new patients beginning therapy with the Company's products and adverse impact on the Company's ability to promote products due to closure or limited operations of many physicians' offices) and decreased certain operating expenses, including travel, marketing and expenses associated with participation in congresses that have been postponed. The Company believes that the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease (or ease).

The Company's operations are subject to certain risks and uncertainties. The principal risks include inability to continue successfully commercializing products, changing market conditions for products and development of competing

products, changing regulatory environment and reimbursement landscape, litigation related to opioid marketing and distribution practices, manufacture of adequate commercial inventory, inability to secure adequate supplies of active pharmaceutical ingredients, key personnel retention, protection of intellectual property, and patent infringement litigation.

**Liquidity**

The Company believes that its cash and cash equivalents at December 31, 2020, together with expected cash inflows from the commercialization of its products, will enable the Company to fund its operating expenses, debt service and capital expenditure requirements under its current business plan for the foreseeable future.

The Company has experienced net losses since its inception, and as of December 31, 2020, had an accumulated deficit of $333,147. A successful transition to sustainable profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Accounting**

The consolidated financial statements include the accounts of Collegium Pharmaceutical, Inc. as well as the accounts of its subsidiaries Collegium Securities Corp. (a Massachusetts corporation), incorporated in December 2015, and Collegium NF LLC (a Delaware limited liability company), incorporated in December 2017, both wholly owned subsidiaries requiring consolidation. The consolidated financial statements are prepared in conformity with generally accepted accounting principles in the United States of America ("GAAP"). All intercompany balances and transactions have been eliminated in consolidation.

**Use of Estimates**

The preparation of consolidated financial statements in accordance with GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. Estimates in the Company's consolidated financial statements include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of products, estimates of useful lives with respect to intangible assets, accounting for stock based compensation, contingencies, impairment of intangible assets and tax valuation allowances. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates under different assumptions or conditions.

**Fair Value Measurements**

Disclosures of fair value information about financial instruments are required, whether or not recognized in the balance sheet, for financial instruments with respect to which it is practicable to estimate that value. Fair value measurements and disclosures describe the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, as follows:

| | |
|---|---|
| **Level 1 inputs:** | Quoted prices (unadjusted) in active markets for identical assets or liabilities |
| **Level 2 inputs:** | Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly |
| **Level 3 inputs:** | Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability |

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2020 and 2019.

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at December 31, 2020 and 2019.

| | Total | Quoted Prices in active markets (Level 1) | Significant other observable inputs (Level 2) | Significant unobservable inputs (Level 3) |
|---|---|---|---|---|
| **December 31, 2020** | | | | |
| Money market funds, included in cash equivalents | $ 45,069 | $ 45,069 | $ — | $ — |
| **December 31, 2019** | | | | |
| Money market funds, included in cash equivalents | $ 94,841 | $ 94,841 | $ — | $ — |

The Company's convertible senior notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined using broker quotes in a non-active market for valuation. As of December 31, 2020, the convertible senior notes had a fair value of approximately $139,643 and a net carrying value of $99,575.

The Company's term notes fall into the Level 2 category within the fair value level hierarchy and the fair value was determined using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals.

As of December 31, 2020, and December 31, 2019, the carrying amounts of the cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, accrued rebates, returns and discounts, and term notes payable reasonably approximated their estimated fair values.

**Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents and accounts receivable. The Company maintains its cash deposits primarily with one reputable and nationally recognized financial institution. In addition, as of December 31, 2020, the Company's cash equivalents were invested in money market funds. The Company has not experienced any material losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the financial institutions in which those deposits are held.

Three customers comprised 10% or more of the Company's accounts receivable balance as of December 31, 2020. These customers comprised 46%, 34% and 17% of the accounts receivable balance, respectively. The same three customers comprised 10% or more of the Company's revenue during the year ended December 31, 2020. These customers comprised 34%, 31% and 31% of revenue, 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 balance is collectible as of December 31, 2020. The Company has no financial instruments with off-balance sheet risk of loss.

**Cash and Cash Equivalents**

Cash and cash equivalents include cash in readily available checking and savings accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

The Company's cash equivalents, which consist of money market funds, are measured at fair value on a recurring basis. As of December 31, 2020 and 2019, the carrying amount of cash equivalents was $45,069 and $94,841, respectively, which approximates fair value and was determined based upon Level 1 inputs. Money market funds are valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1.

**Restricted Cash**

Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months. As of December 31, 2020, the Company had restricted cash of $2,547, which represents cash held in a depository account at a financial institution to collateralize conditional stand by letters of credit for the Company's corporate credit card program, its lease of its corporate headquarters, and its leases of vehicles for its field-based employees. The Company had no restricted cash as of December 31, 2019.

**Inventory**

Inventories are stated at the lower of cost or net realizable value. Inventory costs consist of costs related to the manufacturing of the Company's products, which are primarily the costs of contract manufacturing and active pharmaceutical ingredient. The Company determines the cost of its inventories on a specific identification basis, and removes amounts from inventories on a first-in, first-out basis. If the Company identifies excess, obsolete or unsalable items, inventories are written down to their realizable value in the period in which the impairment is identified. These adjustments are recorded based upon various factors, including the level of product manufactured by the Company, the level of product in the distribution channel, current and projected demand and the expected shelf-life of the inventory components. As of December 31, 2020, cumulative estimates of excess inventory recorded as a component of cost of product revenues were immaterial.

The Company outsources the manufacturing of Xtampza ER and the Nucynta Products to contract manufacturers that produce the finished product. In addition, the Company currently relies on a sole supplier for the active pharmaceutical ingredient in Xtampza ER and the Nucynta Products. Accordingly, the Company has concentration risk associated with its commercial manufacturing of Xtampza ER and the Nucynta Products.

The Company has capitalized $15,614 of inventory as of December 31, 2020. The Company expects sales of the capitalized units to occur during the next twelve months.

**Property and Equipment**

Property and equipment, including leasehold improvements, are recorded at cost. Maintenance and repair costs are expensed as incurred. Costs which materially improve or extend the lives of existing assets are capitalized. Property and equipment are depreciated when placed into service using the straight-line method based on their estimated useful lives as follows:

| Asset Category | Estimated Useful Life |
|---|---|
| Computers and office equipment | 3-5 years |
| Laboratory equipment | 5 years |
| Furniture and fixtures | 7 years |
| Manufacturing equipment | 5-13 years |
| Leasehold improvements | Lesser of remaining lease term and estimated useful life |

Costs for capital assets not yet placed into service have been capitalized as construction-in-progress, and will be depreciated in accordance with the above guidelines once placed into service.

Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recorded in the statements of operations.

**Intangible Assets**

The Company records the fair value of finite-lived intangible assets as of the transaction date. Intangible assets are then amortized over their estimated useful lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. The Company tests intangible assets for

potential impairment whenever triggering events or circumstances present an indication of impairment. If the sum of expected undiscounted future cash flows of the intangible assets is less than the carrying amount of such assets, the intangible assets would be written down to the estimated fair value, calculated based on the present value of expected future cash flows.

**Revenue Recognition**

The Company's revenue to date is from sales of the Company's products, which are primarily sold to distributors, which in turn sell the product to pharmacies for the treatment of patients. In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Please see Note 3 for further detail.

**Research and Development Costs**

Research and development costs are charged to expense as incurred and consist of costs incurred to further the Company's research and development activities. These costs include compensation and employee related costs, including stock based compensation; costs associated with conducting our clinical and non-clinical activities, including clinical and non-clinical trials that the Company conducts for post-marketing requirements; and costs for laboratory supplies, depreciation of lab equipment, and other expenses including allocated expenses for rent and maintenance of facilities.

**Patent Costs**

Costs related to filing and pursuing patent applications are recorded as selling, general and administrative expense as incurred since the recoverability of such expenditures is uncertain.

**Advertising and Product Promotion Costs**

Advertising and product promotion costs are included in selling, general and administrative expenses and were $5,368, $9,527 and $17,497 in the years ended December 31, 2020, 2019, and 2018 respectively. Advertising and product promotion costs are expensed as incurred.

**Stock-Based Compensation**

The Company accounts for grants of stock options, restricted stock units and performance share units to employees, as well as to the Board of Directors, based on their grant date fair value and recognizes compensation expense over their vesting period, net of actual forfeitures. For employee awards with service conditions, the Company recognizes compensation expense on a straight-line basis. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model. The Company estimates restricted stock units based on the fair value of the underlying common stock as determined by management. For awards with performance conditions, the Company estimates the number of shares that will vest based upon the probability of achieving performance metrics.

**Income Taxes**

The Company accounts for income taxes under the liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence,

including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and the absence of carryback available from results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future, in excess of its net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more likely than not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company will recognize interest and penalties related to uncertain tax positions within income tax expense. Any accrued interest and penalties will be included within the related tax liability. As of December 31, 2020 and December 31, 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations.

**Earnings per Share**

Earnings per share is calculated by dividing the net income (loss) attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common shareholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period, as determined in accordance with the treasury stock accounting method. For purposes of the diluted net loss per share calculation, stock options, warrants, unvested restricted stock units and performance share units are considered potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2019 and 2018, diluted net loss per common share is the same as basic net loss per common share for those periods.

**Embedded Derivatives**

The Company accounts for derivative financial instruments as either equity or liabilities in accordance with Accounting Standards Codification Topic 815, *Derivatives and Hedging*, based on the characteristics and provisions of each instrument. Embedded derivatives are required to be bifurcated from the host instruments and recorded at fair value if the derivatives are not clearly and closely related to the host instruments on the date of issuance. The Company's term notes and convertible notes (see Note 12) contain certain features that, in accordance with ASC 815, are not clearly and closely related to the host instrument and represent derivatives that are required to be re-measured at fair value each reporting period. The Company determined that the estimated fair value of the derivatives at issuance and as of December 31, 2020 were not material based on a scenario-based cash flow model that uses unobservable inputs that reflect the Company's own assumptions. Should the Company's assessment of the probabilities around these scenarios change, including due to changes in market conditions, there could be a change to the fair value.

**Reclassifications**

The Company has reclassified certain amounts in its Consolidated Statements of Operations for the years ended December 31, 2019 and 2018 to conform to the 2020 presentation. Specifically, the Company disaggregated previously reported cost of product revenues of $193,660 for the year ended December 31, 2019 into the captions Cost of product revenues (excluding intangible asset amortization) of $178,908 and Intangible asset amortization of $14,752. In addition, the Company disaggregated previously reported cost of product revenues of $165,677 for the year ended December 31, 2018 into the captions Cost of product revenues (excluding intangible asset amortization) of $55,843 and Intangible asset amortization of $109,834. The reclassifications relate to the presentation of the Company's gross profit and amortization expense and were made to provide the readers of the Company's consolidated financial statements with additional insight into how the Company and its management view and evaluate its performance and profitability. This reclassification within the consolidated statements of operations for the years ended December 31, 2019 and 2018 had no impact on previously reported total consolidated revenues or consolidated results of operations.

**Recently Adopted Accounting Pronouncements**

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective dates.

The Company adopted Accounting Standard Updated ("ASU") 2016-13, *Financial Instruments – Credit Losses (ASC Topic 326)*: *Measurement of Credit Losses on Financial Instruments*, which requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Subsequent to issuance, the FASB issued ASUs 2019-04, 2019-05, 2019-10, 2019-11 and 2020-03 to provide additional guidance on the adoption of ASU 2016-13. The Company adopted ASU 2016-13 on January 1, 2020 and the adoption did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848)*: *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, to ease the potential burden in accounting for reference rate reform. The amendments in ASU 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. The new standard became effective immediately and may be applied prospectively to contracts and transactions through December 31, 2022. Subsequent to issuance, the FASB issued ASU 2021-01 in January 2021 to refine and clarify some its guidance on ASU 2020-04. Upon the transition of the Company's contracts and transactions to new reference rates in connection with reference rate reform, the Company will prospectively apply the standard and disclose the effect on its consolidated financial statements.

**Recently Issued Accounting Pronouncements Not Yet Adopted**

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 affect a wide variety of income tax accounting standards with the objective of reducing their complexity. The new standard is effective for annual and interim periods beginning after December 15, 2020. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In June 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The amendments in ASU 2020-06 aim to reduce the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The new standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently evaluating the standard's effect on the Company's consolidated financial statements.

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the consolidated financial statements upon future adoption.

**3. REVENUE FROM CONTRACTS WITH CUSTOMERS**

The Company's revenue to date is from sales of the Company's products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients ("end users").

*Revenue Recognition*

In accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 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 obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity 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 Topic 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.

*Performance Obligations*

The Company determined that performance obligations are satisfied and revenue is recognized when a customer takes control of the Company's product, which occurs at a point in time. This generally occurs upon delivery of the products to customers, at which point the Company recognizes revenue and records accounts receivable. Payment is typically received 30 to 90 days after satisfaction of the Company's performance obligations. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

*Transaction Price and Variable Consideration*

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). The transaction price for product sales includes variable consideration related to sales deductions, including (1) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (2) product returns, including return estimates for both the Xtampza ER and the Nucynta Products; and, (3) trade allowances and chargebacks, including fees for distribution service fees, prompt pay discounts, and chargebacks. The Company will estimate the amount of variable consideration that should be included in the transaction price under the expected value method for all sales deductions other than trade allowances, which are estimated under the most likely amount method. These provisions reflect the expected amount of consideration to which the Company is entitled based on the terms of the contract. In addition, the Company made a policy election to exclude from the measurement of the transaction price all taxes that are assessed by a governmental authority that are imposed on revenue-producing transactions.

Provisions for rebates and incentives are based on the estimated amount of rebates and incentives to be claimed on the related sales from the period. As the Company's rebates and incentives are based on products dispensed to patients, the Company is required to estimate the expected value of claims at the time of product delivery to distributors. Given that distributors sell the product to pharmacies, which in turn dispense the product to patients, claims can be submitted significantly after the related sales are recognized. The Company's estimates of these claims are based on the historical experience of existing or similar programs, including current contractual and statutory requirements, specific known market events and trends, industry data, and estimated distribution channel inventory levels. Accruals and related reserves required for rebates and incentives are adjusted as new information becomes available, including actual claims. If actual results vary, the Company may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

Provisions for product returns are based on product-level historical trends, as well as relevant market events and other factors. For Xtampza ER, since the product has only been commercially sold since June 2016, estimates of product returns are based on a combination of historical returns processed to date, taking into consideration the expiration date of the product upon delivery to customers, as well as forecasted customer buying patterns, shipment and prescription trends, channel inventory levels, and other specifically known market events and trends. For the Nucynta Products, estimates of product returns are primarily based on historical trends as the Nucynta Products have been commercially sold for a number of years.

Provisions for trade allowances and chargebacks are primarily based on customer-level contractual terms. Accruals and related reserves are adjusted as new information becomes available, which generally consists of actual trade allowances and chargebacks processed relating to sales recognized in the period.

The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. In general, performance obligations do not include any estimated amounts of variable consideration that are constrained. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the years ended December 31, 2020 and 2019, respectively:

| | Rebates and Incentives (1) | Product Returns (2) | Trade Allowances and Chargebacks (3) |
|---|---|---|---|
| Balance at December 31, 2018 | $ 129,318 | $ 15,465 | $ 14,841 |
| Provision related to current period sales | 263,315 | 14,991 | 65,155 |
| Changes in estimate related to prior period sales | (2,865) | — | — |
| Credits/payments made | (259,867) | (2,808) | (65,679) |
| Balance at December 31, 2019 | $ 129,901 | $ 27,648 | $ 14,020 |
| Provision related to current period sales | 326,280 | 10,900 | 75,554 |
| Changes in estimate related to prior period sales | (539) | — | (403) |
| Credits/payments made | (322,867) | (14,769) | (70,116) |
| Balance at December 31, 2020 | $ 132,775 | $ 23,779 | $ 19,055 |

(1) Provisions for rebates and incentives includes managed care rebates, government rebates and co-pay program incentives. Provisions for rebates and incentives are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Consolidated Balance Sheets.
(2) Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Consolidated Balance Sheets.
(3) Provisions for trade allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. Trade allowances and chargebacks are deducted from gross revenue at the time revenues are recognized and are recorded as a reduction to accounts receivable in the Company's Consolidated Balance Sheets.

As of December 31, 2020, the Company did not have any transaction price allocated to remaining performance obligations and any costs to obtain contracts with customers, including pre-contract costs and set up costs, were immaterial.

*Disaggregation of Revenue*

The Company disaggregates its product revenue, net from contracts with customers into the categories included in the

table below. These categories depict how the nature, timing and uncertainty of revenue and cash flows are affected by economic factors:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Xtampza ER | $ 127,984 | $ 105,012 | $ 69,383 |
| Nucynta Products[(1)] | 182,032 | 191,689 | 211,030 |
| Total product revenues, net | $ 310,016 | $ 296,701 | $ 280,413 |

For the year ended December 31, 2020, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $116,318 and $65,714 respectively. For the year ended December 31, 2019, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $117,680 and $74,009, respectively. For the year ended December 31, 2018, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $129,917 and $81,113, respectively.

**4. LICENSE AGREEMENTS**

The Company periodically enters into license agreements to develop and commercialize its products. As of December 31, 2019, the Company's only license agreement was the Nucynta Commercialization Agreement. Upon the closing of the Nucynta Acquisition in February 2020, the Nucynta Commercialization Agreement was effectively terminated.

On January 9, 2018 (the "Nucynta Commercialization Closing Date"), the Company consummated the transactions contemplated by the Nucynta Commercialization Agreement, pursuant to which Assertio agreed to grant a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization in the United States. The Company began recording revenues from sales of the Nucynta Products on the Nucynta Commercialization Closing Date and began commercial promotion of the Nucynta Products in February 2018. Pursuant to the Nucynta Commercialization Agreement, the Company paid a one-time, non-refundable license fee of $10,000 to Assertio on the Nucynta Commercialization Closing Date, $6,223 for transferred inventory and $1,987 as reimbursement for prepaid expenses. The Company also assumed the existing liabilities of the Nucynta Products, including $22,660 related to sales of Nucynta Products that occurred prior to the Nucynta Commercialization Closing Date. The Nucynta Commercialization Agreement initially required the Company to pay a guaranteed minimum royalty of $135,000 per year through December 2021, payable in quarterly payments of $33,750, prorated in 2018 for the Nucynta Commercialization Closing Date, as well as a variable royalty based on annual net sales over $233,000. Beginning January 2022 and for each year of the Nucynta Commercialization Agreement term thereafter, the Company was required to pay a variable royalty on annual net sales of the Nucynta Products, but without a guaranteed minimum.

Effective August 2018, the Company entered into a Second Amendment to the Nucynta Commercialization Agreement to clarify the mechanism for transferring title of products to be sold by the Company pursuant to the agreement and various related matters. The Second Amendment did not have an impact on the Company's financial statements.

Effective November 2018, the Company entered into the Third Amendment to the Nucynta Commercialization Agreement to adjust the royalty structure and termination clauses. Pursuant to the amended Nucynta Commercialization Agreement, the $135,000 guaranteed minimum annual royalties were eliminated, and the Company was no longer required to secure its royalty payment obligations with a standby letter of credit. Beginning on January 1, 2019, the Company was conditionally obligated to make royalty payments to Assertio conditional upon net sales and based on the following royalty structure for the period between January 1, 2019 and December 31, 2021:

(i) 65% of annual net sales of the Nucynta Products up to $180,000, plus
(ii) 14% of annual net sales of the Nucynta Products between $180,000 and $210,000, plus
(iii) 58% of annual net sales of the Nucynta Products between $210,000 and $233,000, plus
(iv) 20% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(v) 15% of annual net sales of the Nucynta Products in excess of $258,000.

The Third Amendment did not modify the royalties payable on sales of the Nucynta Products on and after January 1, 2022, which remained as contemplated by the Nucynta Commercialization Agreement as in effect on January 9, 2018, based on the following royalty structure:

(i) 58% of annual net sales of the Nucynta Products up to $233,000, plus
(ii) 25% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(iii) 17.5% of annual net sales of the Nucynta Products in excess of $258,000.

In addition, prior to January 1, 2022, if the annual net sales of the Nucynta Products were in the range of $180,000 to $243,000, the Company would have been required to pay a supplemental royalty to Assertio, for ultimate payment to Grünenthal GmbH, not to exceed a maximum of 4.9% of net sales of the Nucynta Products. If annual net sales of Products were less than $180,000 in any 12-month period through January 1, 2022, or if they were less than $170,000 in any 12-month period commencing on January 1, 2022, then Assertio would have had the right to terminate the Nucynta Commercialization Agreement without penalty. The Amendment further provided that the Company did not have a right to terminate the Nucynta Commercialization Agreement prior to December 31, 2021. The Company would have been required to pay a $5,000 termination fee to Assertio in connection with any termination by the Company with an effective date between December 31, 2021 and December 31, 2022. In connection with execution of the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company (the “Warrant”) at an exercise price of $19.20 per share. The Warrant will expire in November 2022 and includes customary adjustments for changes in the Company’s capitalization.

Upon the closing of the Nucynta Acquisition, the Nucynta Commercialization Agreement was effectively terminated and the Company’s royalty payment obligations to Assertio thereunder ceased. Following the closing, the Company no longer pays royalties to Assertio and the Company’s only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

The assets acquired, liabilities assumed, and equity interests issued by the Company in connection with the Nucynta Commercialization Agreement are further described in Note 9.

**5. EARNINGS PER SHARE**

Basic net earnings 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 earnings per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock, plus potentially dilutive securities outstanding for the period, as determined in accordance with the treasury stock accounting method. Potentially dilutive securities

outstanding include stock options, unvested restricted stock units, performance share units, warrants, and shares related to the convertible senior notes, but are only included to the extent that their addition is dilutive.

The following table presents the computations of basic and dilutive earnings (loss) per common share:

| | Years ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| *Numerator:* | | | |
| Net income (loss) | $ 26,752 | $ (22,722) | $ (39,128) |
| *Denominator:* | | | |
| Weighted-average shares outstanding — basic | 34,407,959 | 33,453,844 | 32,953,808 |
| Effect of dilutive securities: | | | |
| Stock options | 431,524 | — | — |
| Restricted stock units | 271,542 | — | — |
| Performance share units | 27,002 | — | — |
| Employee stock purchase plan | 567 | — | — |
| Warrants | 12,759 | — | — |
| | | | |
| Weighted average shares outstanding — diluted | 35,151,353 | 33,453,844 | 32,953,808 |
| | | | |
| Earnings (loss) per share — basic | $ 0.78 | $ (0.68) | $ (1.19) |
| Earnings (loss) per share — diluted | $ 0.76 | $ (0.68) | $ (1.19) |

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 in cash, shares or a combination of the two. Since the Company intends to settle the principal amount of the convertible senior notes in cash, the Company used the treasury stock method for determining the potential dilution in the diluted earnings per share computation.

The following table presents dilutive securities excluded from the calculation of diluted earnings per share:

| | Years ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Stock options | 2,294,961 | 3,955,887 | 3,585,856 |
| Restricted stock units | 4,809 | 849,679 | 514,603 |
| Performance share units | 211,618 | 99,400 | — |
| Warrants | — | 1,041,667 | 1,041,667 |
| Convertible senior notes | 4,925,134 | — | — |
| Unvested restricted stock | — | — | 3,018 |

For performance share units, these securities were excluded from the calculation of diluted earnings per share as the performance-based or market-based vesting conditions were not met as of the end of the reporting period. For all other securities, these securities were excluded from the calculation of diluted earnings per share as their inclusion would have had an antidilutive effect.

**6. INVENTORY**

Inventory consisted of the following:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Raw materials | $ 3,514 | $ 795 |
| Work in process | 1,096 | 1,427 |
| Finished goods | 11,004 | 7,421 |
| Total inventory | $ 15,614 | $ 9,643 |

During the years ended December 31, 2020, 2019 and 2018, the aggregate charges to date related to excess inventory were immaterial. These expenses were recorded as a component of cost of product revenues. During the year ended December 31, 2020, inventory used in the construction and installation of property and equipment was $2,299. During the years ended December 31, 2019 and 2018, inventory used in the construction and installation of property and equipment was immaterial.

**7. PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets consisted of the following:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Prepaid regulatory fees | $ 3,280 | $ 1,222 |
| Prepaid insurance | 656 | 414 |
| Prepaid development costs | 392 | 474 |
| Other prepaid expenses | 450 | 854 |
| Other current assets | 60 | 141 |
| Prepaid expenses and other current assets | $ 4,838 | $ 3,105 |

**8. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Computers and office equipment | $ 1,429 | $ 1,453 |
| Laboratory equipment | 1,299 | 1,220 |
| Furniture and fixtures | 1,073 | 1,066 |
| Manufacturing equipment | 14,119 | 987 |
| Leasehold improvements | 541 | 541 |
| Construction-in-process | 3,583 | 8,875 |
| Total property and equipment | 22,044 | 14,142 |
| Less: accumulated deprecation | (3,056) | (2,288) |
| Property and equipment, net | $ 18,988 | $ 11,854 |

Depreciation expense related to property and equipment amounted to $870, $731 and $1,074 for the years ended December 31, 2020, 2019 and 2018, respectively. During the years ended December 31, 2020, 2019 and 2018, the Company disposed of fully depreciated assets of $102, $280 and $905, respectively. The Company did not have any gains or losses from the retirement, sale or disposal of property and equipment during the years ended December 31, 2020, 2019, or 2018.

**9. INTANGIBLE ASSETS**

As of December 31, 2020 and 2019, the Company's only intangible asset ("Nucynta Intangible Asset") is related to the Nucynta Acquisition and the Nucynta Commercialization Agreement. The gross carrying amount and accumulated amortization of the Nucynta Intangible Asset were as follows:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Gross carrying amount | $ 521,170 | $ 154,089 |
| Accumulated amortization | (185,266) | (124,586) |
| Intangible asset, net | $ 335,904 | $ 29,503 |

*Nucynta Acquisitions*

In February 2020, the Company entered into the Nucynta Purchase Agreement with Assertio, pursuant to which the Company acquired certain intellectual property and manufacturing rights related to the Nucynta Products, including U.S. commercialization rights, U.S. manufacturing rights, and inventory, for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments. The Company also agreed to assume certain regulatory and supply chain contracts, and obligations related to Nucynta Products (see Note 4). In February 2020, the Company entered into a loan agreement (see Note 10) and issued convertible senior notes (see Note 10) to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The consideration transferred in the asset acquisition was measured at cost, including transaction costs, assets transferred by the Company, and royalty obligations discharged by the seller. The table below represents the costs accumulated to acquire the commercial rights for the Nucynta Products based on the terms of the Nucynta Purchase Agreement, as amended:

| | |
|---|---|
| Acquisition consideration: | |
| Base purchase price | $ 375,000 |
| Cash paid for inventory | 6,030 |
| Transaction costs | 6,297 |
| Reduction for 2020 cash transferred to Assertio under the prior Nucynta Commercialization Agreement[(1)] | (13,071) |
| Reduction for accrued royalty obligation discharged upon closing[(1)] | (1,145) |
| Total acquisition consideration: | $ 373,111 |

(1) Represents $14,216 total reduction to the base purchase price comprising of $13,071 of cash payments transferred to Assertio under the prior Nucynta Commercialization Agreement as well as a reduction for $1,145 of discharged pre-acquisition accrued royalties based on sales from January 1, 2020 through closing.

The Company then allocated the consideration transferred to the individual assets acquired on a relative fair value basis as summarized in the table below:

| | |
|---|---|
| Assets acquired: | |
| Nucynta Intangible Asset | $ 367,081 |
| Inventory | 6,030 |
| Total consideration allocated to assets acquired: | $ 373,111 |

The Company concluded that the consideration allocable to the Nucynta Intangible Asset for the additional intellectual

property and manufacturing rights it acquired as part of the Nucynta Acquisition were incremental costs associated with the pre-existing intangible asset from the former Nucynta Commercialization Agreement, as such costs result in probable future economic benefits. Specifically, the additional intellectual property rights acquired in the Nucynta Acquisition enable the Company to eliminate royalty obligations otherwise payable to Assertio under the former Nucynta Commercialization Agreement.

*Nucynta Commercialization Agreement*

The Company determined that the Nucynta Commercialization Agreement, which closed in January 2018, should be accounted for as an asset acquisition in accordance with ASC Topic 805-50, as substantially all of the fair value of the gross assets acquired was concentrated in the sublicense of the Nucynta Products, which is a single identifiable asset. The Company concluded that the fair value estimates of the assets surrendered, liabilities incurred, and equity interests issued were more clearly evident than the fair value of the assets received, and therefore followed a cost accumulation model to determine the consideration transferred in the asset acquisition.

Under the original terms of the Nucynta Commercialization Agreement, the Company was obligated to make guaranteed annual minimum royalty payments of $537,000 to Assertio, which consisted of scheduled payments of $132,000 in 2018, $135,000 in 2019, $135,000 in 2020, and $135,000 in 2021. Due to the nature of the guaranteed minimum royalty payment obligation and the fact that it was required to be settled in cash, the Company determined that the future minimum royalty payments represented a liability that should be recorded at its fair value as of the Nucynta Commercialization Closing Date. The Company calculated the fair value of the future minimum royalty payments to be $482,300 using a discount rate of 5.7%. The discount rate was determined based on a review of observable market data relating to similar liabilities. The Company determined the $54,700 discount should be recognized as interest expense in the Statement of Operations using the effective interest method and over the repayment period from January 9, 2018 through December 2021. Prior to the Third Amendment to the Nucynta Commercialization Agreement in November 2018, the Company recognized interest expense of $19,281 relating to the minimum royalty payments and amortization expense of $107,662 related to the intangible asset.

Effective November 8, 2018 (the “Third Amendment Date”), the Company entered into the Third Amendment to the Nucynta Commercialization Agreement, which eliminated the guaranteed minimum royalty payment obligations for years 2019, 2020 and 2021. As a result, the Company remeasured the remaining contractual obligation as of the Third Amendment Date and recorded a reduction of the acquired intangible asset and obligation. As of December 31, 2018, the Company had paid all of the $132,000 of minimum royalty payment obligation owed under the Nucynta Commercialization Agreement for 2018. In connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The Company estimated the fair value of the warrant on the date of issuance to be approximately $8,043 using the Black-Scholes option-pricing model. See Note 14 for further detail regarding the warrant issued to Assertio.

Effective February 13, 2020, upon the closing of the Nucynta Acquisition, the Nucynta Commercialization Agreement was effectively terminated and the Company’s royalty payment obligations to Assertio thereunder ceased. Following the closing, the Company no longer pay royalties to Assertio and the Company’s only remaining royalty obligation is to pay 14% of net sales of the Nucynta Products directly to Grünenthal.

A summary of the gross carrying amount, accumulated amortization, and net book value of the Nucynta Intangible Asset from the execution of the Nucynta Commercialization Agreement through period end are as follows:

| | Gross Carrying Value | Accumulated Amortization | Net Book Value |
|---|---|---|---|
| Intangible Asset, net | | | |
| Cost basis as of acquisition date | $ 515,627 | $ — | $ 515,627 |
| Amortization expense from acquisition date through Third Amendment Date | — | (107,662) | (107,662) |
| Adjustment due to the remeasurement of liability as of Third Amendment Date | (369,581) | — | (369,581) |
| Additional costs incurred as of Third Amendment Date[(1)] | 8,043 | — | 8,043 |
| Amortization expense from Amendment Date through fiscal year end | — | (2,172) | (2,172) |
| Balance as of December 31, 2018 | $ 154,089 | $ (109,834) | $ 44,255 |
| Amortization expense | — | (14,752) | (14,752) |
| Balance as of December 31, 2019 | $ 154,089 | $ (124,586) | $ 29,503 |
| Amortization expense through Nucynta Acquisition | — | (1,754) | (1,754) |
| Additional cost incurred from Nucynta Acquisition | 367,081 | — | 367,081 |
| Amortization expense from Nucynta Acquisition through period end | — | (58,926) | (58,926) |
| Balance as of December 31, 2020 | $ 521,170 | $ (185,266) | $ 335,904 |

(1) Represents fair value of warrant issued in connection with the Amendment to the Nucynta Commercialization Agreement.

*Amortization*

The Company has been amortizing the Nucynta Intangible Asset over its useful life, which is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The Company had initially determined that the useful life for the intangible asset was approximately 4.0 years from the Nucynta Commercialization Closing Date on the basis of the majority of the cash flows expected to be realized for future product sales under the Nucynta Commercialization Agreement. The Nucynta Acquisition significantly impacted the timing and amount of future cash inflows from the sales of the Nucynta Products, and, therefore, the Company considered it to be a triggering event to remeasure the expected useful life of the Nucynta Intangible Asset. The Company determined that the useful life for the Nucynta Intangible Asset was approximately 5.9 years from the closing date of the Nucynta Acquisition and accordingly, the intangible asset will be amortized prospectively over its revised useful life. The Company will recognize amortization expense as a component of cost of product revenues in the Consolidated Statement of Operations on a straight-line basis over its useful life as it approximates the period of economic benefits expected to be realized from future cash inflows from sales of the Nucynta Products. Prior to the Nucynta Acquisition, the Company had recognized $126,340 of amortization expense related to the Nucynta Intangible Asset. As the accumulated cost basis of the Nucynta Intangible Asset was increased with the Nucynta Acquisition, the Company will continue to prospectively amortize the resulting net intangible asset on a straight-line basis over the remaining useful life.

The following table presents amortization expense recognized for the years ended December 31, 2020, 2019, and 2018:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Nucynta amortization expense included in cost of product revenues | $ 60,680 | $ 14,752 | $ 109,834 |

As of December 31, 2020, the remaining amortization period is approximately 5.0 years and is expected to be recognized in the following periods:

| Years ended December 31, | Amortization Expense |
|---|---|
| 2021 | 67,181 |
| 2022 | 67,181 |
| 2023 | 67,181 |
| 2024 | 67,181 |
| 2025 | 67,180 |
| Remaining amortization expense: | $ 335,904 |

**10. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

| | As of December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Accrued royalties | $ 12,954 | $ 21,893 |
| Accrued bonuses | 4,571 | 4,047 |
| Accrued product taxes and fees | 1,817 | — |
| Accrued incentive compensation | 1,417 | 1,650 |
| Accrued interest | 1,415 | 473 |
| Accrued payroll and related benefits | 892 | 1,154 |
| Accrued audit and legal | 445 | 308 |
| Accrued sales and marketing | 261 | 775 |
| Accrued other operating costs | 884 | 3,180 |
| Total accrued expenses | $ 24,656 | $ 33,480 |

**11. COMMITMENTS AND CONTINGENCIES**

**Legal Proceedings**

From time to time, the Company may face legal claims or actions in the normal course of business. Except as disclosed below, the Company is not currently a party to any litigation and, accordingly, does not have any amounts recorded for any litigation related matters.

***Xtampza ER Litigation***

The Company filed the NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Orange Book, in this case OxyContin. The 505(b)(2) process requires that the Company certify to the FDA that the Company does not infringe any of the patents listed for OxyContin in the Orange Book, or that the patents are invalid. The process also requires that the Company notify Purdue Pharma, L.P ("Purdue"), as the holder of the NDA, and any other Orange Book-listed patent owners that it has made such a certification. On February 11, 2015, the Company made the required certification documenting why Xtampza ER does not infringe any of the 11 Orange Book listed patents for OxyContin, five of which have been invalidated in court proceedings, and provided the required notice to Purdue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

In response to these actions, Purdue sued the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and

7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

The Delaware court transferred the case to the District of Massachusetts. After the Company filed a partial motion for judgment on the pleadings relating to the Orange Book-listed patents, the District Court of Massachusetts ordered judgment in the Company's favor on those three patents, and dismissed the claims asserting infringement of those patents with prejudice. Upon dismissal of those claims, the 30-month stay of FDA approval was lifted. As a result, the Company was able to obtain final approval for Xtampza ER and launch the product commercially.

Purdue subsequently filed two follow-on lawsuits asserting infringement of two patents that had been late-listed in the Orange Book and therefore could not trigger any stay of FDA approval: Purdue filed suit asserting infringement of Patent No. 9,073,933 in November 2015, and asserted infringement of Patent No. 9,522,919 in April 2017. In addition, Purdue filed suit on two patents that had not been listed in the Orange Book, filing suit in June 2016 asserting infringement of Patent No. 9,155,717 and in September 2017, asserting infringement of Patent No. 9,693,961.

On March 13, 2018, the Company filed a Petition for Post-Grant Review ("PGR") of the ′961 patent with the Patent Trial and Appeal Board ("PTAB"). The PGR argues that the ′961 patent is invalid for lack of a written description, for lack of enablement, for indefiniteness, and as being anticipated by prior art. The PTAB held oral argument on the proceedings on July 10, 2019 and was scheduled to issue a decision on the patentability of the ′961 patent by no later than October 4, 2019. On September 15, 2019, Purdue commenced a voluntary case under chapter 11 of title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York. On September 24, 2019, Purdue gave the PTAB notice of its bankruptcy filing and sought the imposition of an automatic stay of the PGR proceedings. On October 2, 2019, the PTAB extended the one-year period for issuing its decision by up to six months.

In October 2017, and in response to the filing of the Company's Supplemental NDA ("sNDA") seeking to update the drug abuse and dependence section of the Xtampza ER label, Purdue filed another suit asserting infringement of the ′933 and ′919 patent. The Company filed a motion to dismiss that action, and the Court granted its motion on January 16, 2018.

The suits that remain pending were consolidated by the District of Massachusetts, which has ruled that the Xtampza ER formulation does not infringe the '497 and ′717 patents. As a result, only the ′933, the ′919, and the ′961 patents remain in dispute. On October 16, 2018, the Company filed a motion to stay proceedings in the district court on the '961 patent pending the PGR. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of the Company's products accused of infringement. The Company has denied all claims and has requested a judgment that the remaining asserted patents are invalid and/or not infringed; the Company is also seeking a judgment that the case is exceptional and has requested an award of the Company's attorneys' fees for defending the case.

A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ′933, ′497, and ′717 patents. No trial date has been scheduled. On September 18, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. On September 20, 2019, the matter was stayed pending further order of the Court.

On September 1, 2020, the Bankruptcy Court entered an Order Granting Motions for Relief from the Automatic Stay, lifting the automatic stays in both the District of Massachusetts and PTAB proceedings. The Company appealed the Bankruptcy Court's Order, in part, and that appeal is stayed, on consent by Purdue, pending the outcome of the PTAB proceedings and any appeal thereto. On September 11, 2020, Purdue filed a motion to terminate the PTAB action on the basis that those proceedings had gone beyond the 18-month statutory period. The Company opposed Purdue's motion and the parties are awaiting PTAB's decision. In light of the PTAB proceeding, the entirety of District of Massachusetts proceedings, beyond the single ′961 patent that is also the subject of the PTAB proceeding, had been stayed. During a January 22, 2021 hearing, Purdue asked the District of Massachusetts Court to lift the stay as to the ′933 and ′919 patents, and advised the Court of its intention to file another patent litigation concerning U.S. Patent No. 10,407,434. The Court set a briefing schedule through mid-March and a hearing for March 18, 2021.

If the stay is lifted, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

***Nucynta Litigation***

On February 7, 2018, Purdue filed a patent infringement suit against the Company in the District of Delaware. Specifically, Purdue argues that the Company's sale of immediate-release and extended-release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

On December 6, 2018, the Company filed an Amended Answer asserting an affirmative defense for patent exhaustion. On December 10, 2018, the Court granted the parties' stipulation for resolution of the Company's affirmative defense of patent exhaustion and stayed the action, with the exception of briefing on and resolution of the Company's Motion for Judgment on the Pleadings related to patent exhaustion and any discovery related to that Motion. Also, on December 10, 2018, the Company filed a Rule 12(c) Motion for Judgment on the Pleadings, arguing that the Purdue's claims were barred by the doctrine of patent exhaustion. On June 18, 2019, the Court heard oral argument on the Company's Rule 12(c) Motion for Judgment on the Pleadings. On June 19, 2019, the Court issued an order stating that "judgment in Collegium's favor is warranted under the doctrine of patent exhaustion to the extent Collegium's alleged infringing activities resulted from sales that fall within the scope of that covenant." The Court explained, however, that based on the current record, it was not possible "to determine whether title of the Nucynta Products was transferred to Collegium" from sales authorized by Purdue's covenant not to sue. The Court ordered discovery on this issue and the case remained "stayed with the exception of discovery and briefing on and resolution of the Company's anticipated motion for summary judgment based on patent exhaustion."

On September 19, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. The Nucynta litigation is subject to the automatic bankruptcy stay.

Pending resolution of the bankruptcy action, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

***Teva Litigation***

Presently, the Company has nineteen patents listed in the FDA Orange Book as covering the Company's abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530, 9,763,883; 9,968,598; 10,004,729; 10,188,644; 10,525,052; 10,525,053; 10,646,485; and 10,668,060 (the "Orange Book Patents").

Teva filed an ANDA seeking FDA approval to market generic extended-release oxycodone capsule products (the "proposed ANDA products"). Teva also filed certifications with the FDA that its proposed ANDA products will not infringe the Orange Book Patents and/or that the Orange Book Patents are invalid. Teva sent the Company a Notice Letter indicating that it had made such certification to the FDA.

On February 22, 2018—within the 45-day period that gives the Company a 30-month stay of FDA approval of Teva's ANDA while the parties have an opportunity to litigate—the Company sued Teva in the District of Delaware on eleven of the twelve Orange Book Patents that were listed at that time. Teva responded to the complaint on May 14, 2018, denying infringement by Teva's proposed ANDA products and asserting counterclaims of non-infringement and invalidity of the asserted patents. The Company answered Teva's counterclaims on June 4, 2018.

The Company listed two additional patents in the Orange Book in 2018 and Teva amended its ANDA to include certifications to the FDA of non-infringement and invalidity with respect to those patents. Teva notified the Company of its certification and the Company filed a second lawsuit in the District of Delaware, asserting those two patents, on November 30, 2018. Teva responded to the complaint on January 11, 2019 denying infringement by Teva's proposed

ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patents. The Company answered Teva's counterclaims on February 1, 2019. The court consolidated the second suit with the first suit, and thus both suits are proceeding on the same schedule.

The parties briefed claim construction and the court heard argument on April 12, 2019. On September 11, 2019, the Court issued a Report and Recommendation construing two of the six terms or sets of terms that are in dispute. The remaining terms will be addressed in one or more forthcoming Report and Recommendations. Fact discovery was scheduled to close on September 20, 2019 and expert discovery was scheduled to close on January 24, 2020.

The Company listed an additional patent in the Orange Book in January 2019 and Teva amended its ANDA to include certifications to the FDA of non-infringement and invalidity with respect to that patent. Teva notified us of its certification and the Company filed a third lawsuit in the District of Delaware, asserting the additional Orange Book Patent, on May 9, 2019. Teva responded to the complaint on June 6, 2019, denying infringement by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patent. The Company answered Teva's counterclaims on June 27, 2019. The parties filed a proposed Scheduling Order, which the Court entered on September 4, 2019.

On September 20, 2019, the parties jointly agreed to stay both litigations.

The Company listed four additional patents in the Orange Book in first half of 2020, which brings the total number of Orange Book Patents for Xtampza ER to nineteen.

Teva and the Company have entered into a Settlement Agreement and License Agreement to resolve the case. On October 7, 2020, the Court entered a Consent Judgment and Order of Permanent Inunction that dismissed with prejudice all affirmative defenses, claims, and counterclaims which have or could have been raised by Teva. The Order states that Teva would infringe each of the Litigated Patents by using, making, offering to sell, selling, and/or importing Teva's ANDA product in or into the United States. It further states that the Litigated Patents, and all claims contained therein, are valid and enforceable, solely with respect to the Teva ANDA and Teva ANDA Product. It further stated that, except as authorized and licensed by the Company under the License, Teva, its officers, agents, employees, affiliates, successors and all persons in active concert or participation with Teva, are permanently enjoined from using, making, offering for sale, or selling in the United States, or importing into the United States, Teva's ANDA Product and/or inducing or assisting others to use, make, offer for sale, or sell in the United States, or import into the United States, Teva's ANDA Product.

On September 29, 2020, the Company entered into a settlement agreement with Teva resolving the patent litigation in the U.S. District Court for the District of Delaware. Pursuant to the terms of the settlement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company will grant Teva a license to market its generic version of Xtampza ER in the United States beginning on or after September 2, 2033 (subject to U.S. Food and Drug Administration approval, and acceleration under certain circumstances). As a result of the settlement, Teva has agreed to a consent judgment confirming that its proposed generic products infringe upon the Company's asserted patents and that those patents are valid and enforceable with respect to Teva's proposed generic products. Additional details regarding the settlement are confidential.

***Opioid Litigation***

As a result of the opioid epidemic, numerous state and local governments, healthcare providers, and other entities have brought suit against manufacturers, wholesale distributors, and pharmacies alleging a variety of claims related to opioid marketing and distribution practices. In late 2017, the U.S. Judicial Panel on Multidistrict Litigation ordered the consolidation of what were then a few hundred cases pending around the country in federal court against opioid manufacturers and distributors into a Multi-District Litigation (MDL) in the Northern District of Ohio. Currently, the Opioid MDL consists of over 2,000 opioid-related cases brought primarily by states, cities, counties, and other local entities. Generally speaking, these suits do not seek damages for injuries to individuals but rather compensation for the cost of public services needed to address the consequences of addicted communities, ranging from emergency response capabilities to rehabilitation services. The Company has been named as a defendant in a small subset of the MDL cases.

Of the 21 MDL cases that have named the Company as a defendant, the allegations against it have been dismissed or withdrawn in 13 cases. In addition, the Company has been dismissed from three non-MDL cases filed in Pennsylvania and Arkansas state courts.

Eight cases that name the Company as a defendant, originally filed in three states, remain pending in the MDL:

- Virginia. On January 11, 2019, the City of Portsmouth filed a lawsuit in Virginia Circuit Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws. On October 3, 2019, the City of Portsmouth case was transferred to the MDL.
- New Jersey. On March 15, 2019, the Company was named in a lawsuit in the MDL by the City of Paterson, New Jersey. The lawsuit alleges violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws, and seeks, generally, penalties and/or injunctive relief. On June 14, 2019, the City of Trenton filed a lawsuit in the New Jersey Superior Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws and the New Jersey Drug Dealer Liability Act. On December 18, 2019, the case was transferred to the MDL.
- Connecticut. On April 9, 2019, the City of Norwich, Connecticut and the Town of Enfield, Connecticut filed lawsuits that name the Company in Connecticut Superior Court. The lawsuits allege violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws. On June 28, 2019, both cases were transferred to the MDL. In October 2019, the Company was named in two additional Connecticut lawsuits: the City of Middletown and the Town of Wethersfield. These cases were both also transferred to the MDL in July 2019. Finally, on January 15, 2020, the Town of Windham, Connecticut filed a lawsuit that names the Company, among other pharmaceutical manufacturers, in Connecticut Superior Court. The lawsuit alleges violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws. On March 3, 2020, the lawsuit was transferred to the MDL.

Each of the lawsuits in the MDL naming the Company seeks, generally, penalties and injunctive relief. None of the lawsuits naming the Company are designated as representative cases in the MDL, and therefore, are effectively currently stayed.

Outside of the MDL, there are several cases pending against the Company in state courts in Pennsylvania and Massachusetts:

- In Pennsylvania, six lawsuits naming the Company have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors. These include lawsuits filed between May 2018 and July 2019 on behalf of Bucks County, Clinton County, Mercer County, Warrington Township, Warminster Townerhip, and the City of Lock Haven, each of Pennsylvania, alleging claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. None of these cases has been designated a Track One case in which discovery would commence, and therefore they are all effectively stayed at present.

- In Massachusetts, there are lawsuits by the City of Worcester, the City of Salem, the City of Framingham, the Town of Lynfield, the City of Springfield, the City of Haverhill, the City of Gloucester, the Town of Canton, the Town of Wakefield, the City of Chicopee, the Town of Natick, the City of Cambridge and the Town of Randolp, all of which have been consolidated before the Business Litigation Session of the Superior Court. The actions allege a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, *Section 11*, unjust enrichment and civil conspiracy. The case brought by the City of Springfield was selected to advance for the purpose of motion practice, defendants' motions to dismiss were denied on January 3, 2020. There is no trial date set for this case.

The Company disputes the allegations in these lawsuits and intends to vigorously defend these actions. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

**Opioid-Related Request and Subpoenas**

The Company, like a number of other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing. The Company has received such subpoenas or civil investigative demands from the Offices of the Attorney General of each of Washington, New Hampshire, Maryland and Massachusetts. The Company is currently cooperating with each of the foregoing states in their respective investigations.

**12. DEBT**

*Pharmakon Term Notes*

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, the Company, together with its subsidiary, Collegium Securities Corporation, entered into a Loan Agreement (the "Loan Agreement") with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon"). The Loan Agreement provides for a $200,000 secured term loan (the "term notes"), the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement. On February 13, 2020 (the "Closing Date"), the Company received the net proceeds.

The term notes bear interest at a rate based upon the three-month LIBOR rate, subject to a LIBOR floor of 2.0%, plus a margin of 7.5% per annum, payable quarterly in arrears. The Company is required to repay the term notes by making equal quarterly payments of principal beginning in the first quarter immediately following the third month anniversary of the Closing Date. The term notes will mature on the calendar quarter end immediately following the 48-month anniversary of the Closing Date and is guaranteed by the Company's material domestic subsidiaries and also secured by substantially all of the Company's material assets. On the Closing Date, the Company paid to Pharmakon a facility fee equal to 2.50% of the aggregate principal amount of the term notes, or $5,000, in addition to $427 of other expenses incurred by Pharmakon and reimbursed by the Company (together, the "discount"). Net proceeds of $194,573 were transferred to Assertio by the Company as agent in partial satisfaction of the Nucynta Purchase Agreement. In addition, the Company capitalized $2,456 of term notes issuance costs, related to legal and advisory fees.

Except with respect to certain prepayments made with the proceeds from new equity issuances as described below, the Loan Agreement permits voluntary prepayment at any time, subject to a prepayment premium. The prepayment premium is equal to 3.00% of the principal amount being prepaid prior to the second-year anniversary of the Closing Date, 2.00% of the principal amount being prepaid on or after the second-year anniversary, but on or prior to the third-year anniversary, of the Closing Date, and 1.00% of the principal amount being prepaid on or after the third-year anniversary of the Closing Date, but prior to the fourth-year anniversary of the Closing Date. The Loan Agreement also includes a make-whole premium if there is a voluntary prepayment, a prepayment due to a change in control or acceleration following an Event of Default on or prior to the second-year anniversary of the Closing Date in an amount equal to foregone interest from the date of prepayment through the second-year anniversary of the Closing Date. A change of control triggers a mandatory prepayment of the term notes.

The Loan Agreement also permits single voluntary prepayments of the Loan Agreement of less than or equal to $50,000 made solely from the proceeds of an equity issuance by the Company. If equity prepayment occurs prior to the second-year anniversary of the Closing Date, a prepayment premium of 5.00% would apply, with no make-whole premium.

The Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, covenants that require the Company to maintain $200,000 in annual net sales and covenants that limit the Company's ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary

course of business, restrictions which limit the Company's ability to pay dividends and restrictions of net assets of subsidiaries. The Loan Agreement also contains customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Failure to comply with these covenants would constitute an event of default under the Loan Agreement, notwithstanding the Company's ability to meet its debt service obligations. The Loan Agreement also includes various customary remedies for Pharmakon following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement. Under certain circumstances, a default interest rate will apply on outstanding obligations during the occurrence and continuance of an event of default.

During the year ended December 31, 2020 the Company recognized interest expense of $19,034 related to the term notes.

As of December 31, 2020, principal repayments under the term notes are estimated to be paid as follows:

| **Years ended December 31,** | **Principal Payments** |
|---|---|
| 2021 | $ 50,000 |
| 2022 | 50,000 |
| 2023 | 50,000 |
| 2024 | 12,500 |
| Total before unamortized discount and issuance costs | $ 162,500 |
| Less: unamortized discount and issuance costs | (4,986) |
| Total term notes | $ 157,514 |

*Silicon Valley Bank Term Loan Facility*

From August 2012 until January 2020, the Company maintained a term loan facility with Silicon Valley Bank ("SVB"), which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan ("Consent and Amendment"), the Company had a term loan facility in an amount of $11,500, which replaced the Company's previously existing term loan facility. The proceeds of the Consent and Amendment were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the previously existing term loan.

The Consent and Amendment bore interest at a rate per annum of 0.75% above the prime rate (as defined in the Consent and Amendment). The Company was eligible to repay the Consent and Amendment in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in January 2020.

In January 2020, the Company prepaid the outstanding principal and accrued interest on the Consent and Amendment along with the required prepayment fees. The loss on extinguishment of the term loan was immaterial and was recorded as a component of interest expense.

*Convertible Senior Notes*

On February 13, 2020, the Company issued 2.625% convertible senior notes due in 2026 (the "convertible notes") in the aggregate principal amount of $143,750, in a public offering registered under the Securities Act of 1933, as amended. The convertible notes were issued in connection with funding the Nucynta Acquisition, and the proceeds of the convertible notes were used to finance a portion of the purchase price payable pursuant to the Nucynta Purchase Agreement. Some of the Company's existing investors participated in the convertible notes offering.

The Company may, at its option, settle the convertible notes in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock. Accordingly, the Company separately accounted for the liability component (the "Liability Component") and the embedded derivative conversion option (the "Equity Component") of the convertible notes by allocating the proceeds between the Liability Component and the Equity Component. In connection with the issuance of the convertible notes, the Company incurred approximately $5,473 of

debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs between the Liability Component and the Equity Component based on the allocation of the proceeds. Of the total debt issuance costs, $1,773 was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $3,700 was allocated to the Liability Component and recorded as a debt discount of the convertible notes. The portion allocated to the Liability Component is amortized to interest expense using the effective interest method over six years.

The convertible notes are the Company's senior unsecured obligations and bear interest at a rate of 2.625% per year payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, 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. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. The initial conversion rate is 34.2618 shares of common stock per $1 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price are subject to adjustment upon the occurrence of certain events.

Holders of the convertible notes may convert all or any portion of their convertible notes, in multiples of $1 principal amount, at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2020, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
(2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") in which the "trading price" per $1 principal amount of the Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day;
(3) upon the occurrence of certain corporate events or distributions on the Company's common stock;
(4) if the Company calls the convertible notes for redemption; or
(5) at any time from, and including, August 15, 2025 until the close of business on the scheduled trading day immediately before the maturity date.

As of December 31, 2020, none of the above circumstances had occurred and as such, the convertible notes could not have been converted.

The Company may not redeem the convertible notes prior to February 15, 2023. On or after February 15, 2023, the Company may redeem the convertible notes, in whole and not in part, at a cash redemption price equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on:

(1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and
(2) the trading day immediately before the date the Company sends such notice.

Calling any convertible note for redemption will constitute a make-whole fundamental change with respect to that convertible note, in which case the conversion rate applicable to the conversion of that convertible note, if it is converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The convertible notes have customary default provisions, including (i) a default in the payment when due (whether at maturity, upon redemption or repurchase upon fundamental change or otherwise) of the principal of, or the redemption

price or fundamental change repurchase price for, any note; (ii) a default for 30 days in the payment when due of interest on any note; (iii) a default in the Company's obligation to convert a note in accordance with the indenture; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) certain payment or other defaults by the Company or certain subsidiaries with respect to mortgages, agreements or other instruments for indebtedness for money borrowed of at least $20,000; and (vi) certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

The initial carrying amount of the Liability Component of $97,200 was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible borrowing rate for similar debt. The Equity Component of the Notes of $46,550 was recognized as a debt discount. The excess of the principal amount of the Liability Component over its carrying amount is amortized to interest expense using the effective interest method over six years. The Equity Component, which is included in the additional paid in capital portion of stockholders' equity on the Company's consolidated balance sheet, is not remeasured as long as it continues to meet the conditions for equity classification.

As of December 31, 2020, the convertible notes outstanding consisted of the following:

| | | |
|---|---|---|
| Liability component: | | |
| Principal | $ | 143,750 |
| Less: unamortized debt discount and issuance costs | | (44,175) |
| Net carrying amount | $ | 99,575 |
| | | |
| Equity component, net of issuance costs of $1,773 | $ | 44,777 |

The Company determined the expected life of the convertible notes was equal to its six-year term. The effective interest rate on the Liability Component of the convertible notes was 10.27%. As of December 31, 2020, the "if-converted value" did not exceed the remaining principal amount of the convertible notes. The fair value of the convertible notes was determined based on data points other than quoted prices that are observable, either directly or indirectly, and has been classified as Level 2 within the fair value hierarchy. The fair value of the convertible notes, which differs from their carrying value, is influenced by market interest rates, the Company's stock price and stock price volatility.

The following table presents the total interest expense recognized related to the convertible notes during the year ended December 31, 2020:

| | Year ended December 31, 2020 | |
|---|---|---|
| Contractual interest expense | $ | 3,323 |
| Amortization of debt discount | | 5,628 |
| Amortization of debt issuance costs | | 447 |
| Total interest expense | $ | 9,398 |

As of December 31, 2020, the future minimum payments on the convertible notes were as follows:

| Years ended December 31, | Future Minimum Payments |
|---|---|
| 2021 | 3,773 |
| 2022 | 3,773 |
| 2023 | 3,773 |
| 2024 | 3,773 |
| 2025 | 3,773 |
| Thereafter | 145,639 |
| Total minimum payments | $ 164,504 |
| Less: interest | (20,754) |
| Less: unamortized debt discount and issuance costs | (44,175) |
| Convertible senior notes | $ 99,575 |

**13. LEASES**

In accordance with ASC Topic 842, *Lease Accounting*, the Company records lease assets and liabilities for lease arrangements exceeding a 12-month initial term. For operating leases, the Company records a beginning lease liability equal to the present value of minimum lease payments to be made over the lease term discounted using the Company's incremental borrowing rate and a corresponding lease asset adjusted for incentives received and indirect costs. After lease commencement, the Company remeasures the operating liability at the present value of the remaining lease payments discounted using the original incremental borrowing rate and corresponding lease asset adjusted for incentives received, indirect costs and uneven lease payments. The Company records operating lease rent expense in the Statements of Operations on a straight-line basis over the lease term. Variable lease costs, that are primarily associated with non-lease components are not included in the measurement of the operating lease liability, are recognized in the period in which they are incurred. Leases with an initial term of 12 months or less, or short-term leases, are not recorded on the balance sheet. Short-term lease expense is recognized on a straight-line basis over the lease term. The Company does not have any financing lease arrangements.

As of December 31, 2020, the Company had operating lease assets of $8,391 and operating lease liabilities of $9,495 primarily related to operating lease agreements for its corporate headquarters.

*Operating Lease Arrangements*

In March 2018, the Company entered into an operating lease for its new corporate headquarters (the "Stoughton Lease") pursuant to which the Company leases approximately 50,678 of rentable square feet of space, in Stoughton, Massachusetts. The Stoughton Lease commenced in August 2018 when the Company took possession of the space. After the initial four-month free rent period following possession of the space, the operating lease will continue for a term of 10 years. The Company has the right to extend the term of the Stoughton Lease for two additional five-year terms, provided that written notice is provided to the landlord no later than 12 months prior to the expiration of the then current Stoughton Lease term. The Company does not believe the exercise of the extension to be reasonably certain as of the balance sheet date and therefore did not include the extension as part of its recognized lease asset and lease liability. The annual base rent is $1,214, or $23.95 per rentable square foot, and will increase annually by 2.5% to 3.1% over the subsequent years.

In September 2019, the Company determined it had ceased use of its lease for the remaining 9,660 square feet at its former corporate headquarters in Canton, Massachusetts ("Canton Lease"). The Company impaired the operating lease asset and adjusted the operating lease liability to the fair value of cost that will continue to be incurred under the Canton Lease. In December 2019, the Company terminated the Canton Lease and the operating lease liability was reduced to zero.

In January 2016, the Company entered a non-cancellable contract with the contract manufacturing organization ("CMO") of Xtampza ER. The contract term continues through December 2022 and automatically renews for successive two-year terms unless either party gives written notice of termination two-years in advance. Xtampza ER production is

currently conducted in an area of the manufacturing plant that is shared with other clients. Pursuant to the terms of the agreement, since 2016 the CMO has reserved 3,267 square feet of existing manufacturing space for a dedicated production suite for Xtampza ER, which was put into service in the year ended December 31, 2020. As the Company can direct the use of the dedicated space and obtain substantially all the economic benefits of the dedicated space, the Company determined that the arrangement was an embedded operating lease. The Company expects the lease term to continue at least through December 2026 and separated the agreement's lease and non-lease components in determining the operating lease assets and liabilities. The Company determined its best estimate of stand-alone prices for each of the lease and nonlease components by considering observable information including gross margins expected to be recovered from the Company's service provider and terms of similar lease contracts.

*Short-Term Lease Arrangements*

In December 2018, the Company began entering into 12-month, non-cancelable vehicle leases for its field-based employees. Each vehicle lease is executed separately and expires at varying times with automatic renewal options that are cancelable at any time. The rent expense for these leases is therefore recognized on a straight-line basis over the lease term in the period in which it is incurred.

*Variable Lease Costs*

Variable lease costs associated with non-lease components primarily include utilities, property taxes, and other operating costs that are passed on from the lessor.

The components of lease cost for the years ended December 31, 2020 and 2019 are as follows:

| | Year ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Lease Cost | | |
| Operating lease cost | $ 1,305 | $ 1,446 |
| Short-term lease cost | 1,312 | 752 |
| Variable lease cost | 331 | 283 |
| Total lease cost | $ 2,948 | $ 2,481 |

The lease term and discount rate for operating leases for the years ended December 31, 2020 and 2019 are as follows:

| | As of December 31, | |
|---|---|---|
| Lease Term and Discount Rate: | **2020** | **2019** |
| Weighted-average remaining lease term — operating leases (years) | 8.6 | 9.6 |
| Weighted-average discount rate — operating leases | 6.1% | 6.1% |

Other information related to operating leases for the years ended December 31, 2020 and 2019 is as follows:

| | Year ended December 31, | |
|---|---|---|
| Other Information: | **2020** | **2019** |
| Cash paid for amounts included in the measurement of operating leases liabilities | $ 1,249 | $ 1,133 |
| Leased assets obtained in exchange for new operating lease liabilities | — | — |

The Company's aggregate future minimum lease payments for its operating leases, including embedded operating lease arrangements, as of December 31, 2020, are as follows:

| | | |
|---|---|---|
| 2021 | $ | 1,287 |
| 2022 | | 1,325 |
| 2023 | | 1,363 |
| 2024 | | 1,401 |
| 2025 | | 1,439 |
| After 2025 | | 5,537 |
| Total minimum lease payments | $ | 12,352 |
| Less: Present value discount | | 2,857 |
| Present value of lease liabilities | $ | 9,495 |

**14. EQUITY**

**Common Stock**

In May 2015, the Company adopted the Amended and Restated 2014 Stock Incentive Plan (the "Plan"), under which an aggregate of 2,700,000 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the Company's board of directors ("Board of Directors") prior to January 1st). As of December 31, 2020, there were 928,261 shares of common stock available for issuance pursuant to the Plan. The Plan provides for granting of both Internal Revenue Service qualified incentive stock options and non-qualified options, restricted stock awards, restricted stock units and performance stock units. The Company's qualified incentive stock options, non-qualified options and restricted stock units generally vest ratably over a four-year period of service. The stock options generally have a ten-year contractual life and, upon termination, vested options are generally exercisable between one and three months following the termination date, while unvested options are forfeited immediately upon termination. Refer to Note 15, *Stock-based Compensation*, for more information.

**Warrants**

As of December 31, 2020, the warrant issued in connection with the Third Amendment to the Nucynta Commercialization Agreement in November 2018 was the Company's only outstanding warrant, which is described in greater detail in Note 9. The warrant expires in November 2022.

**15. STOCK-BASED COMPENSATION**

**Performance Share Units, Restricted Stock Units and Stock Options**

*Performance Share Units*

The Company periodically grants performance share units ("PSUs") to certain members of the Company's senior management team. PSUs vest subject to the satisfaction of annual and cumulative performance and/or market conditions established by the Compensation Committee.

In January 2019, the Company granted PSUs with performance conditions related to 2019, 2020, 2021 and three-year cumulative revenue goals for Xtampza ER. The PSUs were to vest following a three-year performance period, subject to the satisfaction of the performance criteria and the executive's continued employment through the performance period. PSUs may vest in a range between 0% and 200%, based on the satisfaction of performance criteria, and no shares will be issued if the minimum applicable performance metric is not achieved. The Company recognizes compensation expense ratably over the required service period based on its estimate of the number of shares that will

vest based upon the probability of achieving the performance metrics. If there is a change in the estimate of the number of shares that are likely to vest, the Company will cumulatively adjust compensation expense in the period that the change in estimate is made.

In February 2020, the Company granted PSUs with performance criteria related to the relative ranking of the total stockholder return ("TSR") of the Company's common stock in 2020, 2021, 2022 and the cumulative three-year performance period return relative to the TSR of certain peer companies within the S&P Pharmaceutical Select Industry Index. TSR will be measured based on the 30-day average stock price on the first day of each period compared to the 30-day average stock price on the last day of each period. The PSUs subject to the annual performance criteria will vest annually, subject to the satisfaction of the performance criteria and the executive's continued employment through the performance period. The cumulative PSUs will vest following the three-year performance period, subject to the satisfaction of the performance criteria and the executive's continued employment through the performance period. PSUs may vest in a range between 0% and 200%, based on the satisfaction of performance, and no shares will be issued if the minimum applicable performance metric is not achieved. As these PSUs vest based on the achievement of market conditions, the grant date fair values were determined using a Monte-Carlo valuation model. The Monte-Carlo valuation model considered a variety of potential future share prices for the Company as well as its peer companies in the selected market index. The weighted-average grant date fair value of 2020 PSUs granted with market-based vesting conditions was $28.81 based on the valuation model.

In December 2020, the Company's board of directors approved a modification of PSUs that were originally granted to the Company's senior management team in January 2019. The modification replaced the original performance criteria for the 2020, 2021 and cumulative performance periods from being based on Xtampza 2020, 2021 and three-year cumulative revenue goals to being based on total shareholder return ("TSR") for 2020, 2021 and the corresponding two-year cumulative period. The PSUs achieved based on 2019 Xtampza revenues goals were not changed as part of the modification. The Company accounted for this modification under ASC 718, and, per guidance, determined the modification created incremental value as the fair value of these awards was increased upon modification. The increase in fair value resulted in an accelerated recognition of stock-based compensation expense on the modification date of $906. The total expense for these PSUs in years ended December 31, 2020 and 2019 was $950 and $136, respectively.

A summary of the Company's performance share units activity for the year ended December 31, 2020 and related information is as follows:

| | Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2019 | 99,400 | $ 15.90 |
| Granted | 187,978 | 28.49 |
| Vested | — | — |
| Forfeited | — | — |
| Performance adjustment | (4,155) | 15.90 |
| Outstanding at December 31, 2020 | 283,223 | $ 24.26 |

The number of PSUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares earned may vary based on the satisfaction of performance criteria. The weighted-average grant date fair value of PSUs granted for the years ended December 31, 2020 and 2019 was $28.49 and $15.90, respectively. There were no PSUs granted in the year ended December 31, 2018.

For the years ended December 31, 2020 and 2019, the stock-based compensation expense for PSUs was $3,551 and $136, respectively. There was no expense for PSUs in the year ended December 31, 2018.

As of December 31, 2020, the unrecognized compensation cost related to performance share units was $3,555 and is expected to be recognized as expense over approximately 1.6 years.

*Restricted Stock Units*

A summary of the Company's restricted stock units activity for the year ended December 31, 2020 and related information is as follows:

| | Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2019 | 849,679 | $ 17.10 |
| Granted | 767,634 | 21.35 |
| Vested | (335,524) | 17.85 |
| Forfeited | (39,402) | 20.20 |
| Outstanding at December 31, 2020 | 1,242,387 | $ 19.42 |

The weighted-average grant date fair value of RSUs granted for the years ended December 31, 2020, 2019 and 2018 was $21.35, $15.48 and $23.41. The total fair value of RSUs vested (measured on the date of vesting) for the years ended December 31, 2020, 2019 and 2018 was $6,992, $2,683 and $1,782 respectively.

As of December 31, 2020, the unrecognized compensation cost related to restricted stock units was $16,816 and is expected to be recognized as expense over approximately 2.6 years. The fair value of restricted stock units vested during the year ended December 31, 2020 was $5,989.

*Stock Options*

The Company granted stock options to employees for the years ended December 31, 2020, 2019 and 2018. The Company estimates the fair value of stock options as of the date of grant using the Black-Scholes option pricing model and restricted stock awards and restricted stock units based on the fair value of the award.

A summary of the Company's stock option activity for the year ended December 31, 2020 and related information is as follows:

| | Shares | Weighted-Average Exercise Price per Share | Weighted-Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2019 | 3,955,887 | $ 16.00 | 7.5 | $ 21,257 |
| Granted | 717,304 | 21.30 | | |
| Exercised | (637,924) | 10.44 | | |
| Cancelled | (174,786) | 18.82 | | |
| Outstanding at December 31, 2020 | 3,860,481 | $ 17.78 | 7.2 | $ 13,011 |
| Exercisable at December 31, 2020 | 2,373,097 | $ 17.00 | 6.4 | $ 9,770 |

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Risk-free interest rate | 1.3 % | 2.4 % | 2.6 % |
| Volatility | 66.2 % | 63.3 % | 64.8 % |
| Expected term (years) | 6.0 | 6.1 | 6.1 |
| Expected dividend yield | — % | — % | — % |

***Risk-free Interest Rate.*** The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the stock option grants.

***Expected Volatility.*** Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption is based on the Company's volatility as well as the historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology and pharmaceutical industries. In evaluating similarity, the Company considers factors such as industry, stage of life cycle and size.

***Expected Term.*** The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior through December 31, 2020 it determined the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

***Expected Dividend Yield.*** The expected dividend yield assumption is based on the fact that the Company has never paid cash dividends and has no present intention to pay cash dividends.

The weighted-average grant date fair value of stock options granted for the years ended December 31, 2020, 2019, and 2018 was $12.78, $9.07 and $14.51 respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2020, 2019, and 2018 was $7,516, $1,506 and $3,970, respectively.

As of December 31, 2020, the unrecognized compensation cost related to outstanding options was $14,170 and is expected to be recognized as expense over approximately 2.4 years.

In June 2018, the Company's board of directors approved a modification of equity-based awards granted to the former President and Chief Executive Officer to provide that all of those awards, to the extent unvested as of the Company's 2020 annual meeting of shareholders, will vest on such date, subject to his continued service on the Company's board of directors through such date. This modification was effective on June 4, 2018 and affected 116,250 shares of non-vested restricted stock units and 225,625 unvested stock options to purchase the Company's common stock. The Company accounted for this modification under ASC 718, and, per guidance, determined the modification did not create incremental value as the fair value of these awards was unchanged. The shorter requisite service period resulted in the accelerated recognition of stock-based compensation expense from the modification date through the date of the annual meeting of shareholders in May 2020.

**Employee Stock Purchase Plan**

The Company's 2015 Employee Stock Purchase Plan allows employees as designated by the Company's Board of Directors to purchase shares of the Company's common stock. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on (1) the first day of the purchase period or (2) the last day of the purchase period. During the year ended December 31, 2020, 67,512 shares of common stock were purchased for total proceeds of $758. As of December 31, 2020, there were 1,315,844 shares of common stock authorized for issuance pursuant to the employee stock purchase plan. The expense for the years ended December 31, 2020, 2019 and 2018 was $342, $358 and $493 respectively.

**Stock-Based Compensation Expense**

Stock-based compensation for all stock options, restricted stock awards, restricted stock units, performance share units and for the employee stock purchase plan are reported within the following:

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Research and development expenses | $ 3,909 | $ 2,126 | $ 1,468 |
| Selling, general and administrative expenses | 18,001 | 14,402 | 12,310 |
| Total stock-based compensation expense | $ 21,910 | $ 16,528 | $ 13,778 |

**16. INCOME TAXES**

For the year ended December 31, 2020, the Company recorded a current state tax expense of $830. For the years ended December 2019, and 2018 the Company did not record a current or deferred income tax expense or (benefit) due to current and historical losses incurred by the Company. The Company's losses before income taxes consist solely of losses from domestic operations.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

| | As of December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Federal income tax expense at statutory rate | 21.00 % | 21.00 % | 21.00 % |
| (Increase) decrease income tax (benefit) resulting from: | | | |
| State income tax, net of federal benefit | 5.06 | 5.59 | 5.89 |
| Permanent differences | (1.85) | (3.24) | (2.51) |
| Research and development credit | (1.08) | 1.83 | 0.52 |
| Change in valuation allowance | (20.12) | (25.18) | (24.90) |
| Effective income tax rate | 3.01 % | 0.00 % | 0.00 % |

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company’s deferred tax assets and liabilities are comprised of the following:

| | As of December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Deferred tax assets: | | |
| U.S. and state net operating loss carryforwards | $ 57,457 | $ 66,553 |
| Research and development credits | 5,004 | 3,768 |
| Operating lease liabilities | 2,508 | 2,630 |
| Accruals and other (1) | 15,306 | 14,286 |
| Intangible assets | 1,297 | — |
| Depreciation | — | 92 |
| Gross deferred tax assets: | 81,572 | 87,329 |
| Valuation allowance | (65,661) | (77,285) |
| Total deferred tax assets: | 15,911 | 10,044 |
| Deferred tax liabilities: | | |
| Debt discount | (10,809) | — |
| Operating lease assets | (2,217) | (2,357) |
| Intangible assets | — | (7,687) |
| Depreciation | (2,885) | — |
| Net deferred tax assets | $ — | $ — |

(1) Balance includes $7,133 and $5,796 of stock-based compensation expense related to accruals as of December 31, 2020 and 2019, respectively. Balance also includes $6,281 and $7,204 of accrued rebates, returns, and discounts as of December 31, 2020 and 2019, respectively.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2020, and December 31, 2019, based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2020 and

December 31, 2019. The valuation allowance decreased $11,624 during the year ended December 31, 2020 due primarily to the expected utilization of its net operating losses in 2020.

The Company recorded a valuation allowance against all of its deferred tax assets as of December 31, 2020 and 2019. The Company intends to continue to maintain a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. Given the Company's current earnings and anticipated future earnings, however, the Company believes that there is a reasonable possibility that within the next 12 months, sufficient positive evidence may become available to allow the Company to reach a conclusion that a significant portion or all of the valuation allowance will no longer be needed. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to the provision for income taxes for the period the release is recorded. The exact timing and amount of the valuation allowance release, however, are subject to change on the basis of the level of profitability that the Company is able to actually achieve.

As of December 31, 2020, 2019, and 2018, the Company had gross U.S. federal net operating loss carryforwards of $226,824, $292,342, and $324,533, respectively, which may be available to offset future income tax liabilities. The Tax Cuts and Jobs Act of 2017 ("TCJA") will generally allow losses incurred after 2017 to be carried over indefinitely but will generally limit the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Internal Revenue Code Sections 382 and 383). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income (subject to Internal Revenue Code Section 382 and 383) and be available for twenty years from the period the loss was generated.

As of December 31, 2020, 2019, and 2018, the Company also had gross U.S. state net operating loss carryforwards of $170,280, $222,629, and $285,181, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2038.

As of December 31, 2020, 2019 and 2018, the Company had federal research and development tax credit carryforwards of approximately $4,623, $4,044, and $3,628, respectively, available to reduce future tax liabilities which expire at various dates through 2038. As of December 31, 2020, 2019 and 2018 the Company had state research and development tax credit carryforwards of approximately $1,150, $1,112, and $885, respectively, available to reduce future tax liabilities which expire at various dates through 2035.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions.

During 2020, the Company completed an updated study to assess the impact of ownership changes, if any, on the Company's ability to use its NOL and tax credit carryovers as defined under Section 382 of the Internal Revenue Code ("IRC 382"). As a result of the study, the Company concluded that there were ownership changes that occurred during the years 2006, 2012 and 2015 that could be subject to IRC 382 limitations. These IRC 382 annual limitations may limit the Company's ability to use pre-ownership change federal NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially increase the Company's future federal income tax liability.

The Company files income tax returns in the United States and in several states. The federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2017 through December 31, 2020. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. The Company originally recorded an unrecognized tax benefit of $902 (net rate effected unrecognized tax benefit of $235) during 2017 associated with its IRS examination of its 2015 federal income tax return, and accordingly reduced its NOL deferred tax asset during 2017. The Company settled its IRS audit during 2018, which resulted in a total decrease to its NOL carryover of $36. As a result of the IRS settlement, the Company reversed this unrecognized tax benefit and trued-up its NOL carryover during 2018 to reflect the reduction of the $36 to its NOL as required by the IRS

settlement. This is included in the tabular rollforward below of gross unrecognized tax benefits. Since a full valuation allowance has been provided against the Company's net operating loss carryover, the true up of the NOL carryover and associated deferred tax asset during 2018 does not result in any financial statement impact.

For all years through December 31, 2020, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards. The Company has reduced its deferred tax asset for its estimate of credits that could be reduced, and that is included in the tabular rollforward of uncertain tax positions. Since a full valuation allowance has been provided against the Company's research and development credits the reduction in the gross deferred tax asset established for the research and development credit carryforwards does not result in any financial statement impact.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits ("UTB") is as follows:

| | As of December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Gross UTB Balance at January 1 | $ 578 | $ 502 | $ 1,364 |
| Additions based on tax positions related to the current year | 36 | 76 | 64 |
| Additions for tax positions of prior years | — | — | — |
| Reductions for tax positions of prior years | (28) | — | (24) |
| Settlements | — | — | (902) |
| Reductions due to lapse of applicable statute of limitations | — | — | — |
| Gross UTB Balance at December 31 | $ 586 | $ 578 | $ 502 |
| | | | |
| Net UTB impacting the effective tax rate at December 31 (included in the change in the valuation allowance in rate reconciliation) | $ 560 | $ 549 | $ 481 |

**17. EMPLOYEE BENEFITS**

The Company has a retirement savings plan, which is qualified under section 401(k) of the Code, for its employees. The plan allows eligible employees to defer, at the employee's discretion, pretax compensation up to the Internal Revenue Service annual limits. Employees become eligible to participate starting on the first day of employment. The Company is not required to contribute to this plan. Total expense for contributions made by the Company for the years ended December 31, 2020, 2019 and 2018 was $1,260, $1,170 and $1,208 respectively.

## 18. UNAUDITED QUARTERLY OPERATING RESULTS

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2020 and 2019:

| Year ended December 31, 2020 | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| Product revenues, net | $ 76,511 | $ 78,058 | $ 79,176 | $ 76,271 |
| Cost of product revenues | | | | |
| Cost of product revenues (excluding intangible asset amortization) | 27,229 | 12,899 | 14,188 | 15,184 |
| Intangible asset amortization | 10,295 | 16,795 | 16,795 | 16,795 |
| Total cost of products revenues | 37,524 | 29,694 | 30,983 | 31,979 |
| Gross profit | 38,987 | 48,364 | 48,193 | 44,292 |
| Operating expenses | | | | |
| Research and development | 2,666 | 2,493 | 2,141 | 2,472 |
| Selling, general and administrative | 31,260 | 29,322 | 26,426 | 26,824 |
| Total operating expenses | 33,926 | 31,815 | 28,567 | 29,296 |
| Income from operations | 5,061 | 16,549 | 19,626 | 14,996 |
| Interest expense | (4,823) | (8,259) | (8,063) | (7,737) |
| Interest income | 212 | 14 | 3 | 3 |
| Income before income taxes | 450 | 8,304 | 11,566 | 7,262 |
| Provision for income taxes | — | 246 | 280 | 304 |
| Net income | $ 450 | $ 8,058 | $ 11,286 | $ 6,958 |
| | | | | |
| Earnings per share — basic | $ 0.01 | $ 0.23 | $ 0.33 | $ 0.20 |
| Weighted-average shares — basic | 34,100,688 | 34,395,266 | 34,540,126 | 34,592,277 |
| | | | | |
| Earnings (loss) per share — diluted | $ 0.01 | $ 0.23 | $ 0.32 | $ 0.20 |
| Weighted-average shares — diluted | 35,069,693 | 35,091,906 | 35,069,188 | 35,417,623 |

| Year ended December 31, 2019 | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| Product revenues, net | $ 74,516 | $ 75,040 | $ 72,942 | $ 74,203 |
| Cost of product revenues | | | | |
| Cost of product revenues (excluding intangible asset amortization) | 45,476 | 44,966 | 43,066 | 45,400 |
| Intangible asset amortization | 3,688 | 3,688 | 3,688 | 3,688 |
| Total cost of products revenues | 49,164 | 48,654 | 46,754 | 49,088 |
| Gross profit | 25,352 | 26,386 | 26,188 | 25,115 |
| Operating expenses | | | | |
| Research and development | 2,992 | 2,459 | 2,491 | 2,398 |
| Selling, general and administrative | 32,352 | 28,935 | 30,072 | 25,090 |
| Total operating expenses | 35,344 | 31,394 | 32,563 | 27,488 |
| Loss from operations | (9,992) | (5,008) | (6,375) | (2,373) |
| Interest expense | (234) | (236) | (228) | (211) |
| Interest income | 526 | 532 | 494 | 383 |
| Net loss | $ (9,700) | $ (4,712) | $ (6,109) | $ (2,201) |
| | | | | |
| Weighted-average shares - basic and diluted | 33,331,917 | 33,397,709 | 33,481,923 | 33,600,566 |
| Loss per share - basic and diluted | $ (0.29) | $ (0.14) | $ (0.18) | $ (0.07) |

**Exhibit 4.5**

## DESCRIPTION OF THE REGISTRANT'S COMMON STOCK

*References to "the Company," "Collegium," "we," "our" and "us" herein are, unless the context otherwise indicates, only to Collegium Pharmaceutical, Inc. and not to any of its subsidiaries.*

*The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Third Amended and Restated Articles of Incorporation (our "amended and restated articles of incorporation") and amended and restated bylaws, each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.5 is a part. We encourage you to read our amended and restated articles of incorporation, amended and restated bylaws and the applicable provisions of the Virginia Stock Corporation Act, for additional information.*

**Common Stock**

*Authorized Capital Stock.* Our authorized capital stock consists of 105,000,000 shares, 100,000,000 of which are designated as common stock with a par value of $0.001 per share and 5,000,000 of which are designated as preferred stock with a par value of $0.001. Shares of our common stock have the following rights, preferences and privileges:

*Voting Rights*. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the shareholders. With certain exceptions, a majority of the votes cast at a shareholder meeting at which a quorum is present must approve all shareholder matters. Our amended and restated articles of incorporation provide that an amendment to our amended and restated articles of incorporation, a merger, share exchange, domestication, entity conversion, sale of assets that requires shareholder approval or our dissolution must be approved by a majority of all the votes entitled to be cast at a shareholder meeting. Our amended and restated articles of incorporation provide that an amendment to our amended and restated bylaws by the shareholders must be approved by at least a majority of all the votes entitled to be cast. Our amended and restated bylaws also provide that our directors are elected by a majority of the votes cast in non-contested director elections. In contested elections, directors are elected by a plurality of the votes cast plurality of the votes cast.

*Dividends.* Subject to the preferences applicable to any shares of preferred stock outstanding at any time, holders of our common stock are entitled to receive dividends when and as declared by our board of directors from assets or funds legally available therefor. The timing, declaration, amount and payment of future dividends will depend on our financial condition, earnings, capital requirements and debt service obligations, as well as legal requirements, regulatory constraints, industry practice and other factors that our board of directors deems relevant. Our board of directors will make all decisions regarding our payment of dividends from time to time in accordance with applicable law.

*Liquidation.* Subject to any preferential liquidation rights of holders of preferred stock that may be outstanding, upon our dissolution, the holders of our common stock will be entitled to share ratably in our assets legally available for distribution to our shareholders.

*No Preemptive or Similar Rights.* The holders of our common stock do not have any preemptive rights or preferential rights to subscribe for shares of our capital stock or any other securities. Our common stock is not subject to any redemption or sinking fund provisions.

*Transfer Agent and Registrar*. The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

*Listing*. Our common stock is listed on NASDAQ under the symbol "COLL."

**Anti-Takeover Effects of Provisions of our Articles of Incorporation, our Bylaws and Virginia Law**

Various provisions contained in our amended and restated articles of incorporation, our amended and restated bylaws and Virginia law could delay, deter or discourage some transactions involving an actual or potential change in control of the Company.

***Articles of Incorporation and Bylaws***

*Preferred stock*

Our amended and restated articles of incorporation authorize our board of directors to establish one or more series of preferred stock and to determine, with respect to any series of preferred stock, the preferences, rights and other terms of such series. Under this authority, our board of directors could create and issue a series of preferred stock with rights, preferences or restrictions that have the effect of discriminating against an existing or prospective holder of our capital stock as a result of such holder beneficially owning or commencing a tender or exchange offer for a substantial amount of our common stock. One of the effects of authorized but unissued and unreserved shares of preferred stock may be to render it more difficult for, or to discourage an attempt by, a potential acquiror to obtain control of us by means of a merger, tender or exchange offer, proxy contest or otherwise, and thereby protect the continuity of our management. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of our Company without any action by our shareholders.

*Qualification and election of directors*

Our amended and restated bylaws provide that to be eligible to be nominated by a shareholder for election to our board of directors, a person must submit a written questionnaire regarding his or her background and qualifications and must agree to other representations as set forth in our amended and restated bylaws.

Since our initial public offering, our board of directors had been divided into three classes, each serving three-year terms and until each director's successor is duly elected and qualified. Under our amended and restated articles of incorporation, our board of directors will be declassified beginning in 2021. Directors in office immediately after the 2020 annual meeting of shareholders will serve out their three-year terms, but directors elected by shareholders beginning at the 2021 annual meeting will be elected to one-year terms. Beginning at the 2023 annual meeting of shareholders, all directors will be subject to annual election for one-year terms. Our amended and restated articles of incorporation do not provide for cumulative voting in the election of directors.

*Board vacancies; removal*

Our amended and restated articles of incorporation provide that any vacancy occurring on our board of directors will be filled by a majority of directors then in office, even if less than a quorum. Our amended and restated articles of incorporation also provide that our directors can only be removed for cause upon the vote of more than two-thirds of the votes entitled to be cast by holders of common stock.

*Special meetings of shareholders; number of directors and unanimous written consent of shareholders*

Our amended and restated articles of incorporation provide that only the board of directors, the chairman of the board of directors or the president may call a special meeting of the shareholders. Our amended and restated bylaws provide that the authorized number of our directors be changed only by resolution of our board of directors. Our amended and restated bylaws prohibit shareholders from acting by less-than-unanimous written consent.

*Advance notification of shareholder nominations and proposals*

Our amended and restated bylaws establish advance notice procedures with respect to shareholder proposals and the nomination of persons for election as directors, other than nominations made by or at the direction of our board of directors.

***Virginia Anti-Takeover Statutes***

*Affiliated transactions statute*

Virginia law contains provisions governing certain material transactions, or affiliated transactions, between the Company and any holder of more than 10% of any class of its outstanding voting shares, or an interested shareholder. In general, these provisions prohibit a Virginia corporation from engaging in an affiliated transaction with an interested shareholder for a period of three years following the date such person became an interested shareholder, unless (i) a majority of the disinterested directors and the holders of at least two-thirds of the voting shares, other than those beneficially owned by the interested shareholder, approved the affiliated transaction, or (ii) before the date that the person became an interested shareholder, a majority of the disinterested directors approved the transaction that resulted in the person becoming an interested shareholder. After three years, any such transaction must be at a "fair price," as statutorily defined, or must be approved by the holders of at least two-thirds of the voting shares, other than those beneficially owned by the interested shareholder. Affiliated transactions subject to this approval requirement include mergers, share exchanges, material dispositions of corporate assets not in the ordinary course of business, the sale of shares of the corporation or any of its subsidiaries to an interested shareholder having an aggregate fair market value of greater than 5% of the aggregate fair market value of the corporation's outstanding shares, any dissolution of the Company proposed by or on behalf of an interested

shareholder or any reclassification, including reverse stock splits, recapitalization or merger of the Company with its subsidiaries, if any, that increases the percentage of voting shares beneficially owned by an interested shareholder by more than 5%.

The shareholders of a Virginia corporation may adopt an amendment to the corporation's articles of incorporation or bylaws opting out of the provisions of Virginia law governing affiliated transactions but such amendment shall not be effective until 18 months after its adoption. Neither our amended and restated articles of incorporation nor our amended and restated bylaws contain a provision opting out of the provisions of Virginia law governing affiliated transactions.

*Control share acquisitions statute*

Virginia law also contains provisions relating to control share acquisitions, which are transactions causing the voting strength of any person acquiring beneficial ownership of shares of a Virginia public corporation to meet or exceed certain threshold percentages (20%, 33 1 / 3 % or 50%) of the total votes entitled to be cast for the election of directors. Shares acquired in a control share acquisition have no voting rights unless (i) the voting rights are granted by a majority vote of all outstanding shares other than those held by the acquiring person or any officer or employee director of the corporation or (ii) the articles of incorporation or bylaws of the corporation provide that these Virginia law provisions do not apply to acquisitions of its shares. The acquiring person may require that a special meeting of the shareholders be held to consider the grant of voting rights to the shares acquired in the control share acquisition.

As permitted by Virginia law, our amended and restated articles of incorporation contain a provision opting out of the Virginia anti-takeover law regulating control share acquisitions.

*Indemnification and limitation of directors' and officers' liability*

We are a Virginia corporation. As permitted by Virginia law, our amended and restated articles of incorporation provide that no director or officer shall be liable in any proceeding brought by or in the right of us or our shareholders for monetary damages arising out of any transaction, occurrence or other course of conduct, except for liability resulting from willful misconduct or a knowing violation of criminal law or of any federal or state securities laws.

Our amended and restated articles of incorporation require us to indemnify any director or officer who was or is a party to a proceeding, including a proceeding brought by or in the right of the Company, due to his or her status as our director or officer unless he or she engaged in willful misconduct or a knowing violation of criminal law. Our amended and restated articles of incorporation also require us to advance expenses to such person prior to the final disposition of any such proceeding.

We have obtained policies that insure our directors and officers against certain liabilities they may incur in their capacity as directors and officers.

We have entered into indemnification agreements with our directors and executive officers. These agreements contain provisions that may require us, among other things, to advance expenses to and indemnify these directors and officers against certain liabilities that may arise because of their status or service as directors or officers of us.

**Exhibit 21.1**

**Subsidiaries of Collegium Pharmaceutical, Inc.**

| Subsidiary | Jurisdiction of Incorporation |
| --- | --- |
| Collegium Securities Corporation | Massachusetts |
| Collegium NF, LLC | Delaware |

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement Nos. 333-234329 and 333-237200 on Form S-3 and Registration Statement Nos. 333-207744, 333-218767, 333-225498, 333-233092, and 333-245649 on Form S-8 of our reports dated February 25, 2021, relating to the consolidated financial statements of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company"), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Collegium Pharmaceutical, Inc. for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 25, 2021

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joseph Ciaffoni, certify that:

1. I have reviewed this annual report on Form 10-K of Collegium Pharmaceutical, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

/s/ JOSEPH CIAFFONI
Joseph Ciaffoni
*President and Chief Executive Officer*

Dated: February 25, 2021

**Exhibit 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Paul Brannelly, certify that:

1. I have reviewed this annual report on Form 10-K of Collegium Pharmaceutical, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

/s/ PAUL BRANNELLY
Paul Brannelly
*Executive Vice President and Chief Financial Officer*

Dated: February 25, 2021

**Exhibit 32.1**

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

In connection with the annual report on Form 10-K of Collegium Pharmaceutical, Inc. (the "Company") for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph Ciaffoni, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(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.

/s/ JOSEPH CIAFFONI
Joseph Ciaffoni
*President and Chief Executive Officer*

Date: February 25, 2021

**Exhibit 32.2**

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

In connection with the annual report on Form 10-K of Collegium Pharmaceutical, Inc. (the "Company") for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(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.

/s/ PAUL BRANNELLY
Paul Brannelly
*Executive Vice President and Chief Financial Officer*

Date: February 25, 2021