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, 2023

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 **Stoughton, MA** (Address of principal executive offices)	**02072** (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 ☐ (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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023, 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 $741.8 million, based on the closing price of the registrant's common stock on The NASDAQ Global Select Market on June 30, 2023 of $21.49 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, 2024, there were 31,959,828 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 2024 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2023, 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;
- our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products, 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;
- 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 ingredients for each of our products, manufacture adequate quantities of commercially salable inventory and maintain our supply chain;
- 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 business development;
- our ability to comply with the terms of our outstanding indebtedness;
- regulatory and legislative developments in the United States, including the adoption of opioid stewardship and similar taxes that may impact our business;
- our ability to obtain and maintain sufficient intellectual property protection for our products;
- 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;
- 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

Our mission is to build a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. We have leveraged our research and development efforts as well as acquisitions and licensing relationships with third parties, to develop a portfolio of meaningfully differentiated products for use in the treatment of moderate to severe pain. We commercialize our pain portfolio, consisting of Xtampza ER, Nucynta ER and Nucynta IR (collectively the “Nucynta Products”), Belbuca, and Symproic, in the United States.

Xtampza ER

Our company was formed in 2002 to help address the opioid epidemic through the development of Xtampza ER, a pain treatment option designed with abuse deterrent properties. Xtampza ER is an abuse-deterrent, extended-release, oral formulation of oxycodone. 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.

In April 2016, the United States Food and Drug Administration (“FDA”) approved our New Drug Application (“NDA”) for Xtampza ER. Xtampza ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic 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. Xtampza ER’s label indicates a dosing regimen of one capsule every 12 hours, and it must be taken with food. In June 2016, we commercially launched Xtampza ER in the United States.

Xtampza ER, OxyContin, and the authorized generic versions of OxyContin (which are identical to the branded versions) are the only extended-release oxycodone products marketed in the United States as of January 2024. Xtampza ER and OxyContin (along with its authorized generics) feature the same active pharmaceutical ingredient (oxycodone) 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 are committed to ongoing monitoring and public dissemination of our real-world abuse and diversion data, regardless of the results. The two main sources of real-world abuse, misuse, and diversion data are RADARS® and Inflexxion, an IBH Company. The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System collects product-and geographically-specific data on abuse, misuse, and diversion of prescription drugs through its multiple data sources. Abuse, misuse, and diversion of Xtampza ER has remained low compared to commonly abused

schedule II opioid analgesics for three years after introduction into the U.S. market. Methods to defeat the tamper resistant properties of Xtampza ER are reported but there is no indication of widespread or expanding abuse or misuse in the data streams evaluated. Potential limitations are based upon the fact that the Poison Center and Treatment Center Program cases involve self-reporting which may lead to: (i) differential misidentification among drug groups which may affect observed differences, and (ii) case counts of drug groups comprised primarily of branded products (other abuse-deterrent formulations of ER opioids) may be overestimated when based on self-reporting and drug groups comprised primarily of generic products (non-abuse-deterrent formulations of ER opioids and IR oxycodone) may be underestimated. The RADARS data represents a single snapshot in time and is subject to change. Therefore, we plan to continue monitoring real world data characterizing the rate of abuse, misuse, and diversion of Xtampza.

Nucynta Products

The Nucynta Products are extended-release ("ER") and immediate-release ("IR") oral formulations of tapentadol. In November 2008, the FDA approved Nucynta ER and Nucynta IR. Nucynta ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic, 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 and pediatric patients aged 6 years and older with a body weight of at least 40 kg. In August 2023, the FDA granted New Patient Population exclusivity for Nucynta IR in pediatric patients. This grant extended the period of U.S. exclusivity for Nucynta IR from June 27, 2025 to July 3, 2026.

We began commercializing the Nucynta Products in 2018 pursuant to a commercialization agreement (the "Nucynta Commercialization Agreement") with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio"), pursuant to which Assertio granted us a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization of such products in the United States. In February 2020, we acquired additional assets related to the Nucynta Products from Assertio and assumed all commercialization responsibilities, including sales and marketing, for the Nucynta Products through the acquisition of a license from Grünenthal Gmbh (the "Grünenthal License" and such acquisition, the "Nucynta Acquisition"). Upon closing the Nucynta Acquisition, the Nucynta Commercialization Agreement and our prior royalty obligation to Assertio ceased; our only remaining royalty obligation is to pay royalties directly to Grünenthal Gmbh based on net sales of the Nucynta Products under the Grünenthal License.

Belbuca and Symproic

On March 22, 2022, we acquired BioDelivery Sciences International, Inc. ("BDSI"), a specialty pharmaceutical company working to deliver innovative therapies for individuals living with serious and debilitating chronic conditions (the "BDSI Acquisition"). Upon closing the BDSI Acquisition, we acquired Belbuca and Symproic.

Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative options are inadequate. Symproic was approved by the FDA in March 2017 for the treatment of opioid-induced constipation ("OIC") in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. We began shipping and recognizing product sales related to Belbuca and Symproic in March 2022.

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 to 6 months. The overall prevalence of chronic pain among adults in the United States is 20.9%, affecting approximately 51.6 million Americans. Additionally, 6.9% of the U.S. adult population, approximately 17.1 million people, suffer from high-impact chronic pain that frequently limits life or work activities.

A 2011 report from the Institute of Medicine estimated that chronic pain costs the U.S. between $560.0 and $635.0 billion per year in direct medical costs and lost productivity, which does not include the cost of care for institutionalized

individuals (e.g., nursing home residents, prisoners), military personnel, or children, or the costs associated with caregiving. The estimated annual costs of chronic pain exceed the costs for heart disease, cancer, and diabetes.

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 long-acting/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 2023, there were approximately 139.7 million prescriptions for opioids written in the United States, representing a 3.8% decline from 2022 levels and including approximately 13.6 million prescriptions for long-acting/extended-release opioids, and approximately 126.1 million prescriptions for immediate-release opioids. After marked increases in opioid prescriptions from 2000 to 2015, prescriptions decreased each year since 2015, correlating with rising awareness of the extent and impact of the opioid crisis. However, prescription levels in 2020 returned to levels similar to those seen in the year 2000, when 143.8 million prescriptions for opioids were written in the United States, including 11.4 million prescriptions for extended-release opioids and 132.4 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 to help mitigate the risks of abuse, addiction and other adverse events associated with prescription opioids.

Prescription Opioid Abuse in the United States

Prescription opioids of all kinds, including both immediate-release and extended-release formulations, are subject to manipulation, diversion, 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 U.S. Centers for Disease Control and Prevention ("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. Meanwhile, the predominant opioid cause of death in 2018 involved synthetic opioids other than methadone. While opioid-related 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.

Despite heightened awareness of the risks associated with opioid use, abuse of prescription opioids, including extended-release formulations, continues to be a public health issue. In 2022, 8.9 million, or 3.2% of people aged 12 and older, reported opioid misuse in the prior year as collected by the National Survey on Drug Use and Health sponsored by the Substance Abuse and Mental Health Services Administration ("SAMHSA"). In 2021, the number of reported deaths involving prescription opioids totaled 16,706, worsening from 2019 levels.

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 ("API") (i.e., an effect known as "dose dumping"). By manipulating these products, people who abuse opioids achieve a more intense euphoria as a result of rapid increases in the blood concentration of the API.

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 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 clinical practice 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. On November 4, 2022, the CDC released updated guidance on prescribing opioids for pain. The 2022 prescribing guidelines replaced the 2016 guidelines but retained their principles for prescribing opioids for chronic pain. The updated CDC guidelines note that although opioids should not be considered first-line therapy for pain management, this does not mean that patients should be required to sequentially fail nonpharmacologic and nonopioid therapy before proceeding to opioid therapy, but rather the expected benefits specific to the clinical context should be weighed against risks before initiating therapy.

In addition to CDC, the Department of Health and Human Services ("HHS"), and the Department of Veterans Affairs and the Department of Defense ("VA-DoD") issued clinical practice guidelines in 2017 and updated most recently in 2022 for the evaluation and management of care for patients with chronic pain who are on or being considered for opioid treatment. These guidelines are grounded in patient-centered care and the 2022 update provides algorithms for determining the appropriateness of opioids for chronic pain, determining the initiation of opioids, and maintaining, tapering, discontinuing or switching from full agonist opioid treatment.

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 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.

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, pursuant to a third-party supply agreement. Our microsphere production is currently conducted in a dedicated manufacturing suite as we transitioned the microsphere production to the new suite in 2021. 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 at an alternative location (and with an alternative vendor) if necessary.

The Nucynta Products are manufactured pursuant to supply agreements with third-party manufacturers. Nucynta ER was historically produced by Janssen at a facility in Puerto Rico pursuant to a supply agreement that we assumed from Assertio in connection with the Nucynta Acquisition. In September 2022, we completed the transfer of the Nucynta ER manufacturing process through a technology transfer program to enable manufacturing of Nucynta ER at Patheon in Cincinnati, Ohio. Nucynta ER is currently manufactured by Patheon. Nucynta IR is manufactured by Halo Pharmaceutical, Inc. in Whippany, New Jersey.

Belbuca and Symproic are manufactured pursuant to supply agreements with third-party manufacturers. Belbuca laminate (i.e., bulk product) is produced by Adhesives Research in Glen Rock, Pennsylvania. Belbuca laminate is then sent to either LTS Therapy Systems (formerly Tapemark) in St. Paul, Minnesota or Sharp Packaging Solutions in

Allentown, Pennsylvania where it is converted into individual dosage units and, ultimately, into finished goods. For the Belbuca product portfolio, we are currently qualifying alternate bulk and secondary packaging operations at our existing manufacturer's sites. Symproic is manufactured by UPM Pharmaceuticals in Bristol, Tennessee and packaged by Sharp Packaging Solutions in Allentown, Pennsylvania.

Drug Substances

The API used to formulate the products in our portfolio and DEA drug scheduling are as follows:

Product	API	DEA Drug Schedule
Xtampza ER	Oxycodone	Schedule II
Nucynta IR	Tapentadol	Schedule II
Nucynta ER	Tapentadol	Schedule II
Belbuca	Buprenorphine	Schedule III
Symproic	Naldemedine	Not a controlled substance

Oxycodone, tapentadol, and buprenorphine 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 these products have a high potential for abuse and dependence but are recognized as having an accepted medical use. Belbuca is classified as a Schedule III controlled substance, meaning it has a moderate to low potential for abuse. Due to the controlled substances classification, the manufacturing, shipping, dispensing and storing of these products are subject to a high degree of regulation, as described in more detail under the caption "— Government Regulation — DEA and Opioid Regulation."

We currently procure the API used in our products from a sole supplier or limited number of suppliers.

Marketing and Commercialization

We commercialize our products in the United States with a dedicated field sales force, consisting of approximately 110 sales representatives and managers, to call on the approximately 10,000 health care professionals who write approximately 66% of the branded extended-release opioid prescriptions in the United States, with a primary focus on pain specialists. 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 our 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.

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 twelve 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 Patent Cooperation Treaty ("PCT") application. Our issued U.S. patents are projected to expire in 2025, 2030, and 2036 and our pending patent applications in the United States, if issued, would be projected to expire in 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.

Nucynta IR is protected by one issued patent in the United States (which covers both the drug substance and drug product) that is projected to expire in 2025. Nucynta IR is also covered by New Patient Population exclusivity in

pediatric patients that is projected to expire in 2026. Nucynta ER is protected by four issued patents in the United States (which cover the drug substance, drug product, certain characteristics of the dosage form, and methods of treating patients) that are projected to expire in 2024, 2025, and 2028. Belbuca is protected by three issued patents in the United States (which cover a method of treating patients) that are projected to expire in 2027 and 2032.

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, and a license from Shionogi to commercialize Symproic 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 and Belbuca and Symproic in connection with the BDSI 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 several sources, including pharmaceutical and biotechnology companies, generic and branded drug companies, drug delivery companies and academic and research institutions. However, our primary source of competition stems from the generic opioid market, including both long-acting/extended-release and immediate-release opioid drugs. 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.

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") and regulations;

- submission to the FDA of an Investigational New Drug ("IND") application for human clinical testing, which becomes effective 30 days after submission and, if not placed on clinical hold, 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") and FDA regulations to establish the safety and effectiveness 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 current good manufacturing practices ("cGMP") and regulations;
- submission to the FDA of a NDA or, in the case of a generic drug, an abbreviated NDA ("ANDA");
- satisfactory completion of a review by an FDA advisory committee, if convened; and
- FDA review and approval of the NDA or ANDA.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the application 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 candidate. 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 application 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 application 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 and GCP, an international standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected; 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.

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: This phase includes the initial introduction of an investigational new drug into patients or healthy volunteer subjects. These studies are typically closely monitored and designed to determine the metabolism and pharmacological actions of the drug in humans, the side effects associated with increasing doses, and, in some cases, early evidence of effectiveness.
- Phase 2: This phase includes well-controlled, closely monitored studies conducted in a relatively small number of patients (typically no more than several hundred patients) to assess effectiveness of the drug for particular indication(s) in patients with the diseases or condition under study as well as to determine the common short-term side effects and risks associated with the drug.
- Phase 3: This phase includes expanded controlled and uncontrolled trials which are performed after preliminary evidence suggesting effectiveness of the drug has been obtained. These studies typically include several hundred to several thousand patients and are conducted to gather additional information about the effectiveness and safety of the drug in order to evaluate the overall risk-benefit relationship and provide an adequate basis for labeling.

For opioid 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 abuse potential under controlled conditions, while Category 4 studies analyze post-market data to assess the impact of abuse-deterrent properties on actual abuse. 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 and application type. 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 effectiveness, 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 a 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 a 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 a 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. A REMS is a program to manage known or potential serious risks associated with a drug product and may be required by the FDA 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 (Opioid Analgesic REMS). Extended-release formulations of oxycodone, morphine, hydrocodone and hydromorphone, for example, are required to have a REMS. The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. Manufacturers subject to this class-wide REMS must work together to implement the REMS as part of the Opioid Analgesic REMS Program Companies ("RPC"), which is a collaboration of drug product companies to implement a single shared REMS to reduce the burden on the healthcare system accessed from the RPC REMs website. The content on this website is determined by, hosted on behalf of, and is financially supported by the RPC. The central component of the extended-release/long-acting opioid REMS program is an education program for healthcare providers who prescribe, and healthcare providers involved in the treatment and monitoring of patients who receive opioid analgesics. Specifically, the REMS includes a product-specific Medication Guide and the Patient Counseling Guide available for distribution to patients who are dispensed the drug, as well as a number of ETASU. These ETASU include REMS-compliant accredited continuing education for healthcare providers, which includes all healthcare providers who prescribe or are involved in the management of patients with pain; 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. For the first time, FDA notified companies that have NDAs or ANDAs for certain opioid analgesic drug products ("NDA/ANDA holders") of the elements required for a single REMS for opioid analgesic products, whether branded or generic. 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 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. In addition, the Drug Supply Chain Security Act ("DSCSA"), was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs and biologics distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers that culminated in November 2023. The FDA has issued two compliance policy guidances that establish a one-year stabilization period from November 2023 to November 2024 for trading partners to continue to build and validate interoperable systems and processes to meet certain requirements of the DSCSA. The law's requirements include the quarantine and prompt investigation of a suspicious product, to determine if it is illegitimate, notifying trading partners and the FDA of any illegitimate product, and compliance with product tracking and tracing requirements.

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, including post-marketing surveillance and observational 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 collect additional information to assess a known serious risk or signals of serious risk related to the drug or to monitor for or 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. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others.

The FDA held a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee on April 19, 2023. The committee discussed post-marketing requirements ("PMRs") 3033-11, issued to holders of NDAs for extended-release and long-acting opioid analgesics to evaluate long-term efficacy of opioid analgesics and the risk of opioid-induced hyperalgesia. The discussion focused on a clinical trial designed to address these objectives. We participated in this meeting and as a result, the proposed design of study 3033-11, the enriched enrollment randomized withdrawal design was not supported. As part of the Opioid PMR Consortium, Collegium is working with the FDA to redesign study 3033-11.

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 as referenced listed drugs ("RLDs") 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 RLD and has been shown through bioequivalence testing to be therapeutically equivalent to the RLD. 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.

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 the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the 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 of safety and effectiveness regarding the NCE 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 effectiveness 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 approval 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

Several of 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 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 Schedule II controlled substances under the CSA, while Belbuca is listed as a Schedule III controlled substance. Consequently, the manufacturing, shipping, storing, selling and use of these products is subject to a high degree of regulation. Also, distribution and dispensing of these drugs are highly regulated. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping, and reporting. Further, 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 controls and limits the availability and production of controlled substances in Schedule I or II. Annually, the DEA establishes 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 quarterly to the DEA for individual production and procurement quotas. Xtampza ER and the Nucynta Products are regulated as Schedule II controlled substances, and thus, are subject to the DEA's production and procurement quota system. Our contract manufacturers must receive a quarterly quota from the DEA to produce or procure any Schedule I or Schedule II substance, including oxycodone base for use in manufacturing Xtampza ER and 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.

Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA.

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 the 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 the Centers for Medicare and Medicaid Services ("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 ("AKS") (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 payors. 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, other licensed healthcare practitioners and teaching hospitals. Failure to comply with required reporting requirements under these laws could subject manufacturers and others to substantial civil monetary 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.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Like the AKS, the Patient Protection and Affordable Care Act (the "ACA") amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, also impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions.

The federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), to certain non-physician providers such as physician assistants and nurse

practitioners, and to teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products. In addition, federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers. There are also analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of a pharmaceutical manufacturer's business activities could be subject to challenge under one or more of such laws. Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against a pharmaceutical manufacturer, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, imprisonment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reporting obligations and oversight if we become subject to integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of operations. In addition, commercialization of any drug product outside the U.S. will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Third-Party Payor Coverage and Reimbursement

The commercial success of our 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 continue to experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. As a result, our 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 our 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, non-deductible 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% (later amended to 70%) 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 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 June 17, 2021, in an appeal from a lower court decision holding that the individual mandate under the Affordable Care Act is unconstitutional, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the Affordable Care Act or any of its provisions.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Budget Control Act of 2011 and subsequent legislation has resulted in 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.

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. The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Removal of the drug rebate cap can result in paying rebate payments to Medicaid that are higher than the sale price of the drug.

The Inflation Reduction Act of 2022 ("IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance. Another component of the IRA includes the establishment of rebate payment requirements on Medicare Part D drugs which penalize price increases that outpace inflation. The IRA also redesigned Medicare Part D to reallocate cost across the various stakeholders: CMS, payors, manufacturers, and beneficiaries. Certain aspects of the Part D redesign take effect in 2024 which ultimately shifts some liability from beneficiaries to the payors. Starting in 2025, all remaining components of the Part D Redesign will take effect. Ultimately, the existing coverage gap will be removed and replaced with greater exposure for manufacturers after the beneficiary pays their deductible. Additionally, the exemption previously applied on the low-income subsidy ("LIS") population has been removed and increases manufacturer rebate exposure for that population. Some manufacturers, including Collegium, will qualify for a "phase in" of rebate utilization for the LIS population which should limit our exposure in the short term, but will increase it over time. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of the IRA on our business and the pharmaceutical industry in general is not yet known.

Our Environmental, Social, and Governance ("ESG") Initiatives

Our commitment to serving as a responsible corporate citizen is rooted in our longstanding history of advancing our mission, executing our commercial strategy, governing our business to drive efficiency and value creation, and supporting our communities. We have prioritized corporate governance and risk mitigation; employee development and culture; our environmental footprint; and giving back to our communities. As a reflection of this commitment, our annual Corporate Scorecard has included metrics relating to our performance relative to specific ESG initiatives.

In February 2024, we published our annual ESG report on our corporate website highlighting our ESG accomplishments to date. The information contained in our ESG report is not a part of, nor is it incorporated by reference into, this Form 10-K.

Human Capital Management

Collegium Culture and Employee Engagement

Our employees are foundational to our current and future success, and we believe that their engagement and commitment are among our most valuable assets. As we seek to build and sustain a challenging, inspiring, and inclusive environment for our employees, we have focused on talent acquisition and retention; employee training and development; diversity and inclusion; and employee health and safety.

At Collegium, we recognize that we have a responsibility to hold ourselves to the highest standard of business and professional ethics. Our Core Values are the foundational principles of our organization and guide our work, how we interact with each other and our communities and influence the business strategies we employ to fulfill our mission. Our Core Values are: Uphold Integrity, Embrace Differences, Encourage Expression, and Be Accountable.

We prioritize transparency, recognition, and collaboration to support our team's engagement. We facilitate transparent communications through various channels, such as quarterly all-employee meetings, small-group employee conversations with our Chief Executive Officer, and periodic employee engagement surveys.

Talent Acquisition and Retention

We seek to identify, recruit, retain, incentivize, and integrate our existing and new employees, advisors, and consultants. All full-time employees receive stock-based and cash-based compensation awards through the compensation cycle; stock-based compensation includes restricted stock units for the entire organization. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel as they strive to increase stockholder value and contribute to the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Employee Training and Development

We believe career development begins with good conversations between employees and their managers that ensure regular feedback, and we have implemented tools and annual processes that allow all employees in conjunction with their managers to explore possibilities and drive development action. Our comprehensive performance review process ensures our employees are on track with their development throughout the year.

Diversity, Equity, and Inclusion

We are committed to fostering diversity, equity, and inclusion (“DEI”) in our workplace. We are unwavering in our commitment to treat our colleagues fairly, and we are open-minded and inclusive in our engagements with one other, our partners, and customers. We believe that when people feel appreciated and included, they are more creative, innovative, and successful, which in turn improves our business and performance and enhances shareholder value. We are committed to employing people whose diverse backgrounds contribute to innovation and allow us to approach the complex issues that face our industry from many different perspectives.

We are executing our multi-year DEI strategic plan that strives to integrate DEI with our overall business goals by focusing on topics such as developing, retaining, and attracting talent; creating and sustaining a work environment where all employees feel valued and engaged; and developing a strong reputation and strategic alliance partnerships with the communities we serve.

As of December 2023, we had a total of 197 employees with representation with respect to gender and self-reported race and ethnicity as follows:

Ethnicity	**#**	**%**
Asian (Not Hispanic or Latino)	15	7.6%
Black or African American (Not Hispanic or Latino)	12	6.1%
Hispanic or Latino	5	2.5%
Prefer Not to Disclose	3	1.5%
Two or More Races (Not Hispanic or Latino)	3	1.5%
White (Not Hispanic or Latino)	159	80.8%
Total	**197**	**100%**

Gender	**#**	**%**
Female	98	49.7%
Male	99	50.3%
Total	**197**	**100%**

As in everything we do, we are committed to continuous improvement in this area. While we are proud of the diversity of backgrounds and identities that our workforce exhibits, we will make the necessary investments of time, resources, and engagement to make sustained improvements in this area.

Employee Health and Safety

We believe that 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 all employees and their families with access to a variety of innovative, flexible, and convenient health and wellness programs.

Our Executive Officers

The following table lists the positions, names and ages of our executive officers as of February 22, 2024:

Name	Age	Position(s)
Joseph Ciaffoni	52	Director, President and Chief Executive Officer
Colleen Tupper	48	Executive Vice President and Chief Financial Officer
Scott Dreyer	51	Executive Vice President and Chief Commercial Officer
Shirley Kuhlmann	40	Executive Vice President, General Counsel and Chief Administrative Officer
Thomas Smith	63	Executive Vice President and Chief Medical Officer

Joseph Ciaffoni, Director, President and Chief Executive Officer. Mr. Ciaffoni was appointed as our President and Chief Executive Officer of Collegium Pharmaceutical in July 2018. Mr. Ciaffoni joined us in May 2017 as Executive Vice President and Chief Operating Officer. Prior to joining us, he served as President, U.S. Branded Pharmaceuticals of Endo International plc. Before that, Mr. Ciaffoni held various positions of increasing responsibility at Biogen, 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, he was Executive Vice President and Chief Operating Officer of Shionogi Inc. and President of Shionogi Pharmaceuticals. Mr. Ciaffoni also previously served as Vice President, Sales for Schering-Plough (now Merck) and held several commercial leadership roles at Sanofi-Synthelabo (now Sanofi) and Novartis. Mr. Ciaffoni received a B.A. in Communications and an M.B.A. from Rutgers.

Colleen Tupper, Executive Vice President and Chief Financial Officer. Ms. Tupper joined us in May 2021 as Executive Vice President and Chief Financial Officer. Prior to joining us, Ms. Tupper most recently served as Chief Financial Officer, U.S. Business Unit as well as a member of the U.S. Business Unit Executive Leadership Team and the Global Finance Leadership Team at Takeda from January 2019 to April 2021. Prior to that role, Ms. Tupper held several roles of increasing responsibility at Shire Pharmaceuticals (acquired by Takeda in 2019) including Vice President, U.S. Commercial Finance; Vice President, Finance Integration Lead; and Vice President, Head of Finance Global Neuroscience and Ophthalmics. Earlier in her career, Ms. Tupper served in various finance and accounting roles at both Shire Pharmaceuticals and Antigenics (now Agenus). Ms. Tupper received a B.S. in Accounting from Franklin Pierce University.

Scott Dreyer, Executive Vice President and Chief Commercial Officer. Mr. Dreyer was appointed as our Executive Vice President and Chief Commercial Officer in July 2018. Mr. Dreyer joined us in January 2018 as Senior Vice President of Sales, Marketing, Commercial Capabilities and Training. He has over 25 years of commercial experience across sales, marketing, commercial operations and strategic planning, all within the biopharma industry. Most recently, Mr. Dreyer was Senior Vice President, Marketing and Commercial Operations for The Medicines Company. Prior to joining The Medicines Company, he was Vice President and Chief Marketing Officer-U.S. at Biogen. Prior to Biogen, Mr. Dreyer held various commercial leadership positions of increasing responsibility at Merck & Co, including Vice President-U.S. Hospital and Oncology Sales and Commercial Operations, Vice President-U.S. Primary Care Sales, Executive Director U.S. Regional Marketing Leader – Neuroscience, Executive Director Customer Marketing and Solutions, Sr. Director of Strategic Planning and Director of Cardiovascular Marketing. Mr. Dreyer received a B.S. in Biology from Messiah College.

Shirley Kuhlmann, Executive Vice President, General Counsel and Chief Administrative Officer. Ms. Kuhlmann joined Collegium Pharmaceutical in March 2018 as Executive Vice President, General Counsel and Secretary and has also served as Chief Administrative Officer since March 2022. Prior to joining Collegium, Ms. Kuhlmann was an attorney in the Health Sciences Group of Pepper Hamilton LLP, a law firm headquartered in Philadelphia, Pennsylvania. Ms. Kuhlmann began her career at Pepper Hamilton in 2007 as an Associate and was elected a Partner of the firm in 2016. While with Pepper Hamilton, she advised private and public companies on a range of transactional matters, including securities offerings, mergers and acquisitions and other financing transactions. Ms. Kuhlmann received a B.A. in Economics and Political Science from Columbia University and a J.D. from the Emory University School of Law.

Thomas Smith, M.D., Executive Vice President and Chief Medical Officer. Dr. Smith has served as our Chief Medical Officer since March 2022 following the acquisition of BDSI. Dr. Smith has more than twenty-five years of experience in a variety of leadership roles at various major pharmaceutical companies, including serving as the Chief Medical Officer for BDSI from July 2018 to March 2022, Charleston Laboratories from January 2017 to July 2018, Ameritox and Mallinckrodt Pharmaceuticals. Prior to these, Dr. Smith served in scientific, medical and clinical leadership roles at Abbott Laboratories, Teva Pharmaceuticals and Kendle International. He is a member of several medical and scientific societies, including the American Medical Association and the American Academy of Family Physicians. Dr. Smith earned his M.D. from the Indiana University School of Medicine and a B.S. from Purdue University.

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 annual reports on 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.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following principal risk factors that make an investment in our company speculative or risky. You are encouraged to carefully review our full discussion of the material risk factors relevant to an investment in our business, which follows the brief bulleted list of our principal risk factors set forth below:

- Our ability to maintain profitability is dependent upon our ability to continue successfully commercializing our products and any products we may acquire in the future;
- We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations;
- Adverse developments affecting the financial services industry could adversely affect our business, financial condition, or results of operations;
- If we cannot continue successfully commercializing our products and any products that we may acquire in the future, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline;
- Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling of any of our products, including our abuse-deterrent claims with respect to Xtampza ER, and our ability to market our products successfully may be adversely affected;
- Xtampza ER, the Nucynta Products, and Belbuca are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products;
- Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions;
- Unfavorable outcomes in intellectual property litigation could be costly and potentially limit our ability to commercialize our products;
- If we are unable to obtain or maintain intellectual property rights for our technologies, products or any products we may acquire, we may lose valuable assets or be unable to compete effectively in our market;
- 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;
- 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;
- 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;
- 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;
- Our products 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;
- 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;
- 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;
- 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;
- If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline;
- If the third-party manufacturers of our products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated manufacturing suite 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;
- Because we currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us;
- We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors or their distribution network is disrupted, our financial condition and results of operations may be adversely affected;
- 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;
- We may not realize all of the anticipated benefits from future acquisitions, and we may be unable to successfully integrate future acquisitions;
- Our business may be adversely affected by certain events or circumstances outside our control, including macroeconomic conditions and geopolitical turmoil;
- Litigation or regulatory action regarding opioid medications could negatively affect our business;
- 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;
- Commercial sales of our products 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;
- 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; and
- The price of our common stock may be volatile and you may lose all or part of your investment.

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 that we may 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 that we may 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;
- acquire new products, or develop new indications or line extensions for existing products, in the event that revenues from our existing products are impacted by price controls, loss of intellectual property exclusivity or competition; 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, 2023, we had a U.S. federal net operating loss ("NOL") carryforward of approximately $137.5 million and state NOL carryovers of approximately $202.4 million. The U.S. federal and state NOL carryforwards expire at various dates through 2037. Federal NOLs and certain state NOLs incurred in 2018 and onward have an indefinite expiration under the Tax Cuts and Jobs Act of 2017 and applicable state statutes. We also had U.S. federal tax credits of approximately $1.0 million, and state tax credits of approximately $0.7 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 ("IRC 382").

In 2021, we completed a study to assess the impact of ownership changes, if any, on our ability to use our NOL and tax credit carryovers as defined under IRC 382 (the "IRC 382 Study"). As a result of the study, we concluded that there were ownership changes that occurred during the years 2006, 2012 and 2015 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre-ownership change federal NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses.

As part of the BDSI acquisition, we acquired an estimated $234.7 million of federal NOL carryovers which are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under IRC 382. We performed an IRC 382 study following the BDSI Acquisition in 2022 and concluded that there were ownership changes that occurred during the years 2006 and 2022 that would be subject to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use pre-ownership change federal NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially limit our ability to reduce our future federal income tax liability by using these losses. As of December 31, 2023, remaining net operating losses of $124.3 million are subject to limitation. Refer to Note 18, *Income Taxes*, to our consolidated financial statements included in Part IV of this Annual Report on Form 10-K for more information.

We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations.

In March 2022, we entered into a $650.0 million secured term loan (the "2022 Term Loan") pursuant to our Amended and Restated 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 "2022 Loan Agreement"), of which $412.5 million in principal was outstanding as of December 31, 2023. In addition, we have $26.4 million in 2.625% Convertible Senior Notes due in 2026 (the "2026 Convertible Notes") and $241.5 million in 2.875% Convertible Senior Notes due 2029 (the "2029 Convertible Notes" and, together with the 2026 Convertible Notes, the "Convertible Notes"). 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, and among other things:

- requiring the dedication of a substantial portion of our cash flows 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;
- exposing us to the risk of increased interest rates as certain of our borrowings, including the 2022 Term Loan, are at variable rates of interest;
- 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; and
- increasing our vulnerability to downturns in our business, our industry or the economy in general.

Holders of our Convertible Notes, 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, and any failure by us to repurchase notes or to pay the cash amounts due upon the conversion when required would constitute a default under the indenture.

Additionally, the indentures governing the Convertible Notes and our 2022 Loan Agreement contain certain covenants and obligations applicable to us, including, without limitation, 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, which could limit our ability to capitalize on business opportunities that may arise or otherwise place us at a competitive disadvantage relative to our competitors.

Failure to comply with covenants in the indentures governing the Convertible Notes or in the 2022 Loan Agreement would constitute an event of default under those instruments, notwithstanding our ability to meet our debt service obligations. A default under the indentures or a fundamental change could also result in a default under one or more of the 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 that would become due. The 2022 Loan Agreement includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the 2022 Loan Agreement and execution upon the collateral securing obligations under the 2022 Loan Agreement. In addition, because our assets are pledged as a security under the 2022 Loan Agreement, if we are not able to cure any default or repay outstanding borrowings, our assets would be subject to the risk of foreclosure by our lenders.

Further, amounts outstanding under our 2022 Loan Agreement historically bore interest at a rate based on the London Interbank Offered Rate (“LIBOR”), and, effective July 1, 2023, bears interest at a rate based on the Secured Overnight Financing Rate (“SOFR”) subject to a SOFR floor of 1.2%. We have not hedged our interest rate exposure with respect to our floating rate debt. Accordingly, our interest expense for any period will fluctuate based on SOFR and other variable interest rates, as applicable. To the extent the interest rates applicable to our floating rate debt increase, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition, or results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in early 2023, several financial institutions closed and were taken into receivership by the Federal Deposit Insurance Corporation (“FDIC”). Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. Further, investor concerns regarding domestic or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to cash and liquidity resources could, among other risks, adversely impact our ability to meet our financial obligations, which could have material adverse impacts on our liquidity and our business, financial condition, or results of operations.

Risks Related to our Products

If we cannot continue successfully commercializing our products and any products that we may acquire in the future, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Our business and future success are substantially dependent on our ability to continue successfully commercializing our products, including Xtampza ER, the Nucynta Products, Belbuca and Symproic, and any products that we may acquire in the future.

Our ability to continue successfully commercializing our products will depend on many factors, including but not limited to:

- our ability to manufacture commercial quantities of our products 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;
- with respect to Xtampza ER, 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;
- our ability to acquire new products, or develop new indications or line extensions for existing products, in the event that revenues from our existing products are impacted by price controls, loss of intellectual property exclusivity or competition; 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 any of our products, including our abuse-deterrent claims with respect to Xtampza ER, and our ability to market our products 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 a 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 any of our 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.

Our opioid 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 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. As opioids, Xtampza ER, the Nucynta Products and Belbuca are subject to the Opioid Analgesic REMS.

Any modification of the Opioid Analgesic REMS by the FDA to impose additional or more burdensome requirements could increase the costs associated with marketing these products and/or reduce the willingness of healthcare providers to prescribe these products, which would have a material adverse effect on our ability to continue to successfully commercialize and generate sufficient revenue from these products.

Failure to comply with ongoing governmental regulations for marketing our products, and in particular any failure to promote Xtampza ER's abuse deterrent labeling in compliance with FDA regulations, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

In addition to scrutiny by the FDA, advertising and promotion of any pharmaceutical product marketed in the United States is heavily scrutinized by, among others, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services, 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 government agencies.

In particular, 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.

Engaging in off-label promotion of our products, including Xtampza ER, could subject us to false claims liability under federal and state statutes, and other litigation and/or investigations, and could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of our products, including Xtampza ER.

Further, 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 realizing the full commercial potential of our products.

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could be costly 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 products we may acquire, 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, including in connection with our pending litigation against generic competitors that have filed Paragraph IV Certifications relating to certain of our products. 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 United States Patent and Trademark Office ("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 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, including with respect to our recent acquisition of Belbuca and Symproic, 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.

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 continue to accept and use our products, or accept and use any new products that we may acquire. 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 of physicians and other healthcare community members of 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;
- 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, DEA, 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, the Nucynta Products, Belbuca, and Symproic for substantially all of our revenues for the foreseeable future, the failure of these products to maintain market acceptance would harm our business prospects.

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

Some of our products 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 and the active ingredient in Belbuca, buprenorphine, is classified as a Schedule III controlled substance. A number of states also independently regulate these drugs, including oxycodone, tapentadol and buprenorphine, 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.

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, refer to the section in our Annual Report entitled "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 (for Schedule I and II substances), recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with 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 manufacturing 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 affect our ability to commercialize our products. For example, several states, including New York, have imposed taxes or fees on the sale of opioids. Other states, and even the federal government, 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 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.

In August 2022, the Inflation Reduction Act of 2022 was signed into law. This legislation contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would subject manufacturers of some brand-name medications without generic or biosimilar competition to a price negotiation program that results in a negotiated "maximum fair price" (or pay an excise tax for noncompliance), the establishment of rebate payment requirements on manufacturers of drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and revises the way manufacturers provide discounts on Part D drugs. The IRA also caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000 per year, thereby eliminating the Medicare Part D coverage gap or "donut hole." Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of the IRA on our business and the pharmaceutical industry in general is not yet known.

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 continue to commercialize our 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 products, including 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. Refer to the section in our Annual Report entitled "Business — Government Regulation — Healthcare Reform."

Further changes to and under the Affordable Care Act remain possible. 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 payors. 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 continue 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, the Nucynta Products and Belbuca; 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 payors may not be willing to pay a premium for abuse-deterrent formulations of opioids.

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 in our Annual Report under the caption "Business — Government Regulation — DEA and Opioid Regulation."

If the FDA or other applicable regulatory authorities approve generic products with 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. Additionally, under FDORA, FDA will assign therapeutic equivalence ratings for certain prescription drugs approved via the Section 505(b)(2) NDA pathway with respect to other approved drug products and it is unclear how assignment of these ratings will impact the market opportunity for our products. 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 the past, we have initiated litigation with generic competitors that have filed Paragraph IV Certifications challenging certain of our patents. While we have entered into settlement agreements with certain competitors, we are currently pursuing litigation to defend against Paragraph IV Certifications related to Belbuca. Refer to Note 13, *Commitments and Contingencies*, to our consolidated financial statements included in Part IV of this Annual Report on Form 10-K. We believe that we will continue to be subject to ANDA-related litigation, which can be costly and distracting and has the potential to impact the long-term value of our products.

We may seek FDA pediatric exclusivity for some of our products. Pediatric exclusivity, if granted, adds six months of patent term and marketing exclusivity to existing exclusivity periods for all formulations, dosage forms, and indications for the active moiety, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The regulatory exclusivity period for Nucynta IR in the United States has been extended through July 3, 2026, following the grant of New Patient Population exclusivity in pediatrics by the FDA in August 2023 based on data from pediatric trials which were submitted in response to the FDA's Pediatric Written Request to evaluate the use of Nucynta as a treatment for pain in pediatric patients aged 6 years and older. If FDA deems these data to be responsive to its Written Request, the exclusivity of the entire Nucynta franchise could be extended an additional six months, to December 2025 for Nucynta ER and January 2027 for Nucynta IR. However, there is no guarantee that FDA will agree that the Written Request has been satisfied and that we will receive this additional exclusivity, or that we will maintain such exclusivity, if granted.

In November 2017, the 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 the FDA’s wider focus on assisting developers of generic abuse-deterrent formulations in navigating 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 our products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges with our dedicated manufacturing suite 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 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 for Xtampza ER at a site operated by our contract manufacturing organization, Patheon, part of Thermo Fisher Scientific. This facility requires the maintenance of regulatory approvals and other costs, all of which we absorb. We cannot guarantee that we will be able to continue 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.

We have also transitioned commercial manufacturing for Nucynta ER from Janssen to Patheon. While we were successful in our regulatory approval and validation activities, we could encounter issues in obtaining commercial supply from Patheon's facility due to technical problems or challenges obtaining adequate and/or timely DEA procurement quota.

Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional costs, to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and 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, 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 we could experience technical problems in the operation of our dedicated manufacturing suite;
- 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; and
- 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 our products, which could in turn adversely affect our results of operations and financial condition. Likewise, the inability of any of our sole or limited suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our products. In addition, DEA regulations, through the quota procurement process, limit the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to maintain an appreciable safety stock of finished drug product.

Our reliance on third parties reduces our control over our manufacturing 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 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 inspection deficiencies, a shortage of commercial product, or potential products liability exposure for any noncompliant distributed products. Such failure could also 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, 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 or limited number of suppliers to manufacture the active pharmaceutical ingredient of our products, any production problems with any of these suppliers could have a material adverse effect on us.

We currently rely on a sole supplier or limited number of suppliers to manufacture the active pharmaceutical ingredients of our products. We contract with these suppliers for commercial supply to manufacture our products. Further, our suppliers for Xtampza ER and the Nucynta Products active pharmaceutical ingredients also supply our primary competitor in the extended-release oxycodone space, Purdue. Identifying alternate sources of active pharmaceutical ingredients for our products is generally time-consuming and costly. Any changes that our suppliers make 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 suppliers were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of any disruptions in personnel or the global supply chain), 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.

Global supply chain disruptions and shortages may limit manufacturing and commercial supply of our products and have a material impact on our business.

There are currently global supply chain disruptions and shortages caused by a variety of factors, including geopolitical turmoil, such as the Ukrainian War and current conflict in Israel and Gaza. While we and our suppliers are still able to receive sufficient inventory of the key materials and components needed, we could experience pressure on our supply chain, including shipping delays, higher prices from suppliers, and reduced availability of materials, including excipients and packaging components. To date, supply chain pressure has not had a material impact on our results of operations. However, if these disruptions and shortages continue, we may in the future experience a material interruption to our supply chain. Such an interruption could have a material adverse impact on our business, including but not limited to, our ability to timely manufacture and distribute our products.

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 successfully commercialize our products. 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 or their distribution network is disrupted, our financial condition and results of operations may be adversely affected.

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented greater than 90% of our product shipments for the year ended December 31, 2023. Our loss of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases or a significant disruption to transportation infrastructure or other means of distribution of our products, 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 wholesaler 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.

Certain of our opioid products are subject to post-marketing requirements or commitments, which may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control.

For certain of our products, we are subject to post-marketing requirements to conduct epidemiological studies and clinical trials, or, in some cases, to conduct post-marketing surveillance or observational studies to gather additional information about our products. For our opioid products, we generally 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 the 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 opioid products. Additionally, there may be certain PMRs or post-marketing commitments that we fulfill on our own for our products, including via the conduct of post-marketing surveillance or observational studies. If such studies lead to the discovery of adverse findings regarding the safety or benefit profiles of our products, then the FDA may choose to withdraw or otherwise restrict the approval of our products or the FDA or we may determine that labeling changes are warranted based on their finding. Such withdrawal or restriction or labeling changes for our products would have an adverse impact on our business and financial condition.

Risks Related to Our Business and Strategy

We may not realize all the anticipated benefits from our future acquisitions, and we may be unable to successfully integrate future acquisitions.

Our growth strategy will, in part, rely on acquisitions. We must plan and manage acquisitions effectively to achieve revenue growth and maintain profitability in our evolving market. We may not realize all the anticipated benefits from our future acquisitions, such as increased earnings, cost savings and revenue enhancements, for various reasons, including difficulties integrating operations and personnel, higher than expected acquisition and operating costs or other difficulties, inexperience with operating in new geographic regions, unknown liabilities, inaccurate reserve estimates and fluctuations in market prices.

In addition, integrating acquired businesses and properties involves a number of special risks and unforeseen difficulties can arise in integrating operations and systems and in retaining and assimilating employees. These difficulties include, among other things:

- operating a larger organization;
- coordinating geographically disparate organizations, systems, and facilities;
- integrating corporate, technological, and administrative functions;
- diverting management's attention from regular business concerns;
- diverting financial resources away from existing operations;
- increasing our indebtedness; and
- incurring potential environmental or regulatory liabilities and title problems.

Any of these or other similar risks could lead to potential adverse short-term or long-term effects on our operating results. The process of integrating our operations could cause an interruption of, or loss of momentum in, the activities of our business. Members of our management may be required to devote considerable amounts of time to this integration process, which decreases the time they have to manage our business. If our management is not able to effectively manage the integration process, or if any business activities are interrupted as a result of the integration process, our business could suffer.

Our business may be adversely affected by certain events or circumstances outside our control, including macroeconomic conditions and geopolitical turmoil.

Events or circumstances outside of our control, including macroeconomic conditions such as recession or depression, inflation, and declines in consumer-spending could result in reduced demand for our products. An economic downturn could result in business closures, higher levels of unemployment, or declines in consumer disposable income which

could 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 may make efforts to avoid or postpone seeking non-essential medical care to allocate their resources to other priorities or essential items. These circumstances, in addition to the impact of geopolitical turmoil, such as the ongoing Ukrainian War and current conflict in Israel and Gaza (including any escalation or expansion), social unrest, political instability in the United States and elsewhere, terrorism, cyberwarfare or other acts of war, may result in reduced demand for our products and negatively impact our sales, results of operations, and liquidity.

Security breaches and other disruptions to our, or our vendors', information technology systems may compromise our information and expose us to liability that could adversely impact our financial condition, operations, and reputation.

We, our collaborators, third-party providers, distributors, customers and other contractors utilize information technology systems and networks ("Systems") to transmit, store and otherwise process electronic data in connection with our business activities, including our supply chain processes, operations and communications including, in some cases, our business proprietary information, and Electronic Data Interchange ("EDI") on purchase orders, invoices, chargebacks, among other things. Our Systems, along with those of the third parties whom we rely on to process confidential and sensitive data in a variety of contexts, are potentially vulnerable to a variety of evolving threats that may expose this data to unauthorized persons or otherwise compromise its integrity. These threats may include, but are not limited to, social-engineering attacks (including through phishing attacks), business email compromise, online and offline fraud, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, access attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

We may expend significant resources to try to protect against these threats to our Systems. Certain data privacy and security laws, as well as industry best practice standards, may require us to implement and maintain security measures. While we have implemented security measures designed to protect our Systems and confidential and sensitive data, there can be no assurance that these measures will be effective. Threat actors and their techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. If we, or a third party upon whom we rely, experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Further, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices.

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. These lawsuits generally allege that we had engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. In March 2022, we entered into a Master Settlement Agreement resolving 27 pending opioid-related lawsuits brought against us by cities, counties, and other subdivisions in the United States. As part of the Master Settlement Agreement, we paid $2.75 million to the plaintiffs and the cases were dismissed, with prejudice. In late March 2023, three new cases were filed in three federal courts, naming us as one of numerous defendants, from which we have been dismissed.

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. In December 2021, we entered into an Assurance of Discontinuance with the Massachusetts Attorney General pursuant to which we provided certain assurances and agreed to pay certain of the Massachusetts Attorney General's costs of investigation, in exchange for closure of the investigation and a release of claims pertaining to the subject matter of the investigation. We are cooperating fully in the open 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.

Competition in the pain and opioid market is intense. Our competitors include 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, 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 develop technologies that are, or may be, the basis for competitive products that are safer, more effective or less costly than our products. Moreover, 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 any products we acquire, 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; 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. 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 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. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our business model, prospects or 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 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, 2023, there were outstanding options to purchase an

aggregate of 1,176,750 shares of our common stock at a weighted average exercise price of $19.48 per share, of which options to purchase 1,158,209 shares of our common stock were then exercisable. The exercise of options 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.

There can be no assurance that we will repurchase additional shares of our common stock at all or at favorable prices.

In August 2021, our Board of Directors authorized a repurchase program for the repurchase of up to $100 million of shares of our common stock at any time or times through December 31, 2022 (the "Prior Repurchase Program"). We repurchased $61.9 million of shares pursuant to the Prior Repurchase Program prior to its expiration on December 31, 2022. In January 2023, our Board of Directors authorized a share repurchase program for the repurchase of up to $100.0 million of shares of our common stock through December 31, 2023 (the "2023 Repurchase Program"). We repurchased $75.0 million of shares pursuant to the 2023 Repurchase Program prior to its expiration on December 31, 2023.

In January 2024, our Board of Directors authorized a new share repurchase program for the repurchase of up to $150.0 million of shares of our common stock through June 30, 2025 (the "2024-2025 Repurchase Program"). The 2024-2025 Repurchase Program permits us to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act. Share repurchases under the 2024-2025 Repurchase Program will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our common stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will continue to repurchase shares of our common stock at favorable prices, if at all.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We maintain a cybersecurity program designed to assess, identify, and mitigate risks from cybersecurity threats. This program is informed by the five elements of the National Institute of Standards and Technology framework: identify, protect, detect, respond, and recover. We utilize various methods to achieve these objectives including but not limited to company-wide policies and operating procedures, periodic testing, systems monitoring, patch management, and mandatory ongoing employee trainings. Additionally, we partner with third-party experts to conduct periodic penetration tests and to evaluate our information technology infrastructure for vulnerabilities. We also evaluate cybersecurity risks associated with third-party vendors that provide the hosted applications we use in our financial close process through review of their System and Organization Controls ("SOC") 1 reports at least annually. We continue to invest in our information technology infrastructure and cybersecurity program to strengthen our ability to protect the confidentiality, integrity, and availability of our data and the security of our information systems.

In addition to our cybersecurity program, we assess cybersecurity risks as part of our overall risk management processes, primarily through our annual Enterprise Risk Assessment. Our Enterprise Risk Assessment surveys various employees and leaders throughout our organization with the goal of evaluating our risk landscape, enhancing our overall understanding of risks to our business, and ultimately managing and/or mitigating identified risks. We assess various risks, including cybersecurity related risks, based on the likelihood of an incident occurring, impact to our organization if an incident occurred, and the level of internal control we currently have over the risk. The results are analyzed to identify vulnerabilities and then risk management/mitigation plans are designed, implemented, and evaluated for effectiveness.

If a cybersecurity incident were to occur, we would implement our incident response plan in an effort to contain and mitigate the threat. As part of our incident response plan, our Cybersecurity Incident Response Team (a cross-functional taskforce comprised of senior representatives), would convene to assess the potential impact to our business, including financial reporting requirements and legal implications.

We, like other companies in our industry, face a number of cybersecurity risks in connection with our business. Although such risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we and/or our vendors have, from time to time, experienced threats to, or security incidents, related to our data and systems or that had the potential to otherwise impact our business. For more information about the cybersecurity risks we face, refer to “Item 1A. Risk Factors.”

Governance

One of the key functions of our Board is informed oversight of our risk management process. Our Board administers this oversight function directly through our Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. Our Audit Committee, a subcommittee of our Board, is responsible for the oversight of risks from cybersecurity threats. The Audit Committee receives updates at least quarterly from our Head of Information Technology regarding developments in our information technology infrastructure and cybersecurity program. This includes updates, as appropriate, on key information technology initiatives, new and existing cybersecurity risks, how management is managing those risks, and, if any, material cybersecurity incidents and the impact to our business and performance.

At the management level, our Head of Information Technology is responsible for assessing and managing risks from cybersecurity threats through oversight of our information technology infrastructure and cybersecurity program. The individual occupying this role has over 20 years of experience in information technology and cybersecurity and has served in senior cybersecurity leadership positions for over 10 years. Thus, we believe our Head of Information Technology is well-qualified to serve in this role. Our Head of Information Technology conducts bi-weekly meetings with our information technology department to remain apprised of cybersecurity matters. If a cybersecurity incident were to occur, our Head of Information Technology may inform our Executive Vice President and Head of Technological Operations and/or Audit Committee, depending on the severity of the incident in accordance with the established severity and response matrix as defined in our incident response plan.

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 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 13, *Commitments and Contingencies*, 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 has been 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, 2024, there were 12 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.

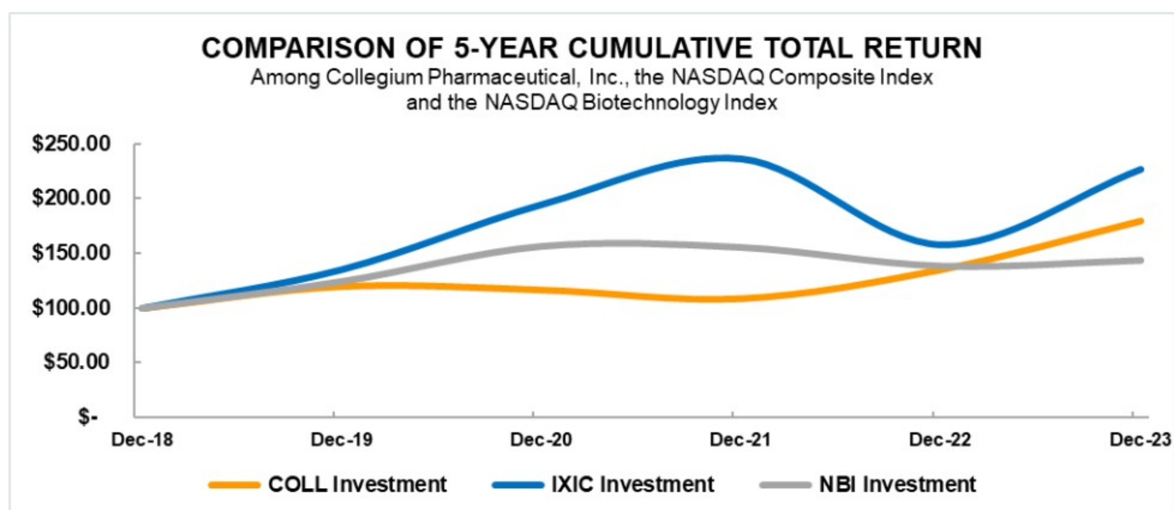
Dividends

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 sets forth the Company's total cumulative shareholder return as compared to the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the 5-year period beginning on December 31, 2018 through December 31, 2023.

Total cumulative shareholder return assumes an investment of $100.00 in cash in our common stock at the beginning of the 5-year period compared to the same investment in the NASDAQ Composite Index and the NASDAQ Biotechnology Index. 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	December 31, 2018		December 31, 2023	
Collegium Pharmaceutical, Inc. (COLL)	$	100.00	$	179.27
NASDAQ Composite Index (IXIC)	$	100.00	$	226.24
NASDAQ Biotechnology Index (NBI)	$	100.00	$	143.60

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 shares of common stock repurchased under our repurchase program authorized by our Board of Directors in January 2023 (the "2023 Repurchase Program"), as well as shares transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of performance share units and restricted stock units during the three months ended December 31, 2023:

Period	Total number of shares purchased	Average Price Paid per Share	Total number of shares purchased as part of publicly announced plans or programs [1]	Maximum approximate dollar value of Shares that may yet be purchased under the plans or programs (in thousands)
October 1, 2023 through October 31, 2023	467,247	$ 23.10	462,442	$ 50,000
November 1, 2023 through November 30, 2023	867,532	27.09	865,426	30,000
December 1, 2023 through December 31, 2023	59,791	27.12	57,349	25,000
Total	1,394,570 [2]	$ 25.75	1,385,217 [2]	$ 25,000

(1) The 2023 Repurchase Program was announced on January 4, 2023. The 2023 Repurchase Program provided for the repurchase of up to $100.0 million of outstanding shares of our common stock at any time or times through December 31, 2023. The 2023 Repurchase Program expired on December 31, 2023 with approximately $25.0 million available for repurchase at the time of expiration.

(2) The difference, if any, between the total number of shares purchased and the total number of shares purchased as part of a publicly announced program relates to common stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of performance share units and restricted stock units granted under our Amended and Restated 2014 Stock Incentive Plan.

Item 6. [Reserved]

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 building a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. We commercialize our pain portfolio, consisting of Xtampza ER, Nucynta ER and Nucynta IR (collectively the "Nucynta Products"), Belbuca, and Symproic, in the United States.

Xtampza ER, an abuse-deterrent, oral formulation of oxycodone, was approved by the United States Food and Drug Administration ("FDA") in April 2016 for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. We commercially launched Xtampza ER in June 2016.

The Nucynta Products are extended-release ("ER") and immediate-release ("IR") formulations of tapentadol. Nucynta ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic, 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 and pediatric patients aged 6 years and older with a body weight of at least 40 kg. We began shipping and recognizing product sales on the Nucynta Products in January 2018 and began marketing the Nucynta Products in February 2018. In August 2023, the FDA granted New Patient Population exclusivity in pediatrics for Nucynta IR. This grant extended the period of U.S. exclusivity for Nucynta IR from June 27, 2025 to July 3, 2026.

On March 22, 2022, we acquired BioDelivery Sciences International, Inc. ("BDSI"), a specialty pharmaceutical company working to deliver innovative therapies for individuals living with serious and debilitating chronic conditions (the "BDSI Acquisition"). Upon closing of the BDSI Acquisition, we acquired Belbuca and Symproic.

Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative options are inadequate. Symproic was approved by the FDA in March 2017 for the treatment of opioid-induced constipation ("OIC") in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. We began shipping and recognizing product sales related to Belbuca and Symproic in March 2022.

Financial Operations Overview

Product Revenues

Product revenues through the year ended December 31, 2023 were primarily generated from sales of Xtampza ER, the Nucynta Products, Belbuca, and Symproic. In accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers,* ("ASC 606") product sales are recorded upon delivery of products to customers (upon the transfer of control of the product to the customer), 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 and impairment expense for the intangible assets acquired in connection with business combinations and asset acquisitions, royalty expenses, 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. Refer to Note 5, *License Agreements*, and Note 11, *Goodwill and Intangible Assets,* for further detail around the intangible assets acquired from the BDSI Acquisition, the Nucynta Intangible Asset and royalty expenses.

Research and Development Expenses

Research and development expenses have historically consisted of product development expenses incurred in identifying, developing, and testing product candidates 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. These costs have historically been expensed as incurred.

As of April 1, 2022, we focused entirely on commercial products rather than research and development and redirected resources from research and development activities. As such, there were no expenses incurred in research and development after the three months ended March 31, 2022.

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. 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 continue to be substantial for the foreseeable future.

Interest Expense

Interest expense consists primarily of cash and non-cash interest costs related to our debt, including the term loan issued in March 2022 in connection with the BDSI Acquisition (the "2022 Term Loan"), the term notes (the "2020 Term Loan") and convertible notes (the "2026 Convertible Notes") issued in February 2020 in connection with the Nucynta Acquisition, and convertible notes issued in February 2023 (the "2029 Convertible Notes").

On March 22, 2022 the outstanding balance related to the 2020 Term Loan was fully paid in connection with the closing of the BDSI Acquisition and establishment of the 2022 Term Loan.

Interest Income

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

Provision for Income Taxes

The provision for income taxes reflects expense or tax benefit for federal and state income taxes, as well as the impact of non-deductible expenses. During the year ended December 31, 2021, we removed the valuation allowance on the substantial majority of our deferred tax assets, resulting in the recognition of a discrete deferred tax benefit of $78.0 million in 2021.

Critical Accounting Policies and Significant Judgments and Estimates

Our "Management's Discussion and Analysis of 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, discounts and allowances related to commercial sales of our products, estimates related to the fair value of assets acquired and liabilities assumed, including acquired intangible assets and the fair value of inventory acquired, estimates utilized in the ongoing valuation of inventory related to potential unsalable product, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets and deferred 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.

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as “critical” because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results. 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 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 and others for the treatment of patients. 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 to our customers 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 to our customers net of estimated chargebacks, rebates, sales incentives and allowances, distribution service fees, as well as estimated product returns.

Sales Deductions

Sales deductions consist primarily of provisions for: (i) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (ii) product returns, including return estimates for our products; and (iii) 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 earnings in the period of the adjustment.

Provisions for product returns, including returns for Xtampza, the Nucynta Products, Belbuca and Symproic, are based on product-level returns rates, including processed as well as unprocessed return claims, in addition to relevant market events and other factors. Estimates of the future product returns are made at the time of revenue recognition to determine the amount of consideration to which we expect to be entitled (that is, excluding the products expected to be returned).

At the end of each reporting period, we analyze trends in returns rates and update our assessment of variable consideration for returns. To the extent we receive amounts in excess of what we expect to be entitled to receive due to a product return, we do not recognize revenue when we transfer products to customers but instead recognize those excess amounts received as a refund liability. We update the measurement of the refund liability at the end of each reporting period for changes in expectations about the amount of refunds with the corresponding adjustments recognized as revenue (or reductions of revenue).

We provide the right of return to our customers for an 18-month window beginning six months prior to expiration and up until twelve months after expiration. Our customers short-pay an existing invoice upon notice of a product return claim. Adjustments to the preliminary short-paid claims are processed when the return claim is validated and finalized. Our return policy requires that product is returned and that the return is claimed within the 18-month window. Refer to Note 3, *Revenue from Contracts with Customers*, for more information.

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. Actual results may differ from these estimates under different assumptions or conditions.

Business Combination Accounting and Valuation of Acquired Assets

We completed the BDSI Acquisition on March 22, 2022, which was accounted for as a business combination. To determine whether the acquisition should be accounted for as a business combination or as an asset acquisition, we made certain judgments regarding whether the acquired set of activities and assets met the definition of a business. Judgment is required in assessing whether the acquired processes or activities, along with their inputs, would be substantive to constitute a business, as defined by U.S. GAAP.

The acquisition method of accounting requires that we recognize the assets acquired and liabilities assumed at their acquisition date fair values. Goodwill is measured as the excess of consideration transferred over the acquisition date net fair values of the assets acquired and the liabilities assumed. The determination of the fair value of the acquired assets and liabilities assumed is a critical accounting estimate because the estimation of fair values requires significant management judgment and requires various assumptions based on non-observable inputs that are included in valuation models. An income approach, which generally relies upon projected cash flow models, is used in estimating the fair value of the acquired intangible assets and the fair value of acquired inventory. These cash flow projections are based on management's estimates of economic and market conditions including the estimated future cash flows from revenues of acquired assets, the timing and projection of costs and expenses and the related profit margins, tax rates, and an appropriate discount rate.

During the measurement period, which occurs before finalization of the purchase price allocation, changes in assumptions and estimates that result in adjustments to the fair values of assets acquired and liabilities assumed, if based on facts and circumstances existing at the acquisition date, are recorded on a retroactive basis as of the acquisition date, with the corresponding offset to goodwill. Any adjustments not based on facts and circumstances existing at the acquisition date, or if subsequent to the conclusion of the measurement period, will be recorded to our consolidated statements of operations.

Intangible Assets

We record the fair value of acquired 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, which is generally based on our cash flow projections. Future events, such as competition, technological advances, or other changes, are subject to uncertainty and could cause subsequent evaluations to cash flow projections. 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 (or asset group) 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, 2023, our intangible assets included those acquired in connection with the BDSI Acquisition and the Nucynta Intangible Asset.

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse.

We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized. In determining the extent to which a valuation allowance for deferred tax assets is required, we evaluate all available evidence including projections of future taxable income, carryback opportunities, reversal of certain deferred tax liabilities, and other tax planning strategies, all of which are subject to uncertainty. Certain deferred tax assets, such as net operating losses and tax credits, expire at varying dates and are generally subject to annual limitations under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC 382"). Significant judgment is required in making these evaluations, including comparing future annual income projections to the expiration dates and annual limitations of such assets. To the extent our future expectations change, we would have to assess the recoverability of these deferred tax assets at that time.

As a result of sustained positive earnings history as demonstrated through cumulative earnings, we are using projections of future taxable income as a source of realizing our deferred tax assets. We have maintained a valuation allowance on the portion of our deferred tax assets that are not more likely than not to be realized due to tax limitation or other conditions of $5.8 million as of December 31, 2023.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2023 compared to the year ended December 31, 2022. For a discussion of the year ended December 31, 2022 compared to the year ended December 31, 2021, 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, 2022.

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes the results of our operations for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Product revenues, net	$ 566,767	$ 463,933
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	94,838	118,190
Intangible asset amortization and impairment	145,760	136,255
Total cost of products revenues	240,598	254,445
Gross profit	326,169	209,488
Operating expenses		
Research and development	—	3,983
Selling, general and administrative	159,208	172,186
Total operating expenses	159,208	176,169
Income from operations	166,961	33,319
Interest expense	(83,339)	(63,213)
Interest income	15,615	1,047
Loss on extinguishment of debt	(23,504)	—
Income (loss) before income taxes	75,733	(28,847)
Provision for (benefit from) income taxes	27,578	(3,845)
Net income (loss)	$ 48,155	$ (25,002)

Product revenues, net

Product revenues, net were $566.8 million for the year ended December 31, 2023 (“2023”), compared to $463.9 million for the year ended December 31, 2022 (“2022”), representing a $102.9 million increase. The $102.9 million increase is primarily due to increases in revenue for Belbuca of $55.6 million, Xtampza ER of $38.6 million, the Nucynta Products of $6.3 million, and Symproic of $4.2 million, partially offset by decreases in other revenue of $1.8 million.

The increase in revenue for Belbuca of $55.6 million and Symproic of $4.2 million is primarily due to a full year of revenue in 2023, compared to a partial year of revenue in 2022 due to the timing of the BDSI Acquisition.

The increase in revenue for Xtampza ER of $38.6 million is primarily due to lower gross-to-net adjustments primarily related to provisions for rebates and higher gross price, partially offset by lower sales volume and higher gross-to-net adjustments related to provisions for returns.

The increase in revenue for the Nucynta Products of $6.3 million is primarily due to lower gross-to-net adjustments primarily related to provisions for rebates and returns and higher gross price, partially offset by decreased sales volume.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $94.8 million for 2023, compared to $118.2 million for 2022. The $23.4 million decrease was primarily related to 2022 including higher cost of product revenues related to the step-up basis in inventory acquired from BDSI as well as lower sales volume in 2023 for Xtampza and the Nucynta Products.

Intangible asset amortization was $145.8 million for 2023, compared to $136.3 million for 2022. The $9.5 million increase in intangible asset amortization was due to a full year of amortization expense recognized in 2023 related to the intangible assets acquired from BDSI of which $435.0 million of consideration was allocated to our acquired intangible assets, compared to a partial year of amortization expense in 2022. This increase was partially offset by a decrease in amortization expense as a result of the FDA granting New Patient Population exclusivity in pediatrics for Nucynta IR to July 3, 2026, resulting in an extension of the estimated useful life of the underlying intangible asset. The intangible assets are amortized on a straight-line basis over the respective estimated useful lives.

Operating expenses

We did not recognize research and development expenses in 2023, compared to $4.0 million recognized in 2022. The $4.0 million decrease was due to redirection of resources from research and development activities during 2022 as we shifted our focus to supporting our commercial products rather than research and development.

Selling, general and administrative expenses were $159.2 million for 2023, compared to $172.2 million for 2022. The $13.0 million decrease was primarily related to:

- a decrease in acquisition related expenses classified as selling, general and administrative of $30.6 million; partially offset by
- an increase in salaries, wages, and benefits of $8.7 million, primarily due to increases in personnel costs for employees retained following the BDSI Acquisition and higher stock-based compensation expenses;
- an overall increase in audit and legal expenses of $5.0 million, primarily due to an $8.5 million litigation settlement;
- an increase in sales and marketing expenses of $3.1 million, primarily due to expenses incurred to support the ongoing commercialization of products acquired from BDSI; and
- an increase in regulatory expenses of $0.8 million, primarily due to a full year of expenses related to products acquired from BDSI.

Interest expense and Interest income

Interest expense was $83.3 million for 2023, compared to $63.2 million for 2022. The $20.1 million increase was primarily due to the 2022 Term Loan that we entered into in connection with the BDSI Acquisition, higher interest rates impacting our variable rate term loan debt, and higher interest expense due to the issuance of the 2029 Convertible Notes (offset by the partial repurchase of the 2026 Convertible Notes).

Interest income was $15.6 million for 2023, compared to $1.0 million for 2022. The $14.6 million increase was primarily due to a higher overall balance invested in 2023 compared to 2022 and higher interest rates earned on cash equivalents and marketable securities.

Loss on extinguishment of debt

We recognized a $23.5 million loss on extinguishment of debt in 2023 in connection with the repurchase of a portion of our 2026 Convertible Notes. This transaction involved a contemporaneous exchange of cash between us and holders of the 2026 Convertible Notes participating in the issuance of the 2029 Convertible Notes. The repurchase of the 2026 Convertible Notes and issuance of the 2029 Convertible Notes were deemed to have substantially different terms based on the present value of the cash flows immediately prior to and after the exchange. Therefore, the repurchase of the 2026 Convertible Notes was accounted for as a debt extinguishment.

Income Taxes

The provision for income taxes was $27.6 million for 2023, compared to a $3.8 million benefit from income taxes for 2022. The tax provision for 2023 was impacted by non-deductible costs, including non-deductible costs associated with the debt extinguishment that occurred in the first quarter of 2023 as well as non-deductible costs related to stock-based compensation, including 162(m) limitations. In 2022, we recognized a deferred tax benefit, partially offset by state income tax expense. The provision for income taxes in 2022 primarily consisted of state income tax for states for which our state-level NOLs did not fully offset state-level taxable income. The effective tax rate was 36.4% and 13.3% for 2023 and 2022, respectively.

Liquidity and Capital Resources

Sources of Liquidity

Historically, we have funded our operations primarily through the private placements and/or public offerings of our preferred stock, common stock, and convertible notes; commercial bank debt; and cash inflows from sales of our products. We are primarily dependent on the commercial success of Belbuca, Xtampza, and the Nucynta Products. In March 2022, our debt balance increased significantly as we modified the 2020 Term Loan with Pharmakon to an increased principal balance of $650.0 million to fund a portion of the consideration paid to complete the BDSI Acquisition. We paid $100.0 million in principal payments during the first year of the 2022 Term Loan and the remaining $550.0 million balance will be paid in equal quarterly installments over the remaining three years of the term note. As of December 31, 2023, the outstanding principal balance of the 2022 Term Loan was $412.5 million, of which $183.3 million in principal payments are due within the next 12 months. As of December 31, 2023, the outstanding principal balance of the Convertible Notes was $267.9 million, of which $26.4 million is due in 2026 and $241.5 million is due in 2029. As of December 31, 2023, and December 31, 2022, we had $238.9 million and $173.7 million in cash and cash equivalents, respectively.

We believe that our cash, cash equivalents, and marketable securities as of December 31, 2023, together with expected cash inflows from operations, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Borrowing Arrangements and Equity Offerings

The following transactions represent our material borrowing arrangements and equity offerings: the 2022 Term Loan, the 2026 Convertible Notes, and the 2029 Convertible Notes. Refer to Note 14, *Debt*, for more information.

Cash flows

In this section, we discuss cash flows for the year ended December 31, 2023 compared to the year ended December 31, 2022. For a discussion of the year ended December 31, 2022 compared to the year ended December 31, 2021, 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, 2022.

	Years Ended December 31,	
	2023	2022
	(in thousands)	
Net cash provided by operating activities	$ 274,749	$ 124,230
Net cash used in investing activities	(70,812)	(573,691)
Net cash (used in) provided by financing activities	(140,178)	436,723
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 63,759	$ (12,738)

Operating activities. Cash provided by operating activities was $274.7 million in 2023, compared to $124.2 million in 2022. The $150.5 million increase in cash provided by operating activities was primarily due to the increase in cash flow from operating results, which reflects operating earnings, after adjustment for non-cash items that are included in net income, including higher intangible asset amortization as a result of the BDSI Acquisition and recognition of a loss on extinguishment of debt in connection with the repurchase of a portion of our 2026 Convertible Notes, as well as changes in working capital.

Investing activities. Cash used in investing activities was $70.8 million in 2023, compared to $573.7 million in 2022. The $502.9 million decrease in cash used in investing activities was primarily due to the use of $572.1 million for the BDSI Acquisition in 2022, net of cash acquired, partially offset by purchases and maturities of marketable securities in 2023.

Financing activities. Cash used in financing activities was $140.2 million in 2023, compared to cash provided by financing activities of $436.7 million in 2022. The $576.9 million decrease was primarily due to:

- the repayment of the outstanding balance of the 2020 Term Loan and establishment of the 2022 Term Loan in connection with the BDSI Acquisition, which was accounted for as a debt modification and resulted in $517.7 million in proceeds from the term note modification in 2022;
- an increase in repayments of term notes of $87.5 million; and
- an increase in repurchases of common stock of $60.9 million, which includes $75.0 million related to accelerated share repurchases executed in 2023; partially offset by
- the repurchase of a portion of our 2026 Convertibles Notes and issuance of our 2029 Convertible Notes which resulted in net proceeds of $96.6 million in 2023.

Funding requirements

We believe that our cash, cash equivalents, and marketable securities as of December 31, 2023, together with expected cash inflows from operations, 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.

We have significant future capital requirements, including:

- expected operating expenses to manufacture and commercialize our products and to operate our organization;
- repayment of outstanding principal amounts and interest in connection with our 2022 Term Loan and Convertible Notes;
- royalties we pay on sales of certain products within our portfolio;
- operating lease obligations;
- minimum purchase obligations in connection with our contract manufacturer; and
- cash paid for income taxes.

In addition, we have significant potential future capital requirements, including:
- we may enter into business development transactions, including acquisitions, collaborations, licensing arrangements and equity investments, that require additional capital; and
- in January 2024, our Board of Directors authorized a new share repurchase program for the repurchase of up to $150.0 million of shares of our common stock through June 30, 2025. Future share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial conditions, the price of our common stock on the NASDAQ Global Select Market, and other factors that we may deem relevant.

Contractual Obligations

Our contractual obligations as of December 31, 2023 that will affect our future liquidity include our term loan, including interest; convertible senior notes, including interest; operating lease obligations; and purchase obligations. For further detail regarding our term notes and convertible senior notes, refer to Note 14, *Debt.* For further detail regarding our operating lease obligations, refer to Note 15, *Leases*.

Our purchase obligations represent the minimum purchase obligations of up to $3.0 million per year with our contract manufacturer which are in effect as of December 31, 2023 and will remain in effect each year until the termination of our manufacturing agreement.

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, and therefore, are not calculable at this time.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we have included information about certain non-GAAP financial measures. We believe the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide analysts, investors, lenders, and other third parties with insights into how we evaluate normal operational activities, including our ability to generate cash from operations, on a comparable year-over-year basis and manage our budgeting and forecasting. In addition, certain non-GAAP financial measures, primarily Adjusted EBITDA, are used to measure performance when determining components of annual compensation for substantially all non-sales force employees, including senior management.

We may discuss the following financial measures that are not calculated in accordance with GAAP in our quarterly and annual reports, earnings press releases and conference calls.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. 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 or 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: (i) 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 (ii) 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 the benefit from or provision for income taxes or the cash requirements to pay taxes;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
- we exclude impairment expenses from adjusted EBITDA and, although these are non-cash expenses, the asset(s) being impaired may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;
- we exclude litigation settlements from adjusted EBITDA, as well as any applicable income items or credit adjustments due to subsequent changes in estimates. This does not include our legal fees to defend claims, which are expensed as incurred;
- we exclude acquisition related expenses as the amount and/or frequency of these expenses are not part of our underlying business. Acquisition related expenses include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete the acquisition, employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, and miscellaneous other acquisition related expenses incurred;
- we exclude recognition of the step-up basis in inventory from acquisitions (i.e., the adjustment to record inventory from historic cost to fair value at acquisition) as the adjustment does not reflect the ongoing expense associated with sale of our products as part of our underlying business; and
- we exclude losses on extinguishments of debt as these expenses are episodic in nature and do not directly correlate to the cost of operating our business on an ongoing basis.

Adjusted EBITDA for the years ended December 31, 2023 and 2022 was as follows:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
GAAP net income (loss)	$ 48,155	$ (25,002)
Adjustments:		
Interest expense	83,339	63,213
Interest income	(15,615)	(1,047)
Loss on extinguishment of debt	23,504	—
Provision for (benefit from) income taxes	27,578	(3,845)
Depreciation	3,496	2,684
Amortization	145,760	131,469
Impairment expense	—	4,786
Stock-based compensation	27,136	22,874
Litigation settlements	8,500	—
Acquisition related expenses	—	31,297
Recognition of step-up basis in inventory	15,116	39,584
Total adjustments	$ 318,814	$ 291,015
Adjusted EBITDA	$ 366,969	$ 266,013

Adjusted EBITDA was $367.0 million for 2023 compared to $266.0 million for 2022. The $101.0 million increase was primarily due to higher revenues and gross profit before excluded costs, partially offset by higher adjusted operating expenses.

The following is a summary of 2023 quarterly Adjusted EBITDA:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands)			
GAAP net (loss) income	$ (17,426)	$ 13,007	$ 20,634	$ 31,940
Adjustments:				
Interest expense	21,427	21,863	20,768	19,281
Interest income	(2,747)	(4,027)	(4,538)	(4,303)
Loss on extinguishment of debt	23,504	—	—	—
(Benefit from) provision for income taxes	(131)	4,790	8,149	14,770
Depreciation	817	895	835	949
Amortization	37,466	37,463	36,317	34,514
Stock-based compensation	6,035	7,072	7,027	7,002
Litigation settlements	8,500	—	—	—
Recognition of step-up basis in inventory	10,170	4,748	198	—
Total adjustments	$ 105,041	$ 72,804	$ 68,756	$ 72,213
Adjusted EBITDA	$ 87,615	$ 85,811	$ 89,390	$ 104,153

Adjusted Operating Expenses

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations.

Adjusted operating expenses for the years ended December 31, 2023 and 2022 were as follows:

	Years Ended December 31,	
	2023	2022
	(in thousands)	
GAAP operating expenses	$ 159,208	$ 176,169
Adjustments:		
Stock-based compensation	27,136	22,874
Litigation settlements	8,500	—
Acquisition related expenses	—	31,297
Total adjustments	$ 35,636	$ 54,171
Adjusted operating expenses	$ 123,572	$ 121,998

Adjusted operating expenses were $123.6 million for 2023 compared to $122.0 million for 2022. The $1.6 million increase was primarily driven by:

- an increase in salaries, wages, and benefits (excluding stock-based compensation) of $1.8 million, primarily due to increases in personnel costs for employees retained following the BDSI Acquisition;
- an increase in sales and marketing expenses of $3.1 million, primarily due to expenses incurred to support the ongoing commercialization of products acquired from BDSI;
- an increase in regulatory expenses of $0.8 million, primarily due to a full year of expenses related to products acquired from BDSI; partially offset by
- a decrease in audit and legal expenses (excluding litigation settlements) of $3.5 million.

The following is a summary of 2023 quarterly adjusted operating expenses:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands)			
GAAP operating expenses	$ 52,775	$ 38,193	$ 35,298	$ 32,942
Adjustments:				
Stock-based compensation	6,035	7,072	7,027	7,002
Litigation settlements	8,500	—	—	—
Total adjustments	14,535	7,072	7,027	7,002
Adjusted operating expenses	$ 38,240	$ 31,121	$ 28,271	$ 25,940

Adjusted Net Income and Adjusted Earnings Per Share

Adjusted net income is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude significant income and expense items that are non-cash or not indicative of ongoing operations, including consideration of the tax effect of the adjustments. Adjusted earnings per share is a non-GAAP financial measure that represents adjusted net income per share. Adjusted weighted-average shares - diluted is calculated in accordance with the treasury stock, if-converted, or contingently issuable accounting methods, depending on the nature of the security.

Adjusted net income and adjusted earnings per share for the years ended December 31, 2023 and 2022 were as follows:

	Years Ended December 31,	
	2023	2022
	(in thousands, except share and per share data)	
GAAP net income (loss)	$ 48,155	$ (25,002)
Adjustments:		
Non-cash interest expense	8,635	8,285
Loss on extinguishment of debt	23,504	—
Amortization	145,760	131,469
Impairment expense	—	4,786
Stock-based compensation	27,136	22,874
Litigation settlements	8,500	—
Acquisition related expenses	—	31,297
Recognition of step-up basis in inventory	15,116	39,584
Income tax effect of above adjustments (1)	(53,526)	(60,553)
Total adjustments	$ 175,125	$ 177,742
Non-GAAP adjusted net income	$ 223,280	$ 152,740
Adjusted weighted-average shares — diluted (2)	41,788,125	39,531,814
Adjusted earnings per share (2)	$ 5.47	$ 3.96

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate to the adjustments that have a tax effect. The blended federal and state statutory rate for the years ended December 31, 2023 and 2022 were 25.9% and 26.0%, respectively. As such, the non-GAAP effective tax rates for the years ended December 31, 2023 and 2022 were 23.4% and 25.4%, respectively.

(2) Adjusted weighted-average shares - diluted were calculated using the "if-converted" method for the convertibles notes in accordance with ASC 260, *Earnings per Share*. As such, adjusted weighted-average shares – diluted includes shares related to the assumed conversion of our convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income. For the years ended December 31, 2023 and 2022, adjusted weighted-average shares – diluted includes 6,793,421 and 4,925,134 shares, respectively, attributable to our convertible notes. In addition, adjusted earnings per share includes other potentially dilutive securities to the extent that they are not antidilutive.

The following is a summary of 2023 quarterly adjusted net income and adjusted earnings per share:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except share and per share data)			
GAAP net (loss) income	$ (17,426)	$ 13,007	$ 20,634	$ 31,940
Adjustments:				
Non-cash interest expense	2,287	2,261	2,124	1,963
Loss on extinguishment of debt	23,504	—	—	—
Amortization	37,466	37,463	36,317	34,514
Stock-based compensation	6,035	7,072	7,027	7,002
Litigation settlements	8,500	—	—	—
Recognition of step-up basis in inventory	10,170	4,748	198	—
Income tax effect of above adjustments (1)	(18,874)	(12,100)	(11,300)	(11,252)
Total adjustments	$ 69,088	$ 39,444	$ 34,366	$ 32,227
Non-GAAP adjusted net income	$ 51,662	$ 52,451	$ 55,000	$ 64,167
Adjusted weighted-average shares — diluted (2)	40,196,015	42,849,952	42,058,820	41,279,982
Adjusted earnings per share (2)	$ 1.32	$ 1.26	$ 1.34	$ 1.58

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate to the adjustments that have a tax effect. The blended federal and state statutory rate for the three months ended March 31, June 30, September 30, and December 31, 2023 were 26.8%, 24.0%, 25.6%, and 25.9%, respectively. As such, the non-GAAP effective tax rates for the three months ended March 31, June 30, September 30, and December 31, 2023 were 21.5%, 23.5%, 24.7%, and 25.9%, respectively.

(2) Adjusted weighted-average shares - diluted were calculated using the "if-converted" method for the convertibles notes in accordance with ASC 260, *Earnings per Share*. As such, adjusted weighted-average shares – diluted includes shares related to the assumed conversion of our convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income. For the three months ended March 31, June 30, September 30, and December 31, 2023, adjusted weighted-average shares – diluted includes 4,646,372, 7,509,104, 7,509,104, and 7,509,104 shares, respectively, attributable to our convertible notes. In addition, adjusted earnings per share includes other potentially dilutive securities to the extent that they are not antidilutive.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Our primary exposure to market risk is interest rate sensitivity in connection with our investment portfolio and the 2022 Term Loan. None of these market risk sensitive instruments are held for trading purposes.

Investment Portfolio

Our investment portfolio includes financial instruments that are sensitive to interest rate risks. Our investment portfolio is used to preserve capital, maintain liquidity sufficient to meet cash flow requirements, and maximize returns commensurate with our risk appetite. We invest in instruments that meet the credit quality, diversification, liquidity, and maturity standards outlined in our investment policy.

As of December 31, 2023, our investment portfolio includes $82.0 million of cash equivalents and $71.6 million of marketable securities, which are primarily comprised of money market funds, U.S. Treasury securities, corporate debt, and government-sponsored securities. Our money market funds are short-term highly liquid investments, and our marketable securities have active secondary or resale markets to help ensure liquidity. We account for marketable securities as available-for-sale, thus, no gains or losses are realized due to changes in the fair value of our marketable securities unless we sell our investments prior to maturity or incur a credit loss. Furthermore, our investment policy includes guidelines limiting the term-to-maturity of our investments. Due to the nature of our investments, we do not believe that the fair value of our investments has a material exposure to interest rate risk.

2022 Term Loan

The 2022 Term Loan bears interest at a rate based upon the Secured Overnight Financing Rate ("SOFR") plus a spread adjustment of 0.26% (subject to a floor of 1.20%), plus a margin of 7.5% per annum. Based on the outstanding principal amount of the 2022 Term Loan as of December 31, 2023 of $412.5 million and the applicable interest rate, a hypothetical 1% increase or decrease in interest rates would increase or decrease future interest expense by approximately $4.1 million.

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, 2023.

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 our evaluation, Management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

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, 2023 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, 2023 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, 2023, 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, 2023, 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, 2023, of the Company and our report dated February 22, 2024, 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 22, 2024

Item 9B. Other Information

Insider Trading Arrangements

During the three months ended December 31, 2023, none of our directors or officers adopted, amended, or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

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 — Our Executive Officers*," the information required to be furnished pursuant to this item is incorporated herein by reference to our definitive proxy statement for the 2024 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.

Insider Trading Policies

Our Board of Directors has adopted an Insider Trading Policy which governs the purchase, sales, and/or other dispositions of our securities by directors, officers, and employees. Our Insider Trading Policy is attached hereto as Exhibit 19 and incorporated herein.

Item 11. Executive Compensation

The information required by this Item 11 is incorporated herein by reference from our definitive proxy statement for the 2024 Annual Meeting of Shareholders under the captions "Compensation Discussion and Analysis," "Executive Compensation" (excluding the information under the heading "Pay Versus Performance"), "Director Compensation" and "Compensation Committee Report."

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 2024 Annual Meeting of Shareholders under the captions "Compensation Discussion and Analysis," "Executive Compensation" (excluding the information under the heading "Pay Versus Performance"), "Director Compensation" and "Compensation Committee Report."

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 2024 Annual Meeting of Shareholders under the captions "Compensation Discussion and Analysis," "Executive Compensation" (excluding the information under the heading "Pay Versus Performance"), "Director Compensation" and "Compensation Committee Report."

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 2024 Annual Meeting of Shareholders under the captions “Compensation Discussion and Analysis,” “Executive Compensation” (excluding the information under the heading “Pay Versus Performance”), “Director Compensation” and “Compensation Committee Report.”

PART IV

Item 15. Exhibits and Financial Statement Schedules

Consolidated Financial Statements

Refer to 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 as of February 14, 2022, by and among Collegium Pharmaceutical, Inc., Bristol Acquisition Company, Inc. and BioDelivery Sciences International, Inc.	(1)
3.1 †	Third Amended and Restated Articles of Incorporation of Collegium Pharmaceutical, Inc.	(2)
3.2 †	Amended and Restated Bylaws of Collegium Pharmaceutical, Inc.	(3)
4.1 †	Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.	(4)
4.2 †	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.	(4)
4.3 †	Form of certificate representing the 2.625% Convertible Senior Notes due 2026 (included as Exhibit A to Exhibit 4.2).	(4)
4.4 †	Indenture, dated as of February 10, 2023, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.	(5)
4.5 †	Form of certificate representing the 2.875% Convertible Senior Notes due 2029 (included as Exhibit A to Exhibit 4.4).	(5)
4.6 †	Description of the Registrant’s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	(6)
10.1 †	Office Lease agreement by and between Campanelli-Trigate 100 TCD Stoughton, LLC, and Collegium Pharmaceutical, Inc as of March 23, 2018.	(7)
10.2 +†	2015 Employee Stock Purchase Plan.	(8)
10.3 +†	Performance Bonus Plan.	(9)
10.4(a) +†	Amended and Restated 2014 Stock Incentive Plan.	(8)
10.4(b) +†	Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.	(8)
10.4(c) +†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan.	(8)
10.4(d) +	Form of Restricted Stock Unit Agreement under the Amended and Restated 2014 Stock Incentive Plan.	
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.	(9)
10.6 +†	Amended & Restated Employment Agreement, dated December 27, 2020, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.	(11)

10.7 +†	Amended & Restated Employment Agreement, dated December 27, 2020, by and between Shirley Kuhlmann and Collegium Pharmaceutical, Inc.	(11)
10.8 +†	Amended & Restated Employment Agreement, dated December 27, 2020, by and between Collegium Pharmaceutical, Inc. and Scott Dreyer.	(11)
10.9 †	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.	(12)
10.10* †	Consent Agreement, dated January 30, 2020, by and among Grünenthal GmbH, Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc.	(12)
10.11* †	Settlement Agreement, dated September 29, 2020, by and among Collegium Pharmaceutical, Inc. and Teva Pharmaceuticals USA, Inc.	(13)
10.12 +†	Employment Agreement, dated May 24, 2021, by and between Colleen Tupper and Collegium Pharmaceutical, Inc.	(14)
10.13* †	Amended and Restated Loan Agreement, dated as of March 22, 2022, by and among Collegium Pharmaceutical, Inc., the guarantors party thereto, BioPharma Credit PLC, and BioPharma Credit Investments V (Master) LP, as lenders.	(15)
10.14	First Amendment and Consent to Amended and Restated Loan Agreement, dated as of January 3, 2023, by and among Collegium Pharmaceutical, Inc., the guarantors party thereto, BioPharma Credit PLC, and BioPharma Credit Investments V (Master) LP, as lenders.	
10.15 †	Second Amendment to Loan Agreement, dated as of February 6, 2023, Amended and Restated Loan Agreement, dated as of March 22, 2022, by and among Collegium Pharmaceutical, Inc., the guarantors party thereto, BioPharma Credit PLC, and BioPharma Credit Investments V (Master) LP, as lenders.	(16)
10.16 †	Third Amendment to Loan Agreement, dated as of June 23, 2023, by and among Collegium Pharmaceutical, Inc., the guarantors party thereto, BioPharma Credit PLC, and Bio Pharma Credit Investments V (Master) LP, as lenders.	(17)
10.17* †	Exclusive License Agreement, dated April 4, 2019, between the Company and Shionogi, Inc. (incorporated by reference to Exhibit 10.19 to the Annual Report on Form 10-K filed by BDSI on March 9, 2022).	(18)
10.18 +†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.	(18)
10.19 +†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Colleen Tupper.	(18)
10.20 +†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Shirley Kuhlmann.	(18)
10.21 +†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Scott Dreyer.	(18)
10.22 +†	Employment Agreement, dated March 23, 2022 by and between Collegium Pharmaceutical, Inc. and Thomas Smith.	(18)
19	Insider Trading Policy	
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.	
97	Compensation Recovery Policy	
101	The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2023, formatted in Inline XBRL: (i) Consolidated Balance Sheets as of December 31, 2023, and 2022, (ii) Consolidated Statements of Operations for the years ended December 31, 2023, 2022 and 2021, (iii) Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2023, 2022 and 2021, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022 and 2021, 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 Securities and Exchange Commission ("SEC") upon request.

(1) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on February 14, 2022.

(2) 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 SEC on August 5, 2020.

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

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

(5) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on February 13, 2023.

(6) Previously filed as an exhibit to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 23, 2023.

(7) 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 SEC on May 9, 2018.

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

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

(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 SEC on May 8, 2019.

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

(12) 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 SEC on May 7, 2020.

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

(14) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 filed with the SEC August 5, 2021.

(15) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the SEC on March 23, 2022.

(16) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 filed with the SEC May 4, 2023.

(17) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023 filed with the SEC August 3, 2023.

(18) Previously filed as an exhibit to the registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022 filed with the SEC May 10, 2022.

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 Joseph Ciaffoni	President and Chief Executive Officer (Principal Executive Officer) and Director	February 22, 2024
/s/ Colleen Tupper Colleen Tupper	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 22, 2024
/s/ Michael T. Heffernan, R.Ph. Michael T. Heffernan, R.Ph.	Chairman of the Board	February 22, 2024
/s/ Rita Balice-Gordon, Ph.D. Rita Balice-Gordon, Ph.D.	Director	February 22, 2024
/s/ Garen G. Bohlin Garen G. Bohlin	Director	February 22, 2024
/s/ John A. Fallon, M.D. John A. Fallon, M.D.	Director	February 22, 2024
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	February 22, 2024
/s/ Gwen Melincoff Gwen Melincoff	Director	February 22, 2024
/s/ Gino Santini Gino Santini	Director	February 22, 2024
/s/ Neil McFarlane Neil McFarlane	Director	February 22, 2024

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

Audited Consolidated Financial Statements	**Pages**
Report of Independent Registered Public Accounting Firm (*PCAOB ID 34*)	F-2
Consolidated Balance Sheets as of December 31, 2023 and 2022	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2023, 2022, and 2021	F-5
Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2023, 2022, and 2021	F-7
Consolidated Statements of Cash Flows for the Years Ended December 31, 2023, 2022, and 2021	F-8
Notes to Consolidated Financial Statements	F-9

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, 2023 and 2022, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 22, 2024, 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 Recognition – Product Return Liability – Refer to Note 3 to the Financial Statements

Critical Audit Matter Description

Revenue is recognized when control is transferred to the customer, which occurs upon delivery, and revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer (“transaction price”). The transaction price for product sales includes variable consideration related to sales deductions and a refund liability is established for estimated product returns. At the end of each reporting period, the Company updates the estimated transaction price (including updating its assessment of whether an estimate of variable consideration should be constrained). Variable consideration, including the risk of customer concessions, is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is subsequently resolved. The Company updates the measurement of the refund liability at the end of each reporting period for changes in expectations about the amount of refunds with the corresponding adjustments recognized as revenue (or reductions of revenue).

Estimating the variable consideration and the provision for the refund liability requires significant judgment by management. Given the complexity and significant level of estimation uncertainty involved in calculating the refund liability, our audit procedures 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 deductions for returns and the refund liability (the "return provision") included the following, among others:

- We tested the effectiveness of controls over the measurement and recognition of the return provision.
- We evaluated the Company's methodology and significant assumptions made in developing the return provision.
- We tested the completeness and accuracy of the data underlying the measurement of the return provision.
- We tested the mathematical accuracy of management's underlying calculation of the return provision.
- We performed a retrospective review, comparing prior period product return estimates to actual product returns.
- We developed independent estimates of the return provision using historical sales and returns activity, product dating and expiration dates, and other information.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 22, 2024

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, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 238,947	$ 173,688
Marketable securities	71,601	—
Accounts receivable, net	179,525	183,119
Inventory	32,332	46,501
Prepaid expenses and other current assets	15,195	16,681
Total current assets	537,600	419,989
Property and equipment, net	15,983	19,521
Operating lease assets	6,029	6,861
Intangible assets, net	421,708	567,468
Restricted cash	1,047	2,547
Deferred tax assets	26,259	23,950
Other noncurrent assets	825	100
Goodwill	133,857	133,695
Total assets	$ 1,143,308	$ 1,174,131
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 8,692	$ 3,494
Accrued liabilities	37,571	36,129
Accrued rebates, returns and discounts	227,331	230,491
Current portion of term notes payable	183,333	162,500
Current portion of operating lease liabilities	988	1,112
Total current liabilities	457,915	433,726
Term notes payable, net of current portion	221,713	397,578
Convertible senior notes	262,125	140,873
Operating lease liabilities, net of current portion	6,124	7,112
Total liabilities	947,877	979,289
Commitments and contingencies (refer to Note 13)		
Shareholders' equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000; 38,192,441 issued and 31,868,549 outstanding shares as of December 31, 2023 and 37,084,759 issued and 33,848,936 outstanding shares as of December 31, 2022	38	37
Additional paid-in capital	565,949	538,073
Treasury stock, at cost; 6,323,892 shares as of December 31, 2023 and 3,235,823 shares as of December 31, 2022	(137,381)	(61,924)
Accumulated other comprehensive income	14	—
Accumulated deficit	(233,189)	(281,344)
Total shareholders' equity	195,431	194,842
Total liabilities and shareholders' equity	$ 1,143,308	$ 1,174,131

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,		
	2023	**2022**	**2021**
Product revenues, net	$ 566,767	$ 463,933	$ 276,868
Cost of product revenues			
Cost of product revenues (excluding intangible asset amortization)	94,838	118,190	59,070
Intangible asset amortization and impairment	145,760	136,255	67,181
Total cost of products revenues	240,598	254,445	126,251
Gross profit	326,169	209,488	150,617
Operating expenses			
Research and development	—	3,983	9,451
Selling, general and administrative	159,208	172,186	118,960
Restructuring	—	—	4,578
Total operating expenses	159,208	176,169	132,989
Income from operations	166,961	33,319	17,628
Interest expense	(83,339)	(63,213)	(21,014)
Interest income	15,615	1,047	12
Loss on extinguishment of debt	(23,504)	—	—
Income (loss) before income taxes	75,733	(28,847)	(3,374)
Provision for (benefit from) income taxes	27,578	(3,845)	(74,891)
Net income (loss)	$ 48,155	$ (25,002)	$ 71,517
Earnings (loss) per share — basic	$ 1.43	$ (0.74)	$ 2.05
Weighted-average shares — basic	33,741,213	33,829,495	34,936,817
Earnings (loss) per share — diluted	$ 1.29	$ (0.74)	$ 1.86
Weighted-average shares — diluted	41,788,125	33,829,495	41,045,805

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

COLLEGIUM PHARMACEUTICAL, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)

	Years Ended December 31,		
	2023	**2022**	**2021**
Net income (loss)	$ 48,155	$ (25,002)	$ 71,517
Other comprehensive income:			
Unrealized gains on marketable securities	14	—	—
Total other comprehensive income	14	—	—
Comprehensive income (loss)	$ 48,169	$ (25,002)	$ 71,517

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 Capital	Treasury Stock		Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount		Shares	Amount			
Balance as of December 31, 2020	34,612,054	$ 35	$ 519,143	—	$ —	$ (333,147)	$ —	$ 186,031
Cumulative effect of adjustment for adoption of ASU 2020-06	—	—	(44,777)	—	—	5,288	—	(39,489)
Exercise of common stock options	803,485	1	11,868	—	—	—	—	11,869
Issuance for employee stock purchase plan	43,719	—	755	—	—	—	—	755
Vesting of RSUs and PSUs	511,743	—	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(164,882)	—	(4,149)	—	—	—	—	(4,149)
Share repurchases	—	—	—	(2,150,717)	(42,861)	—	—	(42,861)
Forward contract on ASR agreement	—	—	(5,000)	—	—	—	—	(5,000)
Stock-based compensation	—	—	24,255	—	—	—	—	24,255
Net income	—	—	—	—	—	71,517	—	71,517
Balance as of December 31, 2021	35,806,119	$ 36	$ 502,095	(2,150,717)	$ (42,861)	$ (256,342)	$ —	$ 202,928
Exercise of common stock options	742,348	—	11,811	—	—	—	—	11,811
Issuance for employee stock purchase plan	22,627	—	337	—	—	—	—	337
Vesting of RSUs and PSUs	699,285	1	—	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(226,286)	—	(4,044)	—	—	—	—	(4,044)
Share repurchases	—	—	5,000	(1,085,106)	(19,063)	—	—	(14,063)
Exercise of warrant	40,666	—	—	—	—	—	—	—
Stock-based compensation	—	—	22,874	—	—	—	—	22,874
Net loss	—	—	—	—	—	(25,002)	—	(25,002)
Balance as of December 31, 2022	37,084,759	$ 37	$ 538,073	(3,235,823)	$ (61,924)	$ (281,344)	$ —	$ 194,842
Exercise of common stock options	498,008	—	8,641	—	—	—	—	8,641
Issuance for employee stock purchase plan	26,505	—	460	—	—	—	—	460
Vesting of RSUs and PSUs	898,817	1	—	—	—	—	—	1
Shares withheld for employee taxes upon vesting of RSUs and PSUs	(315,648)	—	(8,361)	—	—	—	—	(8,361)
Share repurchases	—	—	—	(3,088,069)	(75,457)	—	—	(75,457)
Stock-based compensation	—	—	27,136	—	—	—	—	27,136
Other comprehensive income, net of tax	—	—	—	—	—	—	14	14
Net income	—	—	—	—	—	48,155	—	48,155
Balance as of December 31, 2023	38,192,441	$ 38	$ 565,949	(6,323,892)	$(137,381)	$ (233,189)	$ 14	$ 195,431

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,		
	2023	2022	2021
Operating activities			
Net income (loss)	$ 48,155	$ (25,002)	$ 71,517
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Amortization and impairment expense	145,760	136,255	67,181
Depreciation expense	3,496	2,684	1,736
Deferred income taxes	(2,153)	(8,391)	(78,042)
Stock-based compensation expense	27,136	22,874	24,255
Non-cash lease (benefit) expense	(280)	238	18
Loss on extinguishment of debt	23,504	—	—
Non-cash interest expense for amortization of debt discount and issuance costs	8,635	8,285	3,406
Net amortization of premiums and discounts on investments	(1,235)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	3,594	(21,780)	(22,524)
Inventory	14,169	48,274	(2,296)
Prepaid expenses and other assets	1,439	(4,606)	(1,086)
Accounts payable	5,061	(707)	(5,827)
Accrued liabilities	628	(11,131)	4,777
Accrued rebates, returns and discounts	(3,160)	(22,766)	40,442
Operating lease assets and liabilities	—	3	—
Net cash provided by operating activities	274,749	124,230	103,557
Investing activities			
Purchases of property and equipment	(461)	(1,622)	(1,944)
Purchases of marketable securities	(92,351)	—	—
Maturities of marketable securities	22,000	—	—
Acquisition of BDSI (net of cash acquired)	—	(572,069)	—
Net cash used in investing activities	(70,812)	(573,691)	(1,944)
Financing activities			
Proceeds from issuances of common stock from employee stock purchase plans	460	337	755
Proceeds from the exercise of stock options	8,641	11,811	11,952
Payments made for employee stock tax withholdings	(8,361)	(4,044)	(4,149)
Repurchases of common stock	(75,000)	(14,063)	(47,861)
Repayment of term notes	(162,500)	(75,000)	(50,000)
Proceeds from term note modification	—	517,682	—
Proceeds from issuances of 2029 convertible notes, net of issuance costs of $6,280	235,220	—	—
Repurchase of 2026 Convertible Notes, including premium	(138,638)	—	—
Net cash (used in) provided by financing activities	(140,178)	436,723	(89,303)
Net increase (decrease) in cash, cash equivalents and restricted cash	63,759	(12,738)	12,310
Cash, cash equivalents and restricted cash at beginning of year	176,235	188,973	176,663
Cash, cash equivalents and restricted cash at end of year	$ 239,994	$ 176,235	$ 188,973
Reconciliation of cash, cash equivalents and restricted cash to the Consolidated Balance Sheets:			
Cash and cash equivalents	$ 238,947	$ 173,688	$ 186,426
Restricted cash	1,047	2,547	2,547
Total cash, cash equivalents and restricted cash	$ 239,994	$ 176,235	$ 188,973
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 73,256	$ 52,528	$ 17,608
Cash paid for income taxes	$ 24,205	$ 10,400	$ 3,005
Supplemental disclosure of non-cash activities			
Acquisition of property and equipment in accounts payable and accrued liabilities	$ 176	$ —	$ 72
Excise tax on share repurchases in accrued liabilities	$ 457	$ —	$ —
Inventory used in the construction and installation of property and equipment	$ —	$ —	$ 516

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

1. Nature of Business

Organization

Collegium Pharmaceutical, Inc. (the “Company” or “Collegium”) 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’s mission is to build a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. The Company’s portfolio includes Xtampza ER, Nucynta ER and Nucynta IR (collectively the “Nucynta Products”), Belbuca, and Symproic.

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, product-related litigation, 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.

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 Corporation (a Massachusetts corporation), Collegium NF LLC (a Delaware limited liability company), BioDelivery Sciences International, Inc. (a Delaware corporation), Arius Pharmaceuticals, Inc. (a Delaware corporation), and Arius Two, Inc. (a Delaware corporation), all 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 the 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, discounts and allowances related to commercial sales of products, estimates related to the fair value of assets acquired and liabilities assumed, including acquired intangible assets and the fair value of inventory acquired, estimates utilized in the ongoing valuation of inventory related to potential unsalable product, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, impairment of intangible assets and deferred 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

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. An active market is defined as a market where transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.
Level 2 inputs:	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.
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.

The Company's approach to fair value measurement is aligned with its investment policy focused on capital preservation. The Company invests in instruments within defined credit parameters to minimize credit risk while ensuring liquidity.

There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2023 and 2022.

The following table presents the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument as of December 31, 2023 and 2022.

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2023				
Cash equivalents:				
Money market funds	$ 77,299	$ 77,299	$ —	$ —
U.S. Treasury securities	4,729	—	4,729	—
Marketable securities:				
Corporate debt securities	41,612	—	41,612	—
U.S. Treasury securities	25,468	—	25,468	—
Government-sponsored securities	4,521	—	4,521	—
Total assets measured at fair value	$ 153,629	$ 77,299	$ 76,330	$ —
December 31, 2022				
Cash equivalents:				
Money market funds	$ 172,590	$ 172,590	$ —	$ —
Total assets measured at fair value	$ 172,590	$ 172,590	$ —	$ —

The Company's cash equivalents, which consist of money market funds, are measured at fair value on a recurring basis using quoted market prices. Accordingly, these securities are categorized as Level 1.

Assets and Liabilities Not Carried at Fair Value

The Company's convertible senior notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined based on data points other than quoted prices that are observable, either directly or indirectly, such as broker quotes in a non-active market. As of December 31, 2023, the fair value of the Company's 2.625% convertible senior notes due in 2026 was $25,033 and the net carrying value was $25,992. As of December 31, 2023, the fair value of the Company's 2.875% convertible senior notes due in 2029 was $249,803 and the net carrying value was $236,133.

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, 2023, the carrying amount of the term notes reasonably approximated the estimated fair value.

As of December 31, 2023, and 2022, the carrying amounts of the cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued liabilities, and accrued rebates, returns and discounts, reasonably approximated the 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, 2023, 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 and the nature of the assets in the money market funds.

Three customers comprised 10% or more of the Company's accounts receivable balance as of December 31, 2023. These customers comprised 38%, 35%, and 26% of the accounts receivable balance as of December 31, 2023 and 37%, 33%, and 28% as of December 31, 2022.

The same customers comprised 10% or more of the Company's revenue during the year ended December 31, 2023. These customers comprised 33%, 32%, and 32% of revenue during the year ended December 31, 2023; 33%, 32%, and 31% during the year ended December 31, 2022; and 35%, 31%, and 29% during the year ended December 31, 2021.

To date, the Company has not experienced any credit losses with respect to the collection of its accounts receivable and has not recorded an allowance for credit losses as of December 31, 2023 or 2022. 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, including bank deposits, and investments in 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.

Restricted Cash

Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months. Restricted cash as of December 31, 2023 represents cash held in a depository account at a financial institution to collateralize conditional standby letters of credit for the Company's lease of its corporate headquarters and its leases of vehicles for its field-based employees.

Marketable Securities

As of December 31, 2023, the Company's marketable securities consisted of investments in available-for-sale corporate debt, U.S. Treasury, and government-sponsored securities with readily determinable fair values. The Company classifies available-for-sale marketable securities as current assets on its consolidated balance sheets. The fair value of these securities is based on quoted prices for identical assets or inputs other than quoted prices that are observable for similar assets, either directly or indirectly.

The Company records interest earned and net amortization of premiums and discounts on investments within interest income on its consolidated statements of operations. The Company records unrealized gains (losses) on available-for-

sale debt securities as a component of "*Accumulated other comprehensive income,*" which is a separate component of shareholders' equity on its consolidated balance sheets, until such gains and losses are realized. Realized gains and losses are determined using the specific identification method.

For available-for-sale debt securities with unrealized losses, the Company assesses whether a credit loss allowance is required using an expected loss model. This process involves evaluating whether the fair value of an investment is recoverable when compared to its amortized cost. If an increase in fair value is observed, the Company may reduce any previously recognized credit losses. In determining whether impairments are other-than-temporary, the Company considers its ability and intention to hold the investment until market price recovery, as well as issuer-specific credit ratings, historical losses, and current economic conditions. The Company generally intends to retain investments until their amortized cost is recovered and did not identify any investments with other-than-temporary impairment as of December 31, 2023.

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 ingredients. 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.

The Company outsources the manufacturing of its products to contract manufacturers. In addition, the Company currently relies on a sole supplier or a limited number of suppliers for the active pharmaceutical ingredients in its products. Accordingly, the Company has concentration risk associated with its commercial manufacturing.

The Company expects to use the inventory over its operating cycle.

Business Combination Accounting and Valuation of Acquired Assets

To determine whether acquisitions should be accounted for as a business combination or as an asset acquisition, the Company makes certain judgments regarding whether the acquired set of activities and assets meets the definition of a business. Judgment is required in assessing whether the acquired processes or activities, along with their inputs, would be substantive to constitute a business, as defined by U.S. GAAP.

The acquisition method of accounting requires the recognition of assets acquired and liabilities assumed at their acquisition date fair values. Goodwill is measured as the excess of consideration transferred over the acquisition date net fair values of the assets acquired and the liabilities assumed. The determination of the fair value requires the estimation of fair values based on non-observable inputs that are included in valuation models. An income approach, which generally relies upon projected cash flow models, is used in estimating the fair value of the acquired intangible assets and the fair value of acquired inventory. These cash flow projections are based on management's estimates of economic and market conditions including the estimated future cash flows from revenues of acquired assets, the timing and projection of costs and expenses and the related profit margins, tax rates, and an appropriate discount rate.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the net assets acquired in a business combination. Goodwill is not amortized but is subject to impairment testing at least annually as of October 1 or when a triggering event occurs that could indicate a potential impairment. In performing the goodwill impairment test, the Company may first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying value. Alternatively, the Company may elect to proceed directly to the quantitative impairment test. In performing the quantitative analysis, the Company compares the fair value of the reporting unit with its carrying amount, including goodwill. If the carrying amount of the Company's reporting unit exceeds its fair value, the Company would recognize an impairment charge for the amount by which the carrying amount of the reporting unit exceeds its fair value, up to the amount of goodwill allocated to that reporting unit. The Company performed a qualitative assessment during the annual impairment review as of October 1, 2023 and concluded that it is not more likely than not that the fair value of the Company's reporting unit is less than its carrying amount.

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.

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.

Leases

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. At lease commencement, the Company measures the lease liability at the present value of the remaining lease payments discounted using the incremental borrowing rate and the corresponding lease asset is adjusted for incentives received and indirect costs. The Company records operating lease rent expense in the statements of operations over the lease term. Variable lease costs are not included in the measurement of the operating lease liability and 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 Company's consolidated balance sheets. Short-term lease expense is recognized on a straight-line basis over the lease term. The Company does not have any financing lease arrangements.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment, operating and finance lease assets, and definite-lived intangible assets. The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset (or asset group) would be compared to the carrying value of the asset to determine whether the asset's value is recoverable. If impairment is determined, the Company writes down the asset to its estimated fair value and records an impairment loss equal to the excess of the carrying value of the long-lived asset over its estimated fair value in the period at which such a determination is made.

Revenue Recognition

The Company's revenue to date is from sales of the Company's products, which are primarily sold to wholesale pharmaceutical distributors, which in turn sell the product to pharmacies for the treatment of patients. 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. Refer to Note 3, *Revenue from Contracts with Customers*, for more information.

Research and Development Costs

Research and development expenses have historically consisted of product development expenses incurred in identifying, developing, and testing product candidates. Product development expenses primarily consisted of labor, benefits, and related employee expenses for personnel directly involved in product development activities, fees paid to contract research organizations for managing clinical and non-clinical trials, and regulatory costs.

As of April 1, 2022, the Company focused entirely on commercial products rather than research and development and redirected resources from research and development activities. As such, there were no expenses incurred in research and development after the three months ended March 31, 2022.

Advertising and Product Promotion Costs

Advertising and product promotion costs are included in selling, general and administrative expenses and were $7,406, $11,743, and $4,186 in the years ended December 31, 2023, 2022, and 2021 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 the grant date fair value and recognizes compensation expense over the vesting period, net of actual forfeitures. For awards with service conditions, the Company recognizes compensation expense on a straight-line basis. The Company estimates the grant date fair value of stock options using the Black-Scholes option pricing model. The Company estimates the grant date fair value of restricted stock units based on the fair value of the underlying common stock. For awards with performance conditions, the Company estimates the number of shares that will vest based upon the probability of achieving performance metrics. For awards with market conditions, the Company recognizes compensation expense on an accelerated attribution basis. The Company estimates the grant date fair value of awards with market conditions using the Monte Carlo model.

Restructuring

During the three months ended December 31, 2021, the Company executed a plan to reduce its workforce, primarily related to its salesforce. The arrangements included the payment of a cash severance benefit near the time of separation, together with continued medical benefits and related services. As a result, the Company recognized $4,578 in restructuring expense. Of this amount, $1,335 was paid by December 31, 2021 and the remaining $3,243 was paid in the first half of 2022.

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.

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, 2023, 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

Basic earnings per share is calculated by dividing the net income or loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted earnings per share is computed by dividing the net income or 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, if-converted, or contingently issuable accounting methods, depending on the nature of the security. For purposes of the diluted earnings per share calculation, stock options, restricted stock units, performance share units, and shares potentially issuable in connection with the employee stock purchase plan and convertible senior notes are considered potentially dilutive securities and included to the extent that their addition is not anti-dilutive.

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*, ("ASC 815") 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 (refer to Note 14, *Debt*) 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 through December 31, 2023 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.

Recently Adopted Accounting Pronouncements

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

In August 2020, the FASB issued Accounting Standards Update ("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*. This ASU simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exceptions for contracts in an entity's own equity. Under ASU 2020-06, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital. Consequently, a convertible debt instrument, such as the Company's convertible senior notes, will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance also requires the if-converted method to be applied for all convertible instruments and requires additional disclosures.

The Company elected to early adopt this guidance on January 1, 2021 using the modified retrospective method. Under this transition method, the cumulative effect of the accounting change was removing the impact of recognizing the equity component of the Company's convertible notes (at issuance and the subsequent accounting impact of additional interest expense from debt discount amortization). The cumulative effect of the accounting change as of January 1, 2021 was an increase to the carrying amount of the convertible notes of $39,489, a reduction to accumulated deficit of $5,288, and a reduction to additional paid-in capital of $44,777. Interest expense of the convertible senior notes will be lower as a result of adoption of this guidance and diluted net loss per share will be computed using the if-converted method for the convertible senior notes. As a result of the adoption of this guidance, interest expense decreased and net income increased by $6,488, basic earnings per share was increased by $0.19, and diluted earnings per share was decreased by $0.06 for the year ended December 31, 2021.

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 were elective and applied to all entities that have contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued due to reference rate reform. The 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, *Reference Rate Reform (Topic 848): Scope,* in January 2021 to refine and clarify some of its guidance on ASU 2020-04 and ASU 2022-06, *Reference Rate Reform (Topic 848)* to defer the sunset date of Topic 848 from December 31, 2022 to December 31, 2024, after which entities will no longer be permitted to apply the relief in Topic 848. Following the cessation of LIBOR in the United States on June 30, 2023, the Company elected to apply the optional expedient provided in FASB ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* prospectively. Thus, debt previously referenced to LIBOR was transitioned to the Secured Overnight Financing Rate ("SOFR") effective July 1, 2023, however, such transition did not have a material effect on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07*, Segment Reporting (Topic 280).* The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740).* The amendments in this update expand income tax disclosure requirements, including additional information pertaining to the rate reconciliation, income taxes paid, and other disclosures. This update is effective for annual periods beginning after December 15, 2024. The adoption of this standard is not expected to have a material impact 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 wholesalers (customers), which in turn sell the product to pharmacies or other outlets for the treatment of patients.

Revenue Recognition

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 with a customer, 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, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

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.

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: (i) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (ii) product returns, including return estimates; and (iii) trade allowances and chargebacks, including fees for distribution services, 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.

The Company bases its estimates of variable consideration, which could include estimates of future rebates, returns, and other adjustments, on historical data and other information. Estimates include: (i) timing of the rebates and returns incurred; (ii) pricing adjustments related to rebates and returns; and (iii) the quantity of product that will be rebated or returned in the future. Significant judgment is used in determining the appropriateness of these assumptions at each reporting period.

Rebates and Incentives

Provisions for rebates and incentives are based on the estimated amount of rebates and incentives to be claimed on the related sales. 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 wholesalers. Given that wholesalers 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 future estimates, which could have an effect on earnings in the period of the adjustment.

Product Returns

Provisions for product returns, including returns for Xtampza, the Nucynta Products, Belbuca and Symproic, are based on product-level returns rates, including processed as well as unprocessed return claims, in addition to relevant market events and other factors. Estimates of the future product returns are made at the time of revenue recognition to determine the amount of consideration to which the Company expects to be entitled (that is, excluding the products expected to be returned). At the end of each reporting period, the Company analyzes trends in returns rates and updates its assessment of variable consideration. To the extent the Company receives amounts in excess of what it expects to be entitled to receive due to a product return, the Company does not recognize revenue when it transfers products to customers but instead recognizes those excess amounts received as a refund liability. The Company updates the measurement of the refund liability at the end of each reporting period for changes in expectations about the amount of refunds with the corresponding adjustments recognized as revenue (or reductions of revenue).

The Company provides the right of return to its customers for an 18-month window beginning six months prior to expiration and up until twelve months after expiration. The Company’s customers short-pay an existing invoice upon notice of a product return claim. Adjustments to the preliminary short-paid claims are processed when the return claim is validated and finalized. The Company’s return policy requires that product is returned and that the return is claimed within the 18-month window.

2021 Returns Adjustment

Prior to the year ended December, 31, 2021, estimates of the refund liability for Xtampza product returns were based on a combination of a limited amount of historical actual returns processed to date, taking into consideration the expiration date of product upon delivery to customers, as well as forecasted customer buying and return patterns, channel inventory levels, and other specifically known market events and trends. Sales of Xtampza increased significantly starting in 2018; as a result, the majority of Xtampza sold to customers by the Company had not been eligible for return until the year ended December 31, 2021, or beyond. For the Nucynta Products, estimates of the refund liability for product returns were based on historical returns rates as these products have been commercially sold in the U.S. since 2009 for Nucynta IR and since 2011 for Nucynta ER. Because the Company began selling the Nucynta Products in 2018, most of the Nucynta Products sold to customers by the Company were not eligible for return until the year ended December 31, 2021, or beyond.

During the year ended December 31, 2021, there were unprecedented and significant disruptions in the processing of product returns. Specifically, the Company's customers, via the third-party returns processor that they and many pharmacies engage to process the majority of the Company's product returns, failed to return products to the Company in the ordinary course. The value of actual returned product during the year ended December 31, 2021 represented less than 20% of the value of the product returns claimed during that period. Due to the failure of the customers and their vendor to return product timely in the ordinary course, the Company did not physically receive returned products corresponding to the substantial majority of the returns claimed and could not validate or finalize customer return claims, nor determine if the return was or would be eligible for refund upon the physical return. The lack of timely processing of requested product returns obscures information related to the validation of product returns and increases uncertainty related to the actual volume of product that will be physically returned and credited in accordance with the Company's returns policy.

During the fourth quarter of 2021, after significant and sustained efforts with customers to resolve the unprocessed return claims, the Company formally denied a significant portion of these claims under the Company's return policy. The Company subsequently received payment for only a portion of the denied claims and vigorously pursued collections of the full amount of these short-pay receivables. As a result of discussions with customers related to unprocessed return claims and the uncertainty associated with the ultimate resolution, as well as the impact of unprocessed claims on estimates of future returns, the Company recorded an adjustment to reduce product revenues, net of $38,329, with offsetting reductions in accounts receivable or increases in the refund liability for future product returns.

During the year ended December 31, 2022, the Company revised its estimate of variable consideration associated with unprocessed returns claims that arose in prior periods due to the receipt of payment and settlement, which resulted in an increase to product revenues, net of $4,684. During the year ended December 31, 2021, the Company's adjustment was a $26,644 reduction in product revenues.

Trade Allowances and Chargebacks

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.

At the end of each reporting period, the Company updates the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained). Variable consideration, including the risk of customer concessions, is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is subsequently resolved.

Significant judgment is required to determine the variable consideration included in the transaction price as described above. Adjustments to the estimated variable consideration included in the transaction price occurs when new information indicates that the estimate should be revised. If the value of accepted and processed claims is different than the amount estimated and included in variable consideration, then adjustments would impact product revenues, net and earnings in the period such revisions become known. The amount of variable consideration ultimately received and included in the transaction price may materially differ from the Company's estimates, resulting in additional adjustments recorded to increase or decrease product revenues, net.

The following table summarizes activity in each of the Company's product revenue provision and allowance categories for the years ended December 31, 2023, 2022, and 2021, respectively:

	Rebates and Incentives [1]	Product Returns [2]	Trade Allowances and Chargebacks [3]
Balance as of December 31, 2020	$ 132,775	$ 23,779	$ 19,055
Provision related to current period sales	378,694	27,229	84,470
Changes in estimate related to prior period sales	1,121	8,763	4
Credits/payments made	(370,211)	(5,154)	(90,303)
Balance as of December 31, 2021	$ 142,379	$ 54,617	$ 13,226
Acquired from BDSI	38,074	18,187	7,575
Provision related to current period sales	497,250	38,250	132,547
Changes in estimate related to prior period sales	(619)	2,505	(592)
Credits/payments made	(520,147)	(40,005)	(130,698)
Balance as of December 31, 2022	$ 156,937	$ 73,554	$ 22,058
Provision related to current period sales	424,013	41,993	149,976
Changes in estimate related to prior period sales	(4,802)	4,268	555
Credits/payments made	(426,322)	(42,310)	(151,672)
Balance as of December 31, 2023	$ 149,826	$ 77,505	$ 20,917

(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, 2023, 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 discloses disaggregated revenue from contracts with customers into categories that depict how the nature, amount, timing, and uncertainty of revenue and cash flows are affected by economic factors. As such, the Company disaggregates its product revenues, net from contracts with customers by product, as disclosed in the table below.

	Years Ended December 31,		
	2023	2022	2021
Belbuca	$ 182,095	$ 126,461	$ —
Xtampza ER	177,374	138,804	103,708
Nucynta IR	108,150	112,058	102,222
Nucynta ER	82,653	72,418	70,938
Symproic	16,495	12,267	—
Other	—	1,925	—
Total product revenues, net	$ 566,767	$ 463,933	$ 276,868

The Company began recognizing revenue from net product sales of Belbuca and Symproic following the Acquisition Date as defined in Note 4, *Acquisitions*.

4. Acquisitions

On March 22, 2022 (the “Acquisition Date”), the Company acquired BioDelivery Sciences International, Inc. (“BDSI”), a specialty pharmaceutical company working to deliver innovative therapies for individuals living with serious and debilitating chronic conditions (the “BDSI Acquisition”). Upon closing, the Company acquired Belbuca and Symproic.

The BDSI Acquisition was completed to leverage the Company’s existing sales force and other operations to commercialize additional products that are typically marketed to similar physicians and to develop other synergies. The Company obtained control through the acquisition of shares in an all-cash transaction which closed on March 22, 2022.

The total consideration paid for the BDSI acquisition was approximately $669,431 consisting of the following (in thousands, except per share amounts):

Fair Value of Purchase Price Consideration		**Amount**
Fair value of purchase price consideration paid at closing:		
Cash consideration for all outstanding shares of BDSI's common and preferred stock (103,235,298 shares acquired at $5.60 per share)	$	578,118
Cash consideration paid to settle RSUs and in-the-money options		28,309
Cash paid to settle BDSI debt		63,004
Total purchase consideration	$	669,431

The Company has accounted for the BDSI Acquisition as a business combination and, accordingly, has included the assets acquired, liabilities assumed and results of operations in its financial statements following the Acquisition Date.

The final allocation of the consideration transferred to the assets acquired and liabilities assumed has been completed. During the three months ended March 31, 2023, the Company recorded measurement period adjustments to increase accrued expenses by $134 and deferred tax liabilities by $28, with a corresponding increase to goodwill of $162.

The following tables set forth the final allocation of the BDSI Acquisition purchase price to the estimated fair value of the net assets acquired at the Acquisition Date:

	Amounts Recognized at the Acquisition Date	
Assets Acquired		
Cash and cash equivalents	$	97,362
Accounts receivable		55,495
Inventory		77,382
Prepaid expenses and other current assets		6,125
Property and equipment		1,242
Operating lease assets		481
Intangible assets		435,000
Total assets	$	673,087
Liabilities Assumed		
Accounts payable	$	12
Accrued liabilities		18,249
Accrued rebates, returns and discounts		56,261
Operating lease liabilities		481
Deferred tax liabilities		62,510
Total liabilities	$	137,513
Total identifiable net assets acquired		535,574
Goodwill		133,857
Total consideration transferred	$	669,431

The valuation of the acquired intangible assets is inherently subjective and relies on significant unobservable inputs. The Company used an income approach to value the $435,000 of intangible assets. The valuation for each of these intangible assets was based on estimated projections of expected cash flows to be generated by the assets, discounted to the present value at discount rates commensurate with risk. The Company amortizes the identifiable intangible assets on a straight-line basis over their respective useful lives (refer to Note 11, *Goodwill and Intangible Assets*). In addition, the acquired inventory was recognized at its acquisition-date fair value, which resulted in an increase of $54,700 compared to its preacquisition book value.

The excess of the purchase price over the fair value of identifiable net assets acquired represents goodwill. This goodwill is primarily attributable to synergies of merging operations. The acquired goodwill is not deductible for tax purposes.

Total revenues attributable to BDSI from the Acquisition Date through December 31, 2022 were $140,653. However, earnings attributable to BDSI from the Acquisition Date through December 31, 2022 are not distinguishable due to the rapid integration of BDSI's core operations into the Company.

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the years ended December 31, 2022 and 2021, as if the BDSI Acquisition had occurred on January 1, 2021. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2021, and is not indicative of what such results would be expected for any future period:

	Years Ended December 31,	
	2022	2021
Total revenues	$ 493,284	$ 443,571
Net income	$ 8,674	$ 15,015

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and BDSI. The pro forma financial information primarily reflects the following pro forma adjustments:

- The Company's acquisition related transaction costs of $14,718 were reflected as of January 1, 2021;
- Employee severance related expense of $8,008 was reflected as of January 1, 2021;
- Additional amortization expense from the acquired intangibles;
- Additional cost of product revenues related to the step-up basis in inventory to record inventory at fair value; and
- Adjustments to the Company's interest expense related to repayment of the 2020 Term Loan and entering into the 2022 Term Loan as defined in Note 14, *Debt.*

In addition, all of the above adjustments were adjusted for the applicable tax impact.

Acquisition Related Expenses

During the year ended December 31, 2022, the Company incurred $31,297 of acquisition related expenses as a result of the BDSI Acquisition and the substantial majority were included in "*Selling, general, and administrative"* expenses in the consolidated statements of operations. These costs include transaction costs, which primarily consisted of financial advisory, banking, legal, and regulatory fees, and other consulting fees, incurred to complete the acquisition, employee-related expenses (severance cost and benefits) for terminated employees after the acquisition, BDSI directors and officers insurance, and miscellaneous other acquisition expenses incurred. The Company does not expect to incur any additional expenses related to the BDSI Acquisition.

	Year Ended December 31, 2022	
Transaction costs	$	14,718
Employee-related expenses		8,008
BDSI directors and officers insurance		4,492
Other acquisition expenses		4,079
Total acquisition related expenses	$	31,297

5. Licenses Agreements

The Company periodically enters into license agreements to develop and commercialize its products.

Shionogi license and supply agreement

Prior to the BDSI Acquisition, BDSI and Shionogi Inc. ("Shionogi") entered into an exclusive license agreement (the "Shionogi License Agreement") for the commercialization of Symproic in the United States including Puerto Rico (the "Shionogi Territory") for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain (the "Shionogi Field").

Pursuant to the terms of the Shionogi License Agreement, tiered royalty payments on net sales of Symproic in the Shionogi Territory are payable quarterly based on a royalty rate that ranges from 8.5% to 17.5% (plus an additional 1% of net sales on a pass-through basis to a third-party licensor of Shionogi) based on volume of net sales and whether Symproic is being sold as an authorized generic. Unless earlier terminated, the Shionogi License Agreement will continue in effect until the expiration of the royalty obligations, as defined therein. Upon expiration of the Shionogi License Agreement, all licenses granted for Symproic in the Shionogi Field and in the Shionogi Territory survive and become fully-paid, royalty-free, perpetual and irrevocable.

BDSI and Shionogi also had entered into a supply agreement under which Shionogi will supply Symproic at cost plus an agreed upon markup. In the event that Symproic is sourced from a third-party supplier, Shionogi would continue to supply naldemedine tosylate for use in Symproic manufacturing at cost plus such agreed upon markup for the duration of the Shionogi License Agreement.

6. Earnings Per Share

Basic earnings per share is calculated by dividing the net income or loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted earnings per share is computed by dividing the net income or 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, if-converted, or contingently issuable accounting methods, depending on the nature of the security. For purposes of the diluted earnings per share calculation, stock options, restricted stock units ("RSUs"), performance share units ("PSUs"), and shares potentially issuable in connection with the employee stock purchase plan and convertible senior notes are considered potentially dilutive securities and included to the extent that their addition is not anti-dilutive.

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

	Years Ended December 31,		
	2023	2022	2021
Numerator:			
Net income (loss)	$ 48,155	$ (25,002)	$ 71,517
Adjustment for interest expense recognized on convertible senior notes:	5,889	—	4,675
Net (loss) income — diluted	$ 54,044	$ (25,002)	$ 76,192
Denominator:			
Weighted-average shares outstanding — basic	33,741,213	33,829,495	34,936,817
Effect of dilutive securities:			
Stock options	271,540	—	504,699
Restricted stock units	714,190	—	461,471
Performance share units	267,761	—	85,229
Employee stock purchase plan	—	—	1,198
Warrants	—	—	131,257
Convertible senior notes	6,793,421	—	4,925,134
Weighted average shares outstanding — diluted	41,788,125	33,829,495	41,045,805
Earnings (loss) per share — basic	$ 1.43	$ (0.74)	$ 2.05
Earnings (loss) per share — diluted	$ 1.29	$ (0.74)	$ 1.86

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 and 2029 in cash, shares or a combination of the two. The Company uses the if-converted method for the convertible senior notes.

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

	Years Ended December 31,		
	2023	2022	2021
Stock options	259,405	1,683,805	1,202,403
Restricted stock units	31,050	2,047,571	22,605
Performance share units	308,680	447,770	242,714
Employee stock purchase plan	18,591	—	—
Convertible senior notes	—	4,925,134	—

For PSUs, 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. All other securities presented in the table above were excluded from the calculation of diluted earnings per share as their inclusion would have had an antidilutive effect.

7. Marketable Securities

Available-for-sale debt securities were classified on the consolidated balance sheets at fair value as follows:

	December 31, 2023
Cash and cash equivalents	$ 4,729
Marketable securities	71,601
Total	$ 76,330

The following table summarizes the available-for-sale securities held as of December 31, 2023:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities	$ 41,610	$ 47	$ (45)	$ 41,612
U.S. Treasury securities	30,189	8	—	30,197
Government-sponsored securities	4,517	4	—	4,521
Total	$ 76,316	$ 59	$ (45)	$ 76,330

The following table summarizes the contractual maturities of available-for-sale securities other than investments in money market funds as of December 31, 2023:

	December 31, 2023
Matures within one year	$ 61,672
Matures after one year through five years	14,658
Total	$ 76,330

The Company did not record any allowances for credit losses to adjust the fair value of available-for-sale debt securities during the year ended December 31, 2023.

The Company did not hold marketable securities as of December 31, 2022.

There were no sales of marketable securities during the year ended December 31, 2023. Net unrealized holding gains or losses for the period that have been included in other comprehensive income were not material to the Company's consolidated results of operations.

8. Inventory

Inventory consisted of the following:

	Years Ended December 31,	
	2023	2022
Raw materials	$ 10,384	$ 5,600
Work in process	6,740	24,672
Finished goods	15,208	16,229
Total inventory	$ 32,332	$ 46,501

During the years ended December 31, 2023 and 2022, the expenses related to excess and obsolete inventory that were recorded as a component of cost of products revenues were $1,624 and $1,814, respectively. Expenses related to excess and obsolete inventory were immaterial for the year ended December 31, 2021.

During the years ended December 31, 2023, 2022, and 2021, inventory used in the construction and installation of property and equipment was immaterial.

9. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	Years Ended December 31,	
	2023	2022
Prepaid regulatory fees	$ 5,938	$ 5,614
Prepaid income taxes	1,416	5,138
Prepaid co-pay program incentives	1,758	1,907
Prepaid insurance	672	960
Manufacturing deposits	2,640	—
Other current assets	93	57
Other prepaid expenses	2,678	3,005
Prepaid expenses and other current assets	$ 15,195	$ 16,681

10. Property and Equipment

Property and equipment consisted of the following:

	Years Ended December 31,	
	2023	2022
Computers and office equipment	$ 2,388	$ 2,491
Laboratory equipment	436	436
Furniture and fixtures	1,133	1,133
Manufacturing equipment	20,643	20,910
Leasehold improvements	1,061	874
Total property and equipment	25,661	25,844
Less: accumulated depreciation	(9,678)	(6,323)
Property and equipment, net	$ 15,983	$ 19,521

Depreciation expense related to property and equipment amounted to $3,496, $2,684, and $1,736 for the years ended December 31, 2023, 2022, and 2021, respectively. During the years ended December 31, 2023, 2022, and 2021 the Company disposed of fully depreciated assets of $141, $1,040, and $96 respectively. Any gains or losses from the retirement, sale or disposal of property and equipment during the years ended December 31, 2023, 2022, and 2021 were immaterial.

11. Goodwill and Intangible Assets

The Company's goodwill resulted from the BDSI Acquisition. Refer to Note 4, *Acquisitions,* for more information.

The following tables summarizes the changes in the carrying amount of goodwill:

	Amount
Balance as of December 31, 2021	$ —
Goodwill resulting from BDSI Acquisition	133,695
Balance as of December 31, 2022	$ 133,695
Measurement period adjustments from BDSI Acquisition	162
Balance as of December 31, 2023	$ 133,857

The following table sets forth the cost, accumulated amortization, and carrying amount of intangible assets as of December 31, 2023 and 2022:

	Amortization Period (Years)	As of December 31, 2023			As of December 31, 2022		
		Cost	Accumulated Amortization	Carrying Amount	Cost	Accumulated Amortization	Carrying Amount
Belbuca	4.8	$ 360,000	$ (133,821)	$ 226,179	$ 360,000	$ (58,428)	$ 301,572
Nucynta Products [1]	8.5	521,170	(382,710)	138,460	521,170	(319,628)	201,542
Symproic	9.6	70,000	(12,931)	57,069	70,000	(5,646)	64,354
Elyxyb	—	—	—	—	5,000	(5,000)	—
Total intangibles		$ 951,170	$ (529,462)	$ 421,708	$ 956,170	$ (388,702)	$ 567,468

The following table presents amortization and impairment expense recognized in cost of product revenues for the years ended December 31, 2023, 2022, and 2021:

	Years Ended December 31,		
	2023	2022	2021
Belbuca	$ 75,393	$ 58,428	$ —
Nucynta Products [1]	63,082	67,181	67,181
Symproic	7,285	5,646	—
Elyxyb [2]	—	5,000	—
Total amortization and impairment expense	$ 145,760	$ 136,255	$ 67,181

(1) During the three months ended September 30, 2023, the United States Food and Drug Administration ("FDA") granted New Patient Population exclusivity in pediatrics for Nucynta IR which extends the period of U.S. exclusivity for Nucynta IR to July 3, 2026, resulting in an extension of the estimated useful life of the underlying intangible asset from 8.0 years to 8.5 years. This change in estimate resulted in a decrease of amortization expense of $4,099 and an increase in net income of $3,037 during the year ended December 31, 2023. The impact to earnings per share — basic and earnings per share — diluted was $0.09 and $0.07, respectively, during the year ended December 31, 2023.

(2) Includes $214 of amortization expense and $4,786 of impairment expense.

Intangible Asset Impairment

During the three months ended December 31, 2022, the Company made the decision to discontinue the commercialization of Elyxyb. Accordingly, an asset impairment evaluation performed during the three months ended December 31, 2022 resulted in the Company recognizing $4,786 of impairment expense related to the Elyxyb intangible asset, which was equivalent to the carrying amount of the Elyxyb asset at the time of the impairment determination. The impairment expense reflects that no significant proceeds are expected to be realized from its disposition. The impairment expense is included in "*Intangible asset amortization and impairment*" in the consolidated statements of operations. Other expenses associated with the discontinuation of Elyxyb were immaterial.

The revenues generated from sales of Elyxyb to date were immaterial. Elyxyb is not considered a significant component of the entity's business and therefore, is not presented as a discontinued operation.

There were no employees impacted by the decision to discontinue the commercialization of Elyxyb and therefore, no severance or employee benefit expenses were recognized. In addition, contract termination costs related to the discontinuation were immaterial and expensed upon the termination of the contracts. In February 2023, the Company entered into the Elyxyb Sale Agreement with Scilex to transfer to Scilex all assets, rights, and obligations necessary to commercialize Elyxyb in the United States and Canada.

As of December 31, 2023, the remaining amortization expense expected to be recognized is as follows:

Years ended December 31,	Belbuca	Nucynta Products	Symproic	Total
2024	$ 75,393	$ 55,384	$ 7,285	$ 138,062
2025	75,393	55,384	7,285	138,062
2026	75,393	27,692	7,285	110,370
2027	—	—	7,285	7,285
2028	—	—	7,285	7,285
Thereafter	—	—	20,644	20,644
Remaining amortization expense	$ 226,179	$ 138,460	$ 57,069	$ 421,708

12. Accrued Liabilities

Accrued liabilities consisted of the following:

	As of December 31,	
	2023	2022
Accrued royalties	$ 14,198	$ 13,770
Accrued product taxes and fees	5,013	4,352
Accrued bonuses	4,987	6,347
Accrued interest	2,853	1,410
Accrued income taxes	2,136	—
Accrued payroll and related benefits	1,511	1,208
Accrued incentive compensation	1,375	1,507
Accrued sales and marketing	1,198	2,130
Accrued audit and legal	700	1,957
Accrued other operating costs	3,600	3,448
Total accrued liabilities	$ 37,571	$ 36,129

13. 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 material litigation and, accordingly, does not have any other amounts recorded for any litigation related matters.

Xtampza ER Litigation

On March 24, 2015, Purdue sued the Company in the U.S. District Court for the District of Delaware 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). The lawsuit was initiated in response to the Company filing the New Drug Application ("NDA") for Xtampza ER as a 505(b)(2) application referencing data from Purdue's OxyContin NDA, and under the Drug Price Competition and Patent Term Restoration Act of 1984, triggered a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

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 which lifted the 30-month stay of FDA approval. Following this judgment, the Company obtained final approval for Xtampza ER and launched 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 asserted infringement of Patent No. 9,073,933 in November 2015 and Patent No. 9,522,919 in April 2017. In addition, Purdue invoked two non-Orange Book-listed patents, 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 ʼ961 patent with the Patent Trial and Appeal Board ("PTAB"). The PGR argued that the ʼ961 patent is invalid.

On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ʼ933, ʼ497, and ʼ717 patents. The Court issued an order on September 28, 2018, in which it ruled that the Xtampza ER formulation does not infringe the ʼ497 and ʼ717 patents.

On September 15, 2019, Purdue commenced chapter 11 bankruptcy proceedings in the United States Bankruptcy Court for the Southern District of New York. Later in September 2019, Purdue gave the District Court of Massachusetts, as well as the PTAB, notice of its bankruptcy filing and sought the imposition of an automatic stay of proceedings. Both the Court and the PTAB granted Purdue's requests to stay the pending matters.

On September 1, 2020, the Bankruptcy Court entered an Order, lifting the automatic stays in both the District of Massachusetts and PTAB proceedings. 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. On November 19, 2021, the PTAB: (i) denied Purdue's motion to terminate the PGR; and (ii) issued its Final Written Decision, finding that the asserted claims of the ʼ961 patent were invalid for lack of written description and anticipation. Purdue appealed the decision to Federal Circuit, which issued its decision on November 21, 2023, affirming the authority of the PTAB to issue its Final Written Decision and upholding the PTAB's finding of invalidity relative to the '961 patent.

On April 2, 2021, the Court granted Purdue's Motion to Lift the Stay in the District of Massachusetts that was entered following Purdue's Notice of Bankruptcy. On April 9, 2021, Purdue filed another follow-on lawsuit asserting infringement of U.S. Patent No. 10,407,434. The Company responded to Purdue's complaint with a motion to dismiss. On May 21, 2021, and in response to the Company's motion to dismiss, Purdue filed an amended complaint. The Company renewed its motion to dismiss on June 4, 2021, arguing: (i) Purdue cannot, as a matter of law, state a claim for infringement under § 271(e)(2)(A); (ii) Purdue cannot, as a matter of law, state a claim for product-by-process infringement under §271(g); and (iii) Purdue has not alleged facts sufficient to support any indirect infringement theory under §271(b) or (c). The Court held a hearing on the Company's motion to dismiss on October 13, 2021, and the motion is pending before the Court.

Like the prior follow-on lawsuits, the '434 patent litigation was consolidated into the lead case and a scheduling order was entered. On May 15, 2023, the Court issued an order that: (i) vacated the existing deadlines with respect to the ʼ933, ʼ919, and ʼ434 patents and stayed the case pending the Federal Circuit's decision in a different litigation that invalidated certain claims of the ʼ933 and ʼ919 patents; and (ii) continued the existing stay concerning the ʼ961 patent pending resolution of Purdue's appeal rights relating to the decision invalidating the claims of the ʼ961 patent. The Court has not set a deadline for dispositive motions or trial.

The remaining patents-in-suit in the lead consolidated action in the District of Massachusetts are the ʼ933, ʼ919, ʼ434, and ʼ961 patents. Purdue has made a demand for monetary relief, and 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.

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 U.S. District Court for the District of Delaware, in which it 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. 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 Purdue's claims were barred by the doctrine of patent exhaustion. On June 19, 2019, the Court issued an order calling for discovery on a factual predicate for the patent exhaustion defense and noted that 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 notified the Court of its bankruptcy filing and sought an automatic stay of proceedings, which was granted. The Nucynta litigation currently remains subject to the bankruptcy stay.

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.

Opioid Litigation

As a result of the opioid epidemic, numerous state and local governments and other entities brought suit against manufacturers, 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 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. The Company was initially named as a defendant in 21 of the MDL cases. By April 19, 2022, all MDL cases naming the Company were dismissed or withdrawn.

Outside of the MDL, several cases were filed against the Company in Arkansas, Pennsylvania, and Massachusetts state courts with allegations similar to those in the MDL related to opioid marketing and distribution practices, as well as allegations including violations of state consumer protections laws.

On March 21, 2019, the Arkansas state court litigation was dismissed. On December 24, 2021, the Company entered into a settlement framework with Scott+Scott Attorneys at Law, LLP, the law firm representing plaintiffs in 27 jurisdictions filed either in Pennsylvania and Massachusetts state courts, or filed in other state courts and removed to the MDL. Pursuant to the terms of the settlement, the Company paid $2,750 in exchange for dismissal, with prejudice, of each plaintiff's lawsuit and a release of claims related to such lawsuits. The Company is currently dismissed from all cases.

The Company settled to efficiently resolve these litigations and did not admit any liability or acknowledge any wrongdoing in connection with the settlement.

Opioid-Related Request and Subpoenas

The Company, like several other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing practices, from the Offices of the Attorney General of Washington, New Hampshire, Maryland, and Massachusetts.

On December 16, 2021, the Company entered into an Assurance of Discontinuance with the Massachusetts Attorney General's Office. The Company is currently cooperating with each of the remaining states in their respective investigations.

Aquestive Litigation

On September 22, 2014, Reckitt Benckiser, Inc., Indivior PLC (formerly RB Pharmaceuticals Limited, "Indivior"), and Aquestive Therapeutics, Inc. (formerly MonoSol Rx, "Aquestive") (collectively, the "RB Plaintiffs") filed an action in the District Court in the District of New Jersey alleging patent infringement against BDSI related to its Bunavail product. The RB Plaintiffs claimed that Bunavail, whose formulation and manufacturing processes have never been disclosed publicly, infringed U.S. Patent No. 8,765,167 (the "'167 Patent").

On January 13, 2017, Aquestive filed a complaint in the District Court for the District of New Jersey against BDSI alleging Belbuca also infringed the '167 Patent. On March 8, 2023, the parties filed a stipulation of dismissal after agreeing to settle the dispute. Under the terms of the settlement agreement, BDSI resolved both the Bunavail and Belbuca litigations in exchange for a one-time, lump-sum payment of $8,500 to Aquestive, which was recognized as an expense included in "*selling, general and administrative expenses*" in the consolidated statements of operations for the year ended December 31, 2023.

Litigation Related to the BDSI Acquisition

On February 25, 2022, in connection with the BDSI Acquisition, a purported individual stockholder of BDSI filed a complaint in the District Court for the Southern District of New York naming as defendants BDSI and each member of its Board of Directors as of the date of the Merger Agreement ("*Stein* Action"). On February 28, 2022, two additional cases were filed by purported individual stockholders of BDSI in the same court: the "*Sanford* Action" and the "*Higley* Action." In March 2022, two additional cases were filed by purported individual stockholders of BDSI in the District Court for the Eastern District of New York: the "*Justice* Action" and the *"Zomber* Action" (together with the *Stein*, *Sanford*, and *Higley* Actions, the "Actions"). The Actions and any similar subsequently filed cases involving BDSI, its officers or Board of Directors, or any committee thereof, and/or any of the Company's officers or directors relating directly or indirectly to the Merger Agreement, the BDSI Acquisition or any related transaction, are referred to as the "Merger Litigations."

The Merger Litigations filed to date generally allege that the Schedule 14D-9 is materially incomplete and misleading. The Merger Litigations assert violations of Section 14(e) of the Exchange Act and violations of Section 20(a) of the Exchange Act against BDSI's Board of Directors. The Merger Litigations seek, among other things: an injunction enjoining consummation of the Merger, rescission of the Merger Agreement, a declaration that BDSI and its Board of Directors violated Sections 14(e) and 20(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, damages, costs of the action, including plaintiffs' attorneys' fees and experts' fees and expenses, and any other relief the court may deem just and proper.

In addition, between February and March of 2022, BDSI received demand letters from three purported stockholders of BDSI seeking to inspect certain books and records of BDSI related to the Merger (collectively, the "Inspection Letters"). In March 2022, BDSI received demand letters from four purported stockholders alleging that the Schedule 14D-9 omits purportedly material information relating to the Merger (collectively, the "Demand Letters").

Plaintiffs in the *Higley, Zomber, and Justice* Actions each filed a notice of voluntary dismissal of their complaint in the second quarter of 2022. On July 28, 2022, plaintiff in the *Sanford* Action filed a partial voluntary dismissal of the individual named defendants, and on October 26, 2022, filed a notice of voluntary dismissal of the BDSI defendant. On February 17, 2023, the *Stein* Action was dismissed.

While the Company believes that the remaining Merger Litigations, Inspection Letters, and Demand Letters are without merit and that the disclosures in the Schedule 14D-9 comply fully with applicable law, solely in order to avoid the expense and distraction of litigation, BDSI previously determined to voluntarily supplement the Schedule 14D-9 with certain supplemental disclosures set forth in BDSI's Schedule 14D-9 filed with the SEC on March 11, 2022 (the "Supplemental Disclosures"). The Company and BDSI believe that the Supplemental Disclosures mooted all allegations or concerns raised in the Merger Litigations, Inspection Letters, and Demand Letters.

Alvogen

On September 7, 2018, BDSI filed a complaint for patent infringement in District Court for the District of Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group, Incorporated (collectively, "Alvogen"), asserting that Alvogen infringed BDSI's Orange Book-listed patents for Belbuca, including U.S. Patent Nos. 8,147,866, 9,655,843 and 9,901,539 (collectively, "the BEMA patents"). This complaint followed receipt by BDSI on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating it had filed an abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Belbuca Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg.

A three-day bench trial was held from March 1-3, 2021. On December 20, 2021, the Court issued an opinion upholding the validity of certain claims in BDSI's ʹ866 patent and certain claims in the ʼ539 patent. The Court entered final judgment on January 21, 2022 upholding the validity of claims of the ʼ866 and ʼ539 patents and thereby extended the effective date of any final approval by the FDA of Alvogen's ANDA until December 21, 2032, (the expiration date of the ʼ539 patent) and enjoining Alvogen from commercially launching its ANDA products until December 21, 2032. Alvogen filed a motion to stay certain provisions of the final judgment. BDSI filed an opposition to Alvogen's request for a stay. The Court retained jurisdiction to decide BDSI's motion for contempt, which was filed on September 21, 2021.

Alvogen filed a notice of appeal to the Federal Circuit seeking to reverse the Court's final judgment. Separately, BDSI filed a cross-appeal to the Federal Circuit seeking to reverse the Court's opinion that claims 3 and 10 of the ʹ866 patent and claims 8, 9 and 20 of the ʼ843 patent are invalid and thus, Alvogen is not liable for infringement of those claims, as well as any other ruling decided adversely to BDSI. On December 21, 2022, the Federal Circuit affirmed the district court judgment that certain claims of the ʹ866 and ʹ539 patent were not invalid as obvious. The Federal Circuit also vacated the district court's judgment that certain claims of the ʹ866 and ʹ843 patent were invalid as obvious and remanded to the district court for further proceedings. The mandate issued on February 10, 2023.

As it has done in the past, the Company intends to vigorously defend its intellectual property against assertions of invalidity or non-infringement.

Chemo Research, S.L.

On March 1, 2019, BDSI filed a complaint for patent infringement in the District Court for the District of Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, the "Chemo Defendants"), asserting that the Chemo Defendants infringe the BEMA patents. This complaint followed receipt by BDSI on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it had filed with the FDA an ANDA containing a Paragraph IV Patent Certification, for a generic version of Belbuca Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg.

Chemo agreed to be bound by the decision of the Court with respect to the validity of the BEMA patents as disputed between BDSI and Alvogen. Accordingly, the December 20, 2021 ruling of the Court upholding the validity of certain claims of the BEMA patents is binding upon Chemo. In March 2022, the Court vacated the bench trial set to begin April 25, 2022 to address the remaining Chemo infringement claims. The Court has not yet set a new trial date.

On August 1, 2022, BDSI received a second Paragraph IV certification notice letter from Chemo indicating it amended its ANDA to: (i) withdraw its generic version of the 75 mcg and 150 mcg strengths of Belbuca; and (ii) include its generic version of the 600 mcg and 750 mcg strengths of Belbuca, in addition to the 300 mcg, 450 mcg, and 900 mcg strengths identified in the first Chemo Paragraph IV certification notice letter. In response, BDSI filed a complaint for patent infringement in Federal District Court for the District of Delaware. Chemo answered the complaint on December 1, 2022. The Court has not yet set a schedule for this litigation.

On August 24, 2022, the Court instructed the parties to update the Court at such time as the FDA addresses Chemo's July 29, 2022 response to the FDA. On February 8, 2023, the Court denied Chemo's request for a trial date in the spring, and

again instructed the parties to update the Court at such time as the FDA addresses Chemo's July 29, 2022 response to the FDA. Chemo received a complete response letter with respect to its July 29, 2022 ANDA in April 2023. Chemo submitted a further amended ANDA to FDA in September 2023.

The Company plans to litigate 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.

14. Debt

2020 Term Loan

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 "2020 Loan Agreement") with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon"). The 2020 Loan Agreement provided for a $200,000 secured term loan (the "2020 Term Loan"), 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 "2020 Term Loan Closing Date"), the Company received the $200,000 proceeds from the 2020 Term Loan.

On March 22, 2022 the outstanding balance under the 2020 Loan Agreement was fully paid in connection with the closing of the BDSI Acquisition and establishment of the 2022 Term Loan, as described below.

2022 Term Loan

On March 22, 2022, in connection with the closing of the BDSI Acquisition, the Company entered into an Amended and Restated Loan Agreement by and among the Company, and BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon"), as amended (the "2022 Loan Agreement"). The 2022 Loan Agreement provided for a $650,000 secured term loan (the "2022 Term Loan"), the proceeds of which were used to repay the Company's existing term notes and fund a portion of the consideration to be paid to complete the BDSI Acquisition. The 2022 Loan Agreement was accounted for as a debt modification and transaction fees of $173 were expensed. In connection with the 2022 Loan Agreement, the Company paid loan commitment and other fees to the lender of $19,818, which together with preexisting debt issuance costs and note discounts of $2,049 will be amortized over the term of the loan using the effective interest rate.

The 2022 Term Loan will mature on the 48-month anniversary of the closing of the BDSI Acquisition and is guaranteed by the Company's material domestic subsidiaries. The 2022 Term Loan is also secured by substantially all of the assets of the Company and its material domestic subsidiaries. Prior to the cessation of LIBOR on June 30, 2023, the 2022 Term Loan bore interest at a rate based on LIBOR (subject to a LIBOR floor of 1.20%), plus a margin of 7.5% per annum. On June 23, 2023, the Company entered into an amendment to the 2022 Loan Agreement to adjust the interest terms of the 2022 Term Loan to transition from LIBOR to SOFR in anticipation of the cessation of LIBOR. Effective July 1, 2023, the 2022 Term Loan bears interest at a rate based on SOFR plus a spread adjustment of 0.26% (subject to a floor of 1.20%), plus a margin of 7.5% per annum. As of December 31, 2023, the contractual interest rate was 13.2%. The Company paid $100,000 in principal payments under the 2022 Term Loan during the first year and the remaining $550,000 balance is required to be paid in equal quarterly installments over the remaining three years.

The 2022 Loan Agreement permits voluntary prepayment at any time, subject to a prepayment premium. The prepayment premium is equal to 2.00% of the principal amount being prepaid prior to the second-year anniversary of the closing date, or 1.00% of the principal amount being prepaid on or after the second-year anniversary of the closing date. The 2022 Loan Agreement also includes a make-whole premium in the event of a voluntary prepayment, a prepayment due to a change in control or acceleration following an Event of Default (as defined in the 2022 Loan Agreement) on or prior to the second-year anniversary of the closing date, in each case 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 also triggers a mandatory prepayment of the 2022 Term Loan.

The 2022 Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, 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. Failure to comply with these covenants would constitute an Event of Default under the 2022 Loan Agreement, notwithstanding the Company's ability to meet its debt service obligations. The 2022 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 2022 Loan Agreement and execution upon the collateral securing obligations under the 2022 Loan Agreement.

The following table presents the total interest expense recognized related to the 2020 Term Loan and 2022 Term Loan during the years ended December 31, 2023, 2022, and 2021:

	Years Ended December 31,		
	2023	**2022**	**2021**
Contractual interest expense	$ 67,499	$ 51,155	$ 13,834
Amortization of debt issuance costs	7,468	7,378	2,505
Total interest expense	$ 74,967	$ 58,533	$ 16,339

As of December 31, 2023, the effective interest rate on the 2022 Term Loan was 14.7%.

As of December 31, 2023, principal repayments under the 2022 Term Loan are as follows:

Years ended December 31,	**Principal Payments**
2024	$ 183,333
2025	183,333
2026	45,834
Total before unamortized discount and issuance costs	$ 412,500
Less: unamortized discount and issuance costs	(7,454)
Total term notes	$ 405,046

2026 Convertible Notes

On February 13, 2020, the Company issued 2.625% convertible senior notes due in 2026 (the "2026 Convertible Notes") in the aggregate principal amount of $143,750, in a public offering registered under the Securities Act of 1933, as amended. The 2026 Convertible Notes were issued in connection with funding the acquisition of the Nucynta Products. Some of the Company's existing investors participated in the 2026 Convertible Notes offering.

In connection with the issuance of the 2026 Convertible Notes, the Company incurred approximately $5,473 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees.

The 2026 Convertible Notes are 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 2026 Convertible 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 the 2026 Convertible 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 2026 Convertible Notes may convert all or any portion of their 2026 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 2026 Convertible 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 2026 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, 2023, none of the above circumstances had occurred and as such, the 2026 Convertible Notes could not have been converted.

The Company did not have the right to redeem the 2026 Convertible Notes prior to February 15, 2023. On or after February 15, 2023, the Company may redeem the 2026 Convertible Notes, in whole and not in part, at a cash redemption price equal to the principal amount of the 2026 Convertible 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 2026 Convertible Notes for redemption will constitute a make-whole fundamental change, in which case the conversion rate applicable to the conversion of any 2026 Convertibles Notes, if converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The 2026 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, if such default is not cured within 3 calendar days after its occurrence; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) a default in any of the Company's other obligations or agreements under the indenture that are not cured or waived within 60 days after notice to the Company; (vi) certain payment 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 or other defaults by the Company or certain subsidiaries with respect to such indebtedness that result in the acceleration of such indebtedness; (vii) default upon the occurrence of one or more final judgments being rendered against the Company or any of the Company's significant subsidiaries for the payment of at least $20,000; and (viii) certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

Repurchase of a Portion of the 2026 Convertible Notes

Contemporaneously with the offering of the 2029 Convertible Notes (as defined below), the Company entered into separate privately negotiated transactions with certain holders of the 2026 Convertible Notes to repurchase $117,400 aggregate principal amount of the 2026 Convertible Notes for an aggregate of $140,100 of cash, which includes accrued

and unpaid interest on the 2026 Convertible Notes to be repurchased. This transaction involved a contemporaneous exchange of cash between the Company and holders of the 2026 Convertible Notes participating in the issuance of the 2029 Convertible Notes. Accordingly, the Company evaluated the transaction for modification or extinguishment accounting in accordance with Accounting Standards Codification Topic 470-50*, Debt – Modifications and Extinguishments* on a creditor-by-creditor basis depending on whether the exchange was determined to have substantially different terms. The repurchase of the 2026 Convertible Notes and issuance of the 2029 Convertible Notes were deemed to have substantially different terms based on the present value of the cash flows immediately prior to and after the exchange. Therefore, the repurchase of the 2026 Convertible Notes was accounted for as a debt extinguishment. The Company recorded a $23,504 loss on early extinguishment of debt on the consolidated statements of operations during the three months ending March 31, 2023, which includes the recognition of previously deferred financing costs of $2,264. The total remaining principal amount outstanding under the 2026 Convertible Notes as of December 31, 2023 was $26,350.

2029 Convertible Notes

On February 10, 2023, the Company issued 2.875% convertible senior notes due in 2029 (the “2029 Convertible Notes”) in the aggregate principal amount of $241,500, in a private offering to qualified institutional buyers pursuant to Section 4(a)(2) and Rule 144A under the Securities Act of 1933, as amended. The 2029 Convertible Notes were issued to finance the concurrent repurchase of a portion of the 2026 Convertible Notes, and the remainder of the net proceeds may be used for general corporate purposes. In connection with the issuance of the 2029 Convertible Notes, the Company incurred approximately $6,280 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees.

The 2029 Convertible Notes are senior, unsecured obligations and bear interest at a rate of 2.875% per year payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2023. The 2029 Convertible Notes will mature on February 15, 2029, unless earlier repurchased, redeemed or converted. Before November 15, 2028, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after November 15, 2028, 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 initial conversion rate is 27.3553 shares of common stock per $1 principal amount of 2029 Convertible Notes, which represents an initial conversion price of approximately $36.56 per share of common stock. The conversion rate and conversion price are subject to adjustment upon the occurrence of certain events.

Holders of the 2029 Convertible Notes may convert all or any portion of their 2029 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 June 30, 2023, 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 2029 Convertible 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 any or all of the 2029 Convertible Notes for redemption, but only with respect to the 2029 Convertible Notes called for redemption; or
5. at any time from, and including, November 15, 2028 until the close of business on the scheduled trading day immediately before the maturity date.

As of December 31, 2023, none of the above circumstances had occurred and as such, the 2029 Convertible Notes could not have been converted.

The Company may not redeem the 2029 Convertible Notes prior to February 17, 2026. On or after February 17, 2026 and on or before the 40th scheduled trading day before the maturity date, the Company may redeem the 2029 Convertible Notes, in whole or in part, at a cash redemption price equal to the principal amount of the 2029 Convertible 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.

However, the Company may not redeem less than all of the outstanding 2029 Convertible Notes unless at least $75,000 aggregate principal amount of the 2029 Convertible Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice.

Calling any 2029 Convertible Note for redemption will constitute a make-whole fundamental change with respect to that 2029 Convertible Note, in which case the conversion rate applicable to the conversion of that 2029 Convertible Note, if it is converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The 2029 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, if such default is not cured within 3 business days after its occurrence; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) a default in any of the Company's other obligations or agreements under the indenture that are not cured or waived within 60 days after notice to the Company; (vi) certain payment defaults by the Company or certain subsidiaries with respect to mortgages, agreements or other instruments for indebtedness for money borrowed of at least $30,000 or other defaults by the Company or certain subsidiaries with respect to such indebtedness that result in the acceleration of such indebtedness; (vii) default upon the occurrence of one or more final judgments being rendered against the Company or any of the Company's significant subsidiaries for the payment of at least $30,000; and (xiii) upon the occurrence of certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

The 2026 Convertible Notes and 2029 Convertible Notes (together, the "Convertible Notes") are classified on the consolidated balance sheets as of December 31, 2023 as convertible senior notes.

As of December 31, 2023, the Convertible Notes outstanding consisted of the following:

	2026 Convertible Notes	2029 Convertible Notes	Total Convertible Notes
Principal	$ 26,350	$ 241,500	$ 267,850
Less: unamortized issuance costs	(358)	(5,367)	(5,725)
Net carrying amount	$ 25,992	$ 236,133	$ 262,125

The Company determined the expected life of the 2026 Convertible Notes and 2029 Convertible Notes was equal to the six-year term of each. The effective interest rate on the 2026 Convertible Notes and 2029 Convertible Notes is 3.34% and 3.28%, respectively. As of December 31, 2023, the if-converted value did not exceed the remaining principal amount of the Convertible Notes.

The following table presents the total interest expense recognized related to the Convertible Notes during the years ended December 31, 2023, 2022, and 2021:

	Years Ended December 31,		
	2023	2022	2021
Contractual interest expense	$ 7,206	$ 3,773	$ 3,773
Amortization of debt issuance costs	1,166	907	902
Total interest expense	$ 8,372	$ 4,680	$ 4,675

As of December 31, 2023, the future minimum payments on the Convertible Notes were as follows:

Years ended December 31,	2026 Convertible Notes	2029 Convertible Notes	Total Convertible Notes
2024	$ 692	$ 6,943	$ 7,635
2025	692	6,943	7,635
2026	26,696	6,943	33,639
2027	—	6,943	6,943
2028	—	6,943	6,943
Thereafter	—	244,972	244,972
Total minimum payments	$ 28,080	$ 279,687	$ 307,767
Less: interest	(1,730)	(38,187)	(39,917)
Less: unamortized issuance costs	(358)	(5,367)	(5,725)
Convertible Notes carrying value	$ 25,992	$ 236,133	$ 262,125

15. Leases

Operating Lease Arrangements

The Company's main operating lease is for its corporate headquarters in Stoughton, Massachusetts, which was entered into in March 2018 and commenced in August 2018. This lease encompasses approximately 50,678 square feet and is for an initial 10-year term, with options for two additional five-year extensions. The initial annual base rent is $1,214, subject to annual increases between 2.5% to 3.1%.

As of December 31, 2023, the Company's operating lease assets totaled $6,029 and operating lease liabilities amounted to $7,112. This primarily relates to the corporate headquarters lease, with other immaterial operating and embedded operating leases accounted for in the normal course of business.

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 recognized on a straight-line basis over the lease term in the period in which it is incurred.

Variable Lease Costs

Variable lease costs 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, 2023, 2022, and 2021 are as follows:

	Years Ended December 31,		
	2023	2022	2021
Operating lease cost	$ 1,306	$ 1,805	$ 1,305
Short-term lease cost	1,446	993	1,492
Variable lease cost	565	331	292
Total lease cost	$ 3,317	$ 3,129	$ 3,089

The lease term and discount rate for operating leases for the years ended December 31, 2023 and 2022 are as follows:

	Years Ended December 31,	
	2023	2022
Weighted-average remaining lease term — operating leases (years)	5.7	6.6
Weighted-average discount rate — operating leases	6.2%	6.2%

Other information related to operating leases for the years ended December 31, 2023, 2022, and 2021 is as follows:

	Years Ended December 31,		
	2023	2022	2021
Cash paid for amounts included in the measurement of operating leases liabilities	$ 1,585	$ 1,568	$ 1,286
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, 2023, are as follows:

Years ended December 31,	Lease Payments
2024	$ 1,398
2025	1,436
2026	1,474
2027	1,489
2028	1,527
Thereafter	1,169
Total minimum lease payments	$ 8,493
Less: Present value discount	1,381
Present value of lease liabilities	$ 7,112

16. 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 prior to January 1st). As of December 31, 2023, there were 1,876,424 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. Shares issued under all of the Company's plans are funded through the issuance of new shares. Refer to Note 17, *Stock-based Compensation*, for more information.

Warrants

In connection with execution of the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio Therapeutics, Inc. 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 was set to expire in November 2022 and included customary adjustments for changes in the Company's capitalization. In November 2022, the Warrant was exercised through a cashless exercise and the Company issued 40,666 shares. As of December 31, 2023, there were no outstanding warrants remaining.

Share Repurchases

Prior Repurchase Program

In August 2021, the Company's Board of Directors authorized the repurchase of up to $100,000 of shares of its common stock at any time or times through December 31, 2022 (the "Prior Repurchase Program"). The Prior Repurchase Program permitted the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act.

In October 2021, the Company's Board of Directors authorized an accelerated share repurchase ("ASR") program to repurchase $25,000 of the Company's common stock, as part of the Company's $100,000 Prior Repurchase Program. Under the terms of the Company's ASR agreement with an investment bank, the Company paid $25,000 on November 15, 2021, and initially received 1,026,694 shares, representing 80% of the upfront payment on a price per share of $19.48, the closing price on the date the agreement was executed. The remaining shares purchased by the Company were based on the volume-weighted average price of its common stock through January 7, 2022, minus an agreed upon discount between the parties. On January 7, 2022, the ASR agreement settled and the Company received an additional 307,132 shares, bringing the total shares repurchased pursuant to the ASR agreement to 1,333,826.

The ASR agreement was accounted for as two distinct transactions: (1) an immediate repurchase of common stock, recorded as a treasury stock transaction, and (2) a forward contract indexed to the Company's own stock. The forward contract, which represented the remaining shares to be delivered by the investment bank, was recorded as a reduction to stockholders' equity and was still outstanding as of December 31, 2021.

The Prior Repurchase Program expired on December 31, 2022. Through December 31, 2022, the Company repurchased 3,235,823 shares at a weighted-average price of $19.14 per share for a total of $61,924 under the Prior Repurchase Program. Repurchased shares were returned to the Company's pool of authorized but unissued shares. The cost of repurchased shares were recorded as treasury stock in the consolidated balance sheet. Shares repurchased under the Prior Repurchase Program resulted in an immediate reduction of shares outstanding used to calculate the weighted-average common shares outstanding for both basic and diluted earnings per share. As the Company was entitled to receive additional shares of its common stock in connection with the outstanding forward contracts, the receipt of additional shares of common stock was antidilutive. Therefore, no adjustments were made in the computation of earnings per share for the period the forwards were outstanding.

2023 Repurchase Program

In January 2023, the Company's Board of Directors authorized the repurchase of up to $100,000 of shares of its common stock at any time or times through December 31, 2023 (the "2023 Repurchase Program"). The 2023 Repurchase Program permitted the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act.

In July 2023, the Company’s Board of Directors authorized an ASR program to repurchase $50,000 of the Company’s common stock, as part of the Company’s $100,000 2023 Repurchase Program. Under the terms of the Company's ASR agreement with an investment bank, the Company paid $50,000 on August 7, 2023, and received 1,702,852 shares, representing 80% of the upfront payment on a price per share of $23.49, the closing price on the date the agreement was executed. The remaining shares purchased by the Company were based on the volume-weighted average price of its common stock through October 31, 2023, minus an agreed upon discount between the parties. In October 2023, the ASR agreement settled and the Company received an additional 462,442 shares, bringing the total shares repurchased pursuant to the ASR agreement to 2,165,294.

In November 2023, the Company’s Board of Directors authorized a second ASR program as part of the Company’s $100,000 2023 Repurchase Program to repurchase $25,000 of the Company’s common stock. Under the terms of the Company's ASR agreement with an investment bank, the Company paid $25,000 on November 9, 2023, and received 865,426 shares, representing 80% of the upfront payment on a price per share of $23.11, the closing price on the date the agreement was executed. The remaining shares purchased by the Company were based on the volume-weighted average price of its common stock through December 29, 2023, minus an agreed upon discount between the parties. In December 2023, the ASR agreement settled and the Company received an additional 57,349 shares, bringing the total shares repurchased pursuant to the ASR agreement to 922,775.

Each ASR agreement was accounted for as two distinct transactions: (1) an immediate repurchase of common stock, recorded as a treasury stock transaction, and (2) a forward contract indexed to the Company’s own stock. The forward contracts, which represented the remaining shares to be delivered by the investment bank, were recorded as a reduction to stockholders’ equity. Both forward contracts associated with these ASR agreements were settled and not outstanding as of December 31, 2023.

The 2023 Repurchase Program expired on December 31, 2023. Through December 31, 2023, the Company repurchased 3,088,069 shares at a weighted-average price of $24.29 per share for a total of $75,000 under the 2023 Repurchase Program. Repurchased shares were returned to the Company’s pool of authorized but unissued shares. The cost of repurchased shares were recorded as treasury stock in the consolidated balance sheet. Shares repurchased under the 2023 Repurchase Program resulted in an immediate reduction of shares outstanding used to calculate the weighted-average common shares outstanding for both basic and diluted earnings per share. As the Company was entitled to receive additional shares of its common stock in connection with the outstanding forward contracts, the receipt of additional shares of common stock was antidilutive. Therefore, no adjustments were made in the computation of earnings per share for the period the forwards were outstanding.

2024-2025 Repurchase Program

In January 2024, the Company’s Board of Directors authorized the repurchase of up to $150,000 of the Company’s common stock through June 30, 2025 (the “2024-2025 Repurchase Program”). The 2024-2025 Repurchase Program permits the Company to effect repurchases through a variety of methods, including open-market purchases (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, or otherwise in compliance with Rule 10b-18 of the Exchange Act. The timing and amount of any shares purchased on the open market will be determined based on the Company’s evaluation of the market conditions, share price and other factors. The Company plans to utilize existing cash on hand to fund share repurchases.

17. Stock-based Compensation

Performance Share Units, Restricted Stock Units and Stock Options

Performance Share Units

The Company periodically grants 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. During the year ended December 31, 2021, the Company adjusted cumulative compensation expense based on the number of shares that vested.

Beginning in February 2020 and each year thereafter, the Company granted PSUs with performance criteria related to the relative ranking of the total stockholder return ("TSR") of the Company's common stock for each individual year within a three-year performance period as well as 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.

A summary of the Company's PSUs activity for the year ended December 31, 2023 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2022	447,770	$ 28.71
Granted	216,500	38.71
Vested	(223,170)	27.99
Forfeited	—	—
Performance adjustment	62,780	27.14
Outstanding as of December 31, 2023	503,880	$ 33.13

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, 2023, 2022, and 2021 was $38.71, $24.12, and $35.15, respectively.

For the years ended December 31, 2023, 2022, and 2021, the stock-based compensation expense for PSUs was $7,037, $5,398, and $4,817 respectively.

As of December 31, 2023, the unrecognized compensation cost related to performance share units was $5,585 and is expected to be recognized as expense over approximately 1.6 years.

Restricted Stock Units

A summary of the Company's RSUs activity for the year ended December 31, 2023 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding as of December 31, 2022	2,047,571	$ 19.67
Granted	1,278,256	26.25
Vested	(675,647)	19.83
Forfeited	(206,273)	21.91
Outstanding as of December 31, 2023	2,443,907	$ 22.88

The weighted-average grant date fair value of RSUs granted for the years ended December 31, 2023, 2022, and 2021 was $26.25, $17.53, and $24.23, respectively. The total fair value of RSUs vested (measured on the date of vesting) for the years ended December 31, 2023, 2022, and 2021 was $17,677, $10,166, and $11,165, respectively.

As of December 31, 2023, the unrecognized compensation cost related to restricted stock units was $37,022 and is expected to be recognized as expense over approximately 2.6 years. The weighted-average grant date fair value of restricted stock units vested during the years ended December 31, 2023, 2022, and 2021 was $13,398, $12,547, and $8,526, respectively.

Stock Options

A summary of the Company's stock option activity for the year ended December 31, 2023 and related information is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	1,683,805	$ 18.84	5.5	$ 7,953
Exercised	(498,008)	17.34		
Cancelled	(9,047)	18.90		
Outstanding as of December 31, 2023	1,176,750	$ 19.48	4.3	$ 13,297
Exercisable as of December 31, 2023	1,158,209	$ 19.45	4.3	$ 13,120

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:

	Years Ended December 31,		
	2023	2022	2021
Risk-free interest rate	— %	— %	0.7 %
Volatility	— %	— %	67.2 %
Expected term (years)	—	—	6.0
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, 2021, it determined the expected term 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 Company did not grant stock options during the years ended December 31, 2023 and 2022. The weighted-average grant date fair value of stock options granted for the year ended December 31, 2021 was $12.60. The total intrinsic value of stock options exercised for the years ended December 31, 2023, 2022, and 2021 was $4,786, $3,943, and $6,456, respectively.

As of December 31, 2023, the unrecognized compensation cost related to outstanding options was $110 and is expected to be recognized as expense over approximately 0.2 years.

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: (i) the first day of the purchase period; or (ii) the last day of the purchase period. During the year ended December 31, 2023, 26,505 shares of common stock were purchased for total proceeds of $460. As of December 31, 2023, there were 2,244,157 shares of common stock authorized for issuance pursuant to the employee stock purchase plan. The expense for the years ended December 31, 2023, 2022 and 2021 was $209, $117 and $224 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:

	Years Ended December 31,		
	2023	**2022**	**2021**
Research and development	$ —	$ 1,591	$ 3,422
Selling, general and administrative	27,136	21,283	20,833
Total stock-based compensation expense	$ 27,136	$ 22,874	$ 24,255

18. Income Taxes

The provision for (benefit from) income taxes contained the following components:

	Years Ended December 31,		
	2023	**2022**	**2021**
Current provision:			
Federal	$ 21,504	$ 166	$ —
State	8,227	4,540	3,142
	29,731	4,706	3,142
Deferred benefit:			
Federal	$ (1,401)	$ (4,631)	$ (61,445)
State	(752)	(3,920)	(16,588)
	(2,153)	(8,551)	(78,033)
Provision for (benefit from) income taxes	$ 27,578	$ (3,845)	$ (74,891)

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:

	Years Ended December 31,		
	2023	2022	2021
Federal income tax expense at statutory rate	21.0 %	21.0 %	21.0 %
Change resulting from:			
State income tax, net of federal benefit	4.9	5.0	2.9
Permanent difference - debt extinguishment	7.1	—	—
Permanent differences - all other	1.3	(1.9)	(3.9)
Stock compensation	1.0	(5.1)	(18.8)
Research and development credit	—	0.7	16.3
Transaction costs	—	(4.4)	—
Change in tax rates and other	0.4	(2.0)	—
Change in valuation allowance	0.7	—	2,202.5
Effective income tax rate	36.4 %	13.3 %	2,220.0 %

During the year ended December 31, 2023, the effective tax rate was impacted by permanent differences, including the extinguishment of debt in connection with the repurchase of a portion of the Company's 2026 Convertible Notes, for which certain extinguishment costs were not deductible for tax purposes. Stock compensation, including the impact of excess benefits and 162(m) limitations, impacted the effective tax rate at varying percentages each year due to changes in the non-deductible amount and profit before tax. In addition, during the year ended December 31, 2022, non-deductible transaction costs resulting from the BDSI Acquisition impacted the effective tax rate. During the year ended December 31, 2021, the Company released the valuation allowance on the majority of its net operating losses, resulting in a significant discrete deferred tax benefit that impacted the effective tax rate.

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:

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
U.S. and state net operating loss carryforwards	$ 33,800	$ 56,982
Research and development credits	1,769	5,036
Operating lease liabilities	1,803	2,131
Returns and discounts	18,528	19,423
Stock-based compensation	7,570	6,776
Accruals and other	6,257	5,228
163(j) Carryforward	—	3,647
Capitalized R&D	707	929
Intangible assets	32,771	23,592
Gross deferred tax assets:	103,205	123,744
Valuation allowance	(5,781)	(5,254)
Total deferred tax assets:	97,424	118,490
Deferred tax liabilities:		
Debt discount	(344)	(406)
Operating lease assets	(1,529)	(1,778)
Inventory	—	(3,918)
Intangible assets	(65,774)	(84,167)
Property and equipment	(3,518)	(4,271)
Total deferred tax liabilities:	(71,165)	(94,540)
Net deferred tax assets	$ 26,259	$ 23,950

The Company provides a valuation allowance when it is more-likely-than-not that deferred tax assets will not be realized. In determining the extent to which a valuation allowance for deferred tax assets is required, the Company evaluates all available evidence including projections of future taxable income, carryback opportunities, reversal of certain deferred tax liabilities, and other tax planning strategies. The Company maintains a partial valuation against its federal and state operating losses and federal R&D credits as of December 31, 2023. The valuation allowance was $5,781 and $5,254 as of December 31, 2023 and 2022, respectively, and reflects limitations based on the Company's ability to use such assets prior to expiration. The change in the valuation allowance increased the tax provision by $527 for the year ended December 31, 2023. The change in valuation allowance did not impact the tax provision for the year ended December 31, 2022. As a result of sustained positive earnings history through cumulative earnings over the prior three years, as of June 30, during the year ended December 31, 2021, the Company began using projections of future taxable income as a source of realizing its deferred tax assets. Accordingly, the Company recognized a deferred tax benefit of $78,042 for the year ended December 31, 2021 related to the reversal of valuation allowances.

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 net operating loss ("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, 2023, the Company had gross U.S. federal net operating loss carryforwards of $137,459, of which $95,471 arose prior to 2018, which are available to offset future taxable income, if any, through 2037. The remaining $41,988 are available for an indefinite period. As of December 31, 2022, the Company had gross U.S. federal net operating loss carryforwards of $229,797.

As of December 31, 2023 and 2022, the Company also had gross U.S. state net operating loss carryforwards of $202,381 and $252,597, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037.

As of December 31, 2023 and 2022, the Company had federal research and development tax credit carryforwards of approximately $1,025 and $4,231, respectively, available to reduce future tax liabilities which expire at various dates through 2032. As of December 31, 2023 and 2022, the Company had state research and development tax credit carryforwards of approximately $672 and $832, respectively, available to reduce future tax liabilities which expire at various dates through 2036.

The Company has completed studies 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"). The Company concluded that there were ownership changes that occurred during the years 2006, 2012 and 2015 that would be subject to IRC 382 limitations. The Company acquired $234,675 of net operating loss carryforward from the BDSI Acquisition. The Company concluded that there were ownership changes for BDSI that occurred during the years 2006 and 2022 that would 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. As of December 31, 2023, remaining net operating losses of $124,310 are subject to limitation.

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, 2019 through December 31, 2023. 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 has not recognized deferred tax assets for certain federal and state research and development credits related to uncertain tax positions, and that is included in the tabular rollforward of uncertain tax positions. A reconciliation of the beginning and ending amount of gross unrecognized tax benefits ("UTB") is as follows:

	Years Ended December 31,		
	2023	2022	2021
Gross UTB Balance as of January 1	$ 11,400	$ 654	$ 586
Additions based on tax positions related to the current year	—	—	67
Additions for tax positions related to acquisitions	—	10,930	—
(Reductions) additions for tax positions of prior years	(94)	(184)	1
Gross UTB Balance as of December 31	$ 11,306	$ 11,400	$ 654
Net UTB impacting the effective tax rate as of December 31 excluding valuation allowance impacts, if any	$ 11,275	$ 11,368	$ 500

19. 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, 2023, 2022 and 2021 was $1,759, $1,315, and $1,236, respectively.

20. Unaudited Quarterly Operating Results

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2023 and 2022:

Year Ended December 31, 2023	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Product revenues, net	$ 144,767	$ 135,546	$ 136,709	$ 149,745
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	29,899	24,257	20,081	20,601
Intangible asset amortization and impairment	37,466	37,463	36,317	34,514
Total cost of products revenues	67,365	61,720	56,398	55,115
Gross profit	77,402	73,826	80,311	94,630
Operating expenses				
Selling, general and administrative	52,775	38,193	35,298	32,942
Total operating expenses	52,775	38,193	35,298	32,942
Income from operations	24,627	35,633	45,013	61,688
Interest expense	(21,427)	(21,863)	(20,768)	(19,281)
Interest income	2,747	4,027	4,538	4,303
Loss on extinguishment of debt	(23,504)	—	—	—
(Loss) income before income taxes	(17,557)	17,797	28,783	46,710
(Benefit from) provision for income taxes	(131)	4,790	8,149	14,770
Net (loss) income	$ (17,426)	$ 13,007	$ 20,634	$ 31,940
(Loss) earnings per share — basic	$ (0.51)	$ 0.38	$ 0.61	$ 0.99
Weighted-average shares — basic	34,319,291	34,622,284	33,744,209	32,301,211
(Loss) earnings per share — diluted	$ (0.51)	$ 0.34	$ 0.53	$ 0.82
Weighted-average shares — diluted	34,319,291	42,849,952	42,058,821	41,279,981

Year Ended December 31, 2022	First Quarter		Second Quarter		Third Quarter		Fourth Quarter	
Product revenues, net	$	83,751	$	123,549	$	127,013	$	129,620
Cost of product revenues								
Cost of product revenues (excluding intangible asset amortization)		16,332		33,684		30,622		37,552
Intangible asset amortization and impairment		18,923		37,501		37,552		42,279
Total cost of products revenues		35,255		71,185		68,174		79,831
Gross profit		48,496		52,364		58,839		49,789
Operating expenses								
Research and development		3,983		—		—		—
Selling, general and administrative		54,528		41,254		38,372		38,032
Total operating expenses		58,511		41,254		38,372		38,032
(Loss) income from operations		(10,015)		11,110		20,467		11,757
Interest expense		(5,831)		(17,761)		(19,046)		(20,575)
Interest income		4		5		11		1,027
(Loss) income before income taxes		(15,842)		(6,646)		1,432		(7,791)
(Benefit from) provision for income taxes		(2,773)		(1,455)		975		(592)
Net (loss) income	$	(13,069)	$	(5,191)	$	457	$	(7,199)
(Loss) earnings per share — basic	$	(0.39)	$	(0.15)	$	0.01	$	(0.21)
Weighted-average shares — basic		33,673,912		34,001,553		34,058,802		33,582,202
(Loss) earnings per share — diluted	$	(0.39)	$	(0.15)	$	0.01	$	(0.21)
Weighted-average shares — diluted		33,673,912		34,001,553		34,570,319		33,582,202

Exhibit 10.4(d)

COLLEGIUM PHARMACEUTICAL, INC.
AMENDED AND RESTATED 2014 STOCK INCENTIVE PLAN

Restricted Stock Unit Grant Schedule

Grantee's name:	[Name]
Grant Date:	[Date]
Number of Restricted Stock Units granted:	[Quantity]
Vesting:	Subject to the Grantee's continued service to the Company through the applicable vesting dates, the Restricted Stock Units shall vest in accordance with the schedule below. Please refer to *Appendix: Vesting Schedule.*

If the Grantee's service to the Company ceases for any reason, any Restricted Stock Units that are then still subject to vesting conditions as of such date shall be immediately forfeited with no other compensation due to the Grantee. Notwithstanding the foregoing, no Restricted Stock Units subject to this Agreement shall vest unless the Grantee has complied with all applicable provisions of the Hart- Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"). If the Restricted Stock Units subject to this Agreement would have vested pursuant to this Agreement but did not vest solely because the Grantee was not in compliance with all applicable provisions of the HSR Act, the Vesting Date and the Share issuance date for such Restricted Stock Units shall occur on the first date following the date on which such Restricted Stock Units would otherwise have vested pursuant to this Agreement on which the Grantee has complied with all applicable provisions of the HSR Act.

COLLEGIUM PHARMACEUTICAL, INC.

By: ______________________________
Name: ______________________________
Title: ______________________________
Date: ______________________________

COLLEGIUM PHARMACEUTICAL, INC.
AMENDED AND RESTATED 2014 STOCK INCENTIVE PLAN

AWARD AGREEMENT FOR RESTRICTED STOCK UNITS

THIS AWARD AGREEMENT FOR RESTRICTED STOCK UNITS (this "Agreement") is made by Collegium Pharmaceutical, Inc. (the "Company") to the participant named on the grant schedule attached hereto (the "Grantee"), dated as of the date set forth on the grant schedule attached hereto (the "Grant Date").

RECITALS

WHEREAS, the Company desires to award Restricted Stock Units to the Grantee under the Collegium Pharmaceutical, Inc. Amended and Restated 2014 Stock Incentive Plan, as amended (the "Plan"), pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of the grant of Restricted Stock Units are set forth on the grant schedule (the "Grant Schedule") that is attached to, and is a part of, this Agreement.

2. Grant of Restricted Stock Units. As of the Grant Date, pursuant to the Plan, the Company hereby awards to the Grantee the number of Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement and the Plan. The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Capitalized terms used but not defined herein, including the Grant Schedule, will have the same meaning as defined in the Plan.

3. Grant Date. The Grant Date of the Restricted Stock Units is set forth on the Grant Schedule.

4. Vesting. Subject to the further provisions of this Agreement, the Restricted Stock Units will vest as set forth on the Grant Schedule (the date on which Restricted Stock Units vest being referred to as the "Vesting Date").

5. Transferability. The Restricted Stock Units are not transferable or assignable otherwise than by will or by the laws of descent and distribution. Any attempt to transfer Restricted Stock Units, whether by transfer, pledge, hypothecation or otherwise and whether voluntary or involuntary, by operation of law or otherwise, will not vest the transferee with any interest or right in or with respect to such Restricted Stock Units.

6. Issuance of Shares.

    a. Unless otherwise set forth on the Grant Schedule, within ten (10) business days following the Vesting Date (including any accelerated vesting date provided in the Grant Schedule), the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, a number of Shares equal to the number of Restricted Stock Units granted hereunder that have vested as of such date. Any Shares issued to the Grantee hereunder shall be fully paid and non-assessable.

    b. The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Restricted Stock Units, until Shares are issued in settlement of such Restricted Stock Units pursuant to Section 6(a) hereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

7. Securities Matters. The Committee may from time to time impose any conditions on the Shares issuable with respect to Restricted Stock Units as it deems necessary or advisable to ensure that the Plan satisfies the

conditions of Rule 16b-3, and that Shares are issued and resold in compliance with the Securities Act of 1933, as amended.

8. Electronic Delivery of Documents. The Grantee hereby authorizes the Company to deliver electronically any prospectuses or other documentation related to this Award, the Plan and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such plans or arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to the Grantee a paper copy of any document also delivered to the Grantee electronically.

9. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character by the of any breach or default under this Agreement, or any waiver on the part of any party or any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

10. Right of Discharge Preserved. The grant of Restricted Stock Units hereunder will not confer upon the Grantee any right to continue in service with the Company or any of its subsidiaries or Affiliates.

11. The Plan. By accepting this Award, the Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Restricted Stock Units subject to all of the terms and provisions of the Plan, as amended from time to time. Pursuant to the Plan, the Board or its Committee is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or its Committee upon any questions arising under the Plan.

12. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter this Agreement) shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Virginia, without regard to the application of the principles of conflicts of laws.

The Award is made by the Company as of the date stated in the introductory paragraph.

COLLEGIUM PHARMACEUTICAL, INC.

By: ______________________________
Name: ______________________________
Title: ______________________________
Date: ______________________________

COLLEGIUM PHARMACEUTICAL, INC.
AMENDED AND RESTATED 2014 STOCK INCENTIVE PLAN

Appendix: Vesting Schedule

Date	Quantity

Exhibit 10.14

EXECUTION VERSION

CONSENT AND FIRST AMENDMENT TO LOAN AGREEMENT

This Consent and First Amendment to Loan Agreement (this "**Consent and Amendment**"), dated as of January 3, 2023 (the "**Effective Date**"), is entered into by and among COLLEGIUM PHARMACEUTICAL, INC., a Virginia corporation (as "**Borrower**"), the Guarantors from time to time party thereto, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP, a limited partnership established under the laws of English and Wales (as a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "**Lender**").

RECITALS

WHEREAS, Borrower, Guarantors, the Collateral Agent and the Lenders have entered into that certain Amended and Restated Loan Agreement dated as of March 22, 2022 (the "**Loan Agreement**");

WHEREAS, the Borrower intends to launch a share buyback program of its Equity Interests in an aggregate amount of $100,000,000 for the calendar year of 2023 (the "**Repurchases**");

WHEREAS, the Repurchases are prohibited under Section 6.8 of the Loan Agreement;

WHEREAS, notwithstanding anything to the contrary set forth in the Loan Documents, including the requirements set forth in Section 6.8 of the Loan Agreement, the Borrower has requested that the Required Lenders and Collateral Agent consent, and the Required Lenders and Collateral Agent have agreed to consent, to the treatment of the Repurchases as a Permitted Distribution permitted under Section 6.8 of the Loan Agreement (such consent, the "**Specified Consent**); and

WHEREAS, in accordance with Section 11.5 of the Loan Agreement, Borrower (acting for its own behalf and on behalf of the other Credit Parties), Collateral Agent and the Lenders desire to amend the Loan Agreement on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

SECTION 1. Definitions; Interpretation. All capitalized terms used in this Consent & Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement. The rules of interpretation set forth in the first paragraph of Section 13.1 of the Loan Agreement shall be applicable to this Consent and Amendment and are incorporated herein by this reference.

SECTION 2. Consent and Amendment to the Loan Agreement.

(a) The Required Lenders and Collateral Agent hereby consent to the treatment of the Repurchases as a Permitted Distribution.

(b) The Loan Agreement shall be amended by deleting in its entirety Section 8.1(f) of the Loan Agreement and replacing it as follows:

> "ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. With respect to any and all Intellectual Property owned by any Credit Party and included in Collateral, each Credit Party hereby grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, as of the Closing Date: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use), without charge, including the right to sublicense, use and practice, any and all such Intellectual Property in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral, and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) in connection with the Collateral Agent's exercise of its rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral), each Credit Party's rights under all licenses and all franchise Contracts inure to the benefit of all Secured Parties;"

SECTION 3. Representations and Warranties; Reaffirmation.

(c) Borrower hereby represents and warrants to each Lender and the Collateral Agent as follows:

(i) Borrower has all requisite power and authority to enter into this Consent and Amendment and to carry out the transactions contemplated hereby.

(ii) This Consent and Amendment has been duly executed and delivered by Borrower and is the legally valid and binding obligation of such Person, enforceable against such Person in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by general principles of equity.

(iii) The execution, delivery and performance by Borrower of this Consent and Amendment have been duly authorized and do not and will not: (A) conflict with any of such Person's Operating Documents, (B) contravene, conflict with, constitute a default under or violate any material Requirements of Law, (C) contravene, conflict, result in any breach of, or require any payment to be made under any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Person is a party or affecting such Person or the assets or properties of such Person or any of its Subsidiaries, or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of its or their respective properties or assets may be bound, (D) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect), (E) constitute a material breach of or a material default or an event of default (or the equivalent thereof, however described) under, or could be reasonably be expected to give rise to the cancellation, termination or invalidation of or the acceleration of such Person's or any Subsidiary's obligations under any Material Contract or (F) require any approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Person other than a

Governmental Authority, including such Person's stockholders, members or partners, (except such approvals, consents, exemptions, authorizations, actions, notices and filings which have been or will be duly obtained, taken, given or made on or before the Effective Date and are in full force and effect).

(iv) Both before and immediately after giving effect to this Consent and Amendment, no Event of Default or Default has occurred and is continuing.

(d) Borrower hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Consent and Amendment, except as expressly provided herein. By executing this Consent and Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Consent and Amendment.

SECTION 4. References to and Effect on Loan Agreement. Except as specifically set forth herein, this Consent and Amendment shall not modify or in any way or affect any of the terms, conditions, covenants, representations and warranties contained in the Loan Agreement, or any of the rights of the Lenders and the Collateral Agent therein, which shall remain in full force and effect and is hereby ratified and confirmed in all respects. Except as specifically set forth herein, the execution, delivery and effectiveness of this Consent and Amendment shall not directly or indirectly (i) constitute a consent or waiver of any past, present or future breaches, violations or defaults of or under any provisions of the Loan Agreement nor constitute a novation of any of the Obligations under the Loan Agreement, (ii) amend, modify or operate as a waiver of any provision of the Loan Agreement or any right, power or remedy of any Lender or the Collateral Agent, or (iii) constitute a course of dealing or other basis for altering the Loan Agreement or any other Loan Document. Except as set forth herein, each of the Lenders and the Collateral Agent reserves all of its rights, powers, and remedies under the Loan Documents and Requirements of Law. Each of the Credit Parties acknowledges and agrees that the Specified Consent does not in any manner whatsoever limit any right of any of the Lenders or the Collateral Agent to insist upon strict compliance by Borrower with the Loan Agreement.

SECTION 5. Governing Law; Venue; Jury Trial Waiver. This Consent and Amendment shall be construed in accordance with and governed by the law of the State of New York. The provisions of Section 10 (*Choice of Law, Venue and Jury Trial Waiver*) of the Loan Agreement shall apply hereto as if more fully set forth herein as if references therein to "this Agreement" were references to this Consent and Amendment.

SECTION 6. Counterparts. This Consent and Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Consent and Amendment. Delivery of an executed counterpart of a signature page of this Consent and Amendment by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Consent and Amendment. The words "execution," "signed," "signature," and words of like import in this Consent and Amendment shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for under any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the undersigned has caused this Consent and Amendment to be duly executed and delivered as of the date first above written.

COLLEGIUM PHARMACEUTICAL INC.,
as Borrower

By: /s/ Joseph Ciaffoni
Name: Joseph Ciaffoni
Title: President and Chief Executive Officer

COLLEGIUM SECURITIES CORPORATION,
as an additional Credit Party

By: /s/ Joseph Ciaffoni
Name: Joseph Ciaffoni
Title: President

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By: /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BPCR LIMITED PARTNERSHIP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By: /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By: /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

COLLEGIUM PHARMACEUTICAL, INC.

INSIDER TRADING POLICY

Effective February 8, 2023 (the "Effective Date")

INTRODUCTION

This Insider Trading Policy (this "**Policy**") has been adopted by the Board of Directors (the "**Board**") of Collegium Pharmaceutical, Inc. (the "**Company**") and provides the standards of the Company on trading of the Company's securities or securities of other publicly traded companies with whom the Company has a business relationship. This policy applies to all members of the Board (each, a "**director**"), officers and employees of the Company and its subsidiaries.

One of the principal purposes of the federal and state securities laws is to prohibit so-called "insider trading." Simply stated, insider trading occurs when a person uses material, nonpublic information obtained through involvement with a company to make decisions to purchase, sell, or otherwise trade a company's securities or to provide that information to others outside such company. The prohibitions against insider trading apply to trades, tips and recommendations by virtually any person, including all persons associated with the Company, if the information involved is "material" and "nonpublic." (These terms are defined in this Policy under Definitions below.)

This Policy is designed to prevent insider trading or allegations of insider trading, and to protect the Company's and your reputation for integrity and ethical conduct.

You should read the Policy and ask any questions you may have of the Compliance Officer identified below:

General Counsel Collegium Pharmaceutical, Inc.
100 Technology Center Drive, Suite 300
Stoughton, MA 02072

APPLICABILITY

This Policy applies to all transactions in (i) the Company's securities, including common stock, options and any other securities that the Company may issue, such as preferred stock, notes, bonds and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company and (ii) another company's securities, to the extent such securities are of publicly-traded companies with whom the Company has a business relationship, including our vendors, customers, licensees and business partners.

This Policy's trading restrictions generally do not apply to the exercise of a stock option for cash or a true cashless exercise of a stock option. The trading restrictions do apply, however, to any sale of the underlying stock or to a cashless exercise of the option through a broker, as this entails selling a portion of the underlying stock to cover the costs of exercise.

This Policy applies to all directors, officers and employees of the Company and its subsidiaries. The restrictions identified in this Policy also apply to your family members who reside with you, anyone else who lives in your household and any family members who do not live in your household but whose transactions in Company securities are directed by you or are subject to your influence or control (such as parents or children who consult with you before they trade in Company securities). You are responsible for making sure that the purchase or sale of any security covered by this Policy by any such person complies with this Policy.

GENERAL POLICY

NO TRADING OR CAUSING TRADING WHILE IN POSSESSION OF MATERIAL, NONPUBLIC INFORMATION

- No director, officer or employee may purchase or sell any Company security, directly or through family members or other persons or entities, while in possession of material, nonpublic information about the Company. (The terms "material" and "nonpublic" are defined in Definitions – Materiality and – Nonpublic Information below.)

- No director, officer or employee who knows of any material, nonpublic information about the Company may communicate that information or recommend the purchase or sale of the Company's securities to any other person, including family and friends, which is an illegal practice known as "tipping."

- No director, officer or employee may purchase or sell any security of any other public company with whom the Company has a business relationship, whether or not issued by such other company, while in possession of material nonpublic information about that company that was obtained in the course of his or her involvement with the Company. No director, officer or employee who knows of any such material nonpublic information may communicate that information to any other person, including family and friends.

- All Covered Individuals (as defined in Annex A) must "pre-clear" all trading in securities of the Company in accordance with the procedures set forth in Pre-Clearance of Securities Transactions below. Annex A hereto sets forth the list of Covered Individuals as of the date indicated thereon. The Compliance Officer shall update Annex A from time to time as necessary to ensure that it remains current.

Other Prohibited Transactions

Particular types of hedging or monetization transactions allow a person to lock in much of the value of his or her stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow the person to continue to own the

covered securities, but without the full risks and rewards of ownership. When that occurs, the person may no longer have the same objectives as the Company's other shareholders. Accordingly, all trading in the Company's securities by directors, officers or employees, including such person's immediate family and the other members of their household, is subject to the following:

- Short sales. Directors, officers or employees may not sell the Company's securities short (sales of securities that are not then owned), including a "sale against the box" (a sale with delayed delivery);

- Options trading. Directors, officers or employees may not buy or sell puts or calls or other derivative securities on the Company's securities;

- Margin accounts and pledging. Directors, officers or employees may not hold Company securities in a margin account or pledge Company securities as collateral for a loan; and

- Hedging. Directors, officers or employees may not enter into hedging or monetization transactions or similar arrangements with respect to Company securities, including zero-cost collars, prepaid variable forward sale contracts, equity swaps and exchange funds.

BLACKOUT PERIODS

Quarterly Blackout Periods

A quarterly blackout period will begin at the close of business on the date that is two weeks before the end of each fiscal quarter and end at the close of business on the first full trading day following the date of the Company's earnings release with respect to such fiscal quarter in the ordinary course (each such period, a "**Quarterly Blackout Period**").

All Blackout Restricted Persons (as defined in Annex B) are prohibited from trading in the Company's securities; adopting, amending or modifying a 10b5-1 plan to trade in the Company's securities; transferring any Company securities by gift (including charitable donations); or exercising any right to purchase Company securities other than by paying the exercise price therefore in cash during a Quarterly Blackout Period, subject to the limitations and exceptions described below ("**Blackout Restricted Activities**"). Annex B hereto sets forth the list of Blackout Restricted Person as of the date indicated thereon. The Compliance Officer shall update Annex B from time to time as necessary to ensure that it remains current.

Interim Earnings Guidance

The Company may on occasion issue interim earnings guidance or other potentially material financial information by means of a press release, SEC filing on Form 8-K or other means designed to achieve widespread dissemination of the information. All Blackout Restricted Persons should anticipate that trading will be prohibited while the Company is in the process of assembling the information to be released and until the close of business on the first full trading day following the date of the Company's release of such information.

Other Blackout Periods

From time to time, an event may occur that is material to the Company and is known to only a few directors and executives (such as negotiation of mergers, acquisitions or dispositions or new product developments). So long as the event remains material and nonpublic, the persons who are aware of the event may not engage in Blackout Restricted Activities. The existence of an event-specific blackout will not be announced, other than to those who are aware of the event giving rise to the blackout. If, however, a person who (i) is subject to this Policy and (ii) is aware of the event giving rise to the blackout, requests permission to trade in the Company's securities during an event-specific blackout, the Compliance Officer will not grant such pre-clearance.

Hardship Exception

A Blackout Restricted Person who has an unexpected and urgent need to sell Company stock in order to generate cash may, in appropriate circumstances, be permitted to sell Company stock, even during the Quarterly Blackout Period. Hardship exceptions are expected to be requested only rarely, and may be granted only by the Compliance Officer and must be requested at least two days in advance of the proposed trade. A hardship exception may be granted only if the Compliance Officer reasonably concludes that the individual making the hardship exception request does not possess material, nonpublic information.

Exceptions for Approved 10b5-1 Plans

These trading restrictions do not apply to transactions under a pre-existing written plan, contract, instruction or arrangement pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (an "Approved 10b5-1 Plan") that complies with the conditions set forth below:

1. **Approval.** All persons subject to this Policy must obtain the written approval of the Compliance Officer prior to (i) adopting any new plan or (ii) modifying, amending or terminating any existing plan. The Compliance Officer shall review and ensure each proposed plan (or modification, amendment or termination of an existing plan) submitted to the Compliance Officer complies with the provisions of this Policy and applicable law, as then in effect, prior to granting any such approval (which approval shall be evidenced by such Compliance Officer's signature on the approved plan (or modification, amendment, or termination of an existing plan).

2. **Mandatory Cooling-Off Periods.**

   - ***Directors and Executive Officers.*** New plans submitted by a director or an executive officer (as such term is defined in Section 16 of the Securities Act of 1934, as amended, and the rules promulgated thereunder) of the Company, and amendments or modifications to an existing plan, must provide for transactions to occur (i) no earlier than the later of the date (the "Trade Commencement Date") that is (x) ninety (90) days after the effective date of the new plan, or amendment or modification to an existing plan, and (y) two

business days following the disclosure by the Company of its financial results in a Form 10-Q or Form 10-K for the fiscal quarter in which the plan was adopted, amended or modified, provided that the mandatory cooling-off period shall not exceed one hundred twenty (120) days after adoption of the new plan, or amendment or modification to an existing plan, and (ii) no later than one (1) year after the Trade Commencement Date;

- ***All Other Persons.*** New plans submitted by any person subject to this Policy, other than directors and executive officers of the Company, and amendments or modifications to an existing plan by such persons, must provide for transactions to occur (i) no earlier than thirty (30) days after the effective date of the new plan, or amendment or modification to an existing plan, and (ii) no later than one (1) year after the effective date thereof (or, in the case of an amendment, no later than one (1) year after the effective date of such amendment).

3. **Good Faith Certification.** All new plans, and any amendments or modifications of an existing plan, must be entered into in good faith by the trading person at a time when the trading person was not in possession of material nonpublic information about the Company. All directors and executive officers seeking to establish a new plan or amend or modify an existing plan will be required to provide a written representation to the Company certifying that (i) they are not aware of material nonpublic information about the Company or its securities, and (ii) they are adopting the new plan, or modifying or amending an existing plan, in good faith and not as part of a plan or scheme to evade the prohibitions of this Policy or Rule 10b-5-1.

4. **Discretionary Authority.** All new plans, and any modifications or amendments to an existing plan, must give a third party the discretionary authority to execute purchases and sales under the plan, on behalf of but outside the control of the trading person, provided the third party does not possess any material nonpublic information about the Company. Alternatively, the plan must explicitly specify the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions.

5. **Overlapping Plans.** No person subject to this Policy may maintain more than one active plan at the same time, without the pre-approval of the Compliance Officer. Multiple overlapping plans may be approved by the Compliance Officer in limited circumstances as permitted under Rule 10b5-1.

   - A person subject to this Policy may maintain two separate Rule 10b5-1 plans if trading under the later-commencing plan is not authorized to begin until after all trades under the earlier-commencing plan are completed or expire without execution; provided, however, that any early termination of the earlier-commencing plan will trigger a new cooling off period (as set forth in paragraph 2 above) before trades may begin under the later-commencing plan.

   - This restriction on multiple overlapping plans will not apply to a plan adopted solely and exclusively for the purpose of selling securities to satisfy a person's tax obligations

through a "sell-to-cover" method in connection with the vesting of equity awards ("Sell-to-Cover Plans"). Sales under Sell-to-Cover Plans must be strictly limited to the number of securities needed to cover such person's tax obligations and the award holder may not be permitted to exercise control over the timing of such sales. This exemption does not apply to plans for sales incident to the exercise of option awards.

- Separate contracts with different broker-dealers to execute trades pursuant to a single Rule 10b5-1 trading plan may be treated as a single plan, in which case a modification, amendment or termination to any of the individual plans will be considered a modification, amendment or termination of all of the plans.

6. **Single-Trade Plans.** Only one "single-trade plan" may be utilized by a person subject to this policy in any twelve-month period. A single-trade plan is a Rule 10b5-1 trading plan for the open market purchase or sale of the total amount of the securities subject to the plan as a single transaction. This restriction does not apply to Sell-to-Cover Plans.

PRE-CLEARANCE OF SECURITIES TRANSACTIONS

Because Covered Individuals may be likely to obtain material nonpublic information on a regular basis, the Company requires that all Covered Individuals refrain from trading, even when no blackout period is in effect, without first pre-clearing all transactions in the Company's securities.

Except for purchases and sales pursuant to an Approved 10b5-1 Plan, no Covered Individual may, directly or indirectly, purchase or sell (or otherwise make any transfer or gift (including any charitable donation)) any Company security at any time without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by such person's immediate family members and other members of their household, and to transactions by entities over which such person exercises control. In advance of pre-clearance of a transaction in the Company's securities, Covered Individuals must confirm that they are not in possession of material nonpublic information.

A request for pre-clearance should be submitted to the Compliance Officer at least one business day in advance of the proposed transaction. The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days after the day on which it was granted. If the transaction does not occur during the two business day period, pre-clearance of the transaction must be re-requested. For example, if the pre-clearance request was approved on Monday, June 3, 2019, then the Covered Individual must complete his or her transaction on or prior to the close of business on Wednesday, June 5, 2019.

If you seek pre-clearance for a transaction and if permission to engage in the transaction is denied, you should refrain from initiating any transaction in the Company's securities and

should not inform any other person of this denial as such denial could constitute, or signal the existence of, material nonpublic information.

POST-EMPLOYMENT TRANSACTIONS

The trading restrictions of this Policy will continue to apply to all directors, officers and employees of the Company who are aware of material, nonpublic information after they terminate employment or services. Such persons may not trade in the Company's securities until that information has become public or is no longer material. In all other respects, the pre-clearance and blackout procedures set forth in this Policy will cease to apply to such person's transactions in the Company's securities upon the expiration of any "blackout period" that is applicable at the time of such person's termination of employment or services.

COMPLIANCE WITH SECTION 16 AND RULE 144

Directors and executive officers are responsible for compliance with Section 16 of the Securities Exchange Act and Rule 144 of the Securities Act in connection with their transactions in the Company's securities. The requirements of this Policy do not supersede the required compliance with your obligations under Section 16 or Rule 144.

Section 16

Directors and executive officers should be aware that most transactions in the Company stock are subject to the accelerated two business day reporting requirements under Section 16. The Company's policy is to assist directors and officers in completing and filing their Section 16 reports. It is important that the Compliance Officer receive prompt notice of reportable transactions, so that the Company can assist in filing the required reports on a timely basis. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third party effecting transactions on behalf of the trading person who is subject to Section 16 should be instructed to send duplicate confirmations of all such transactions to the Compliance Officer on the trade date in order to facilitate timely Section 16 reporting.

Rule 144

Directors and executive officers are required to file Form 144 before making open market sales of Company stock. This requirement applies whether the shares are legended or unlegended, restricted or unrestricted, held in a brokerage account, represented by a stock certificate or book entry position. Form 144 is generally prepared and filed by such individual's broker.

DEFINITIONS

"Materiality"

Insider trading restrictions come into play only if the information you possess is "material." Information is generally regarded as "material" if it has market significance, that is, if

its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision. Information dealing with the following subjects is reasonably likely to be found material in particular situations:

- significant write-downs in assets or increases in reserves;
- developments regarding significant litigation or government agency investigations;
- liquidity problems;
- projections of future earnings or losses or other earnings guidance;
- changes in earnings estimates or unusual gains or losses in major operations;
- changes in the Company's pricing or cost structure;
- major marketing changes;
- major changes in management;
- developments regarding regulatory approval or disapproval of the Company's products;
- major developments in, or results of, clinical trials of the Company's products;
- a significant cybersecurity incident, such as a computer system failure, accident or security breach, that could result in a material disruption of the company's operations, including its commercialization and drug development programs;
- major events regarding the Company's securities, including the declaration of a stock split, a change in dividend policy or the offering of additional securities;
- extraordinary borrowings or similar financing transactions;
- changes in debt ratings; and
- public offerings or proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, joint ventures, or purchases or sales of substantial assets.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new solution, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the probability that the event will occur is not great. Because trading that receives scrutiny will be evaluated after the fact with the benefit of hindsight, questions concerning the materiality of particular information should be resolved in favor of materiality, and trading should be avoided. If you are unsure whether information is material, you should consult the Compliance Officer before making any decision to disclose such information or to trade in or recommend securities to which that information relates.

"Nonpublic Information"

Insider trading prohibitions come into play only when a person possesses information that is material and "nonpublic." To be "public" the information must have been disseminated in a manner designed to reach investors generally (such as by a press release or an SEC filing), and the investors must be given the opportunity to absorb the information fully. Nonpublic information may include:

- information available to a select group of analysts or brokers or institutional investors;
- undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information.

As a general rule, information should be considered nonpublic until the conclusion of one full trading day after the day on which the information is released. For example, if the Company makes an announcement after the market opens on a Monday, the first time you can buy or sell Company securities is on Wednesday (assuming you are not aware of other material, nonpublic information at that time). As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is "nonpublic" and treat it as confidential.

"Compliance Officer"

The Board of Directors has appointed the General Counsel, or in his or her absence, the General Counsel's designee, as the compliance officer (the "Compliance Officer") for this Policy.

CERTIFICATION

All employees of the Company must certify their understanding of, and intent to comply with, this Policy, on the applicable form attached to this Policy.

VIOLATIONS OF INSIDER TRADING LAWS

Penalties for trading on or communicating material nonpublic information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

Legal Penalties

Violation of this Policy may result in both civil and criminal penalties under applicable securities laws including imprisonment, criminal fines and civil penalties. In addition, a person who tips others may also be liable for transactions by the tippees to whom he or she has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the Securities and Exchange Commission has imposed large penalties even when the tipper did not profit from the transaction.

Company-imposed Penalties

Employees who violate this Policy may be subject to disciplinary action by the Company, including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by

the Compliance Officer and must be provided before any activity contrary to the above requirements takes place.

CERTIFICATION

To Collegium Pharmaceutical, Inc.:

I have received and read a copy of the Collegium Pharmaceutical, Inc. Insider Trading Policy. I understand and acknowledge that I am subject to the Insider Trading Policy and I hereby agree to comply with the requirements of this Policy, including the portion thereof relating to Pre-clearance and Blackout Procedures.

____
(Name)

____
(Signature)

____
(Date)

This document states a policy of Collegium Pharmaceutical, Inc. and is not intended to be regarded as the rendering of legal advice.

ANNEX A
Covered Individuals

As of the Effective Date, the "Covered Individuals" are:

- All directors of the Company;
- All Section 16 executive officers of the Company;
- All members of the executive committee of the Company;
- The vice president of investor relations, vice president of finance, vice president of commercial finance, vice president of commercial operations, senior director of financial operations, controller and each other employee involved in, or with direct access to, the financial close process;
- Each employee involved in business development or market access initiatives; and
- Each other employee that the Compliance Officer may, from time to time, designate in his or her discretion.

ANNEX B
Blackout Restricted Persons

As of the Effective Date, the "Blackout Restricted Persons" are:

- All directors of the Company;
- All Section 16 executive officers of the Company;
- All members of the executive committee of the Company;
- The vice president of investor relations, vice president of finance, vice president of commercial finance, vice president of commercial operations, senior director of financial operations, controller and each other employee involved in, or with direct access to, the financial close process; and
- The vice president of commercial finance, vice president of commercial operations, senior director of finance, controller and each other employee involved in, or with direct access to, the financial close process.

Exhibit 21.1

Subsidiaries of Collegium Pharmaceutical, Inc.

Subsidiary	Jurisdiction of Incorporation
Collegium Securities Corporation	Massachusetts
Collegium NF, LLC	Delaware
BioDelivery Sciences International, Inc.	Delaware
Arius Pharmaceuticals, Inc.	Delaware
Arius Two, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-237200 on Form S-3 and Registration Statement Nos. 333-207744, 333-218767, 333-225498, 333-233092, 333-245649, 333-258752, 333-266778, and 333-273874 on Form S-8 of our reports dated February 22, 2024, relating to the financial statements of Collegium Pharmaceutical, Inc. (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, 2023.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 22, 2024

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 22, 2024

Exhibit 31.2

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

I, Colleen Tupper, 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/ COLLEEN TUPPER
Colleen Tupper
Executive Vice President and Chief Financial Officer

Dated: February 22, 2024

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, 2023 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 their 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 22, 2024

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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Colleen Tupper, 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 their 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/ COLLEEN TUPPER
Colleen Tupper
Executive Vice President and Chief Financial Officer

Date: February 22, 2024

Exhibit 97

COLLEGIUM PHARMACEUTICAL, INC.
CLAWBACK POLICY

Effective February 6, 2020

Amended Effective September 22, 2023 (the "Amended Effective Date")

I. PURPOSE

The Board of Directors (the "Board") of Collegium Pharmaceutical, Inc. (the "Company") believes that it is in the best interest of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's compensation philosophy. The Board has adopted this clawback policy (as amended, the "Clawback Policy") which provides for recoupment of certain executive compensation in the event of a Financial Restatement (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market LLC (the "Exchange"). Capitalized terms used and not otherwise defined herein shall have the meanings given in Article IV below.

II. COVERED PERSONS

A "Covered Individual" under this Clawback Policy means (i) each individual who served as an Executive Officer at any time during the performance period applicable to the Incentive Compensation, whether or not still employed by the Company (and regardless of whether such Incentive Compensation was received during or after such person's service as an Executive Officer) and (ii) such other current or former employees of the Company who may from time to time be deemed subject to this Clawback Policy by the Compensation Committee of the Board (the "Committee").

III. RECOVERY

If the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation from Covered Individuals with respect to such Financial Restatement.

The method of recovery of Erroneously Awarded Compensation will be determined by the Committee and may include (without limitation): (a) recoupment of cash or shares of Company stock; (b) forfeiture of unvested awards; (c) cancellation of outstanding vested awards; (d) offset of other amounts owed to the Covered Individual; (e) reduction of future compensation; and (f) any other remedial or recovery action permitted by law.

If the Erroneously Awarded Compensation includes shares of Company stock (or derivatives thereof), the Committee may seek to require that the Covered Individual repay to the Company any dividends or dividend equivalents paid with respect to those securities, and any profits realized, directly or indirectly, from the sale or other disposition of those securities.

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Individuals are not entitled to indemnification for any Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Clawback Policy.

This Clawback Policy shall be binding and enforceable against all Covered Individuals and their respective beneficiaries, heirs, executors, administrators or other legal representatives.

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Clawback Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

IV. ADDITIONAL DEFINITIONS

1. "Applicable Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. The Applicable Period will include any transition period resulting from a change in the Company's fiscal year, if that transition period occurs within or immediately following those three completed years; provided that a transition period of nine to 12 months will be deemed a completed fiscal year.

2. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

3. "Erroneously Awarded Compensation" means, with respect to any Covered Individual, the excess of (i) the Covered Individual's actual Incentive Compensation over (ii) the Incentive Compensation the Covered Individual otherwise would have earned, became vested in or been granted during the Applicable Period if the Company's financial statements had reflected the restated amounts in a Financial Restatement. Erroneously Awarded Compensation will be computed without regard to taxes paid. Erroneously Awarded Compensation shall not include any Incentive Compensation received by a Covered Individual prior to a Covered Individual's service as an Executive Officer. Calculation of Erroneously Awarded Compensation with respect to Incentive Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs. Incentive Compensation received by a Covered Individual prior to the Amended Effective Date shall be subject to the terms of this Clawback Policy as in effect prior to the Amended Effective Date.

4. "Executive Officer" means any person who served the Company in any of the following roles: the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries

of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

5. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

6. "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period

7. "Incentive Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment, during the Applicable Period, of any Financial Reporting Measure.

8. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

V. TAX CONSIDERATIONS

To the extent that, pursuant to this Clawback Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Individual, the gross amount received (i.e., the amount the Covered Individual received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Individual.

VI. ADMINISTRATION

The Committee has the exclusive power and authority to administer this Clawback Policy, including, without limitation, the right and power to interpret this Clawback Policy and to make all determinations deemed necessary or advisable for the administration of this Clawback Policy; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. All actions, interpretations and determinations taken or made by the Committee will be final, conclusive and binding, and any such actions, interpretations and determinations need not be uniform with respect to all Covered Individuals. The Company's right of recoupment under this Clawback Policy is in addition to any right or remedy otherwise available to the Company, including (without limitation) disciplinary action up to and including termination of employment and the initiation of civil or criminal proceedings; provided that there shall be no duplication of recovery under this Clawback Policy and Section 304 of the Sarbanes-Oxley Act of 2002.

This Clawback Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Clawback Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the

extent the Applicable Rules require recovery of Incentive Compensation in additional circumstances besides those specified above, nothing in this Clawback Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive Compensation to the fullest extent required by the Applicable Rules.