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, 2022

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	**02072**
Stoughton, MA	(Zip Code)
(Address of principal executive offices)	

(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, 2022, 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 $599.6 million, based on the closing price of the registrant's common stock on The NASDAQ Global Select Market on June 30, 2022 of $17.72 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, 2023, there were 34,066,568 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 2023 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed within 120 days of the registrant's year ended December 31, 2022, 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 obtain regulatory approval for any product candidates we may acquire in the future;
- 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 and any future product candidates;
- our ability to comply with stringent government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency ("DEA") compliance;
- our customer concentration, which may adversely affect our financial condition and results of operations;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading "Risk Factors" in this Annual Report on Form 10-K.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Annual Report on Form 10-K (including the exhibits hereto) might not occur. We undertake no obligation, and

specifically decline any obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

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

PART I

Item 1. Business

Overview

We are 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 U.S. Food and Drug Administration (“FDA”) in April 2016 for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We commercially launched Xtampza ER in June 2016.

The Nucynta Products are extended-release (“ER”) and immediate-release (“IR”) formulations of tapentadol. Nucynta ER is indicated for the management of pain severe enough to require daily, around the clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. We began shipping and recognizing product sales on the Nucynta Products in January 2018 and began marketing the Nucynta Products in February 2018.

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, pursuant to an Agreement and Plan of Merger, dated as of February 14, 2022, by and among us, Bristol Acquisition Company Inc., our wholly owned subsidiary, and BDSI (the “BDSI Acquisition”). Upon closing, we acquired the Belbuca, Symproic, and Elyxyb products. We began shipping and recognizing product sales related to Belbuca, Symproic, and Elyxyb in March 2022.

Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment 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. Elyxyb was approved by the FDA in May 2020 for the acute treatment of migraine with or without aura in adults. We discontinued commercialization of Elyxyb in the fourth quarter of 2022 and transferred that product, together with related assets and liabilities, to a third party in the first quarter of 2023.

For the fiscal year ended December 31, 2022, we generated $463.9 million in net revenues across our portfolio.

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

Acute and Chronic Pain

Pain can be classified along many different variables, including severity, duration and etiology. There are two broad categories of pain based on duration: acute pain, or pain that is self-limited and generally requires treatment for no more

than up to a few weeks, and chronic pain, or pain that lasts beyond the healing of an injury or that persists longer than 3-6 months. The overall prevalence of chronic pain among adults in the United States is 20.4%, affecting approximately 50.0 million Americans. Additionally, 7.4% of the U.S. adult population, approximately 19.6 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 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 2022, there were approximately 145.1 million prescriptions for opioids written in the United States, representing a 5% decline from 2021 levels and including approximately 2.6 million prescriptions for branded extended-release opioids, approximately 11.6 million prescriptions for generic extended-release opioids, and approximately 130.9 million prescriptions for immediate-release opioids. After marked increases in opioid prescriptions from 2000 to 2015, prescriptions have decreased each year since 2015, correlating with rising awareness of the extent and impact of the opioid crisis. Indeed, 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, reaching a rate of 4.9 per 100,000 persons in 2018. Meanwhile, the predominant opioid cause of death in 2018 involved synthetic opioids other than methadone. While opioid-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.

The emergence of COVID-19 in early 2020 raised fears that already-rising drug overdose deaths could surge even further amid social isolation, economic stress, and disrupted access to treatment facilities and providers. Prior research showed that overdose deaths immediately spiked to previously unseen levels after the COVID-19 pandemic began to impact the United States domestically in March 2020 and stayed elevated throughout the summer of 2020.

The Department of Health and Human Services (“HHS”) estimates that in 2022, 10.1 million Americans misused prescription opioids in the last year, 1.6 million had an opioid use disorder, and more than 48,000 died from overdosing on synthetic opioids other than methadone. 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.

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 have in recent years enacted new legislation and regulations intended to fight the opioid epidemic. At the federal level (in addition to the DEA and FDA efforts discussed elsewhere in this Annual Report on Form 10-K), in 2016 the CDC issued prescribing guidelines intended to reduce opioid-related harms by encouraging primary care physicians to limit the amount of morphine milligram equivalents (MMEs) that they prescribe for chronic pain patients. 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 newly 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") provided guidance to clinicians initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain.

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.

Our Portfolio

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.

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

Xtampza ER, OxyContin, 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 2023. 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: 1) differential misidentification among drug groups which may affect observed differences, and 2) case counts of drug groups comprised primarily of branded products (other ADF ER opioids) may be overestimated when based on self-reporting and drug groups comprised primarily of generic products (non-ADF 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 oral formulations of tapentadol. Nucynta ER was approved by the FDA in November 2008 for the management of pain severe enough to require daily, around the clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR was approved by the FDA in November 2008 for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

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 14% of net sales of the Nucynta Products directly to Grünenthal Gmbh under the Grünenthal License.

Belbuca and Symproic

Belbuca is a buccal film that contains buprenorphine, a partial opioid agonist, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative options are inadequate.

Symproic is an oral formulation of naldemedine. Symproic was approved by the FDA in March 2017 for the treatment of 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 commercializing Belbuca and Symproic in March 2022 upon consummation of the BDSI Acquisition.

Manufacturing of Our Products

Overview

Xtampza ER is manufactured using a proprietary process. This process is reproducible, scalable, and cost-efficient, and we believe that the microsphere formulation — and the related manufacturing process — is unique in the extended-release opioid market. To date, we have produced Xtampza ER through a contract manufacturing organization, Patheon, a subsidiary of Thermo Fisher Scientific, Inc. Our microsphere production is currently conducted in 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.

Nucynta ER was historically produced at a Janssen 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. Thus, Nuncynta ER is currently manufactured at Patheon, pursuant to a supply agreement. Nucynta IR is produced at a contract manufacturing organization, Cambrex, pursuant to a supply agreement.

Belbuca and Symproic are manufactured pursuant to supply agreements we assumed from BDSI in connection with the BDSI Acquisition. 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. Prior to discontinuation of our commercialization activities, Elyxyb was manufactured and packaged by Contract Pharmaceuticals Limited Canada in Mississauga, Ontario.

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	Buprenorphone	Schedule III
Symproic	Naldemedine	Not a controlled substance
Elyxyb	Celecoxib	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 numbers of suppliers. As part of our business continuity program, we are in the process of qualifying additional API manufacturers.

Marketing and Commercialization

We commercialize our products in the United States with a dedicated field sales force, consisting of approximately 120 sales representatives and managers, to call on the approximately 8,600 health care professionals who write approximately 62% 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. Three of our customers comprised more than 10% of our revenue during the year ended December 31, 2022. These customers comprised 33%, 33% and 31% of revenue, respectively.

As the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. Notwithstanding the fact that the Department of Health and Human Services is planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term.

Intellectual Property

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

Nucynta 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 ER is protected by seven 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 2023, 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 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 Application ("IND") 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 along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or subjects under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations 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 supplemental NDA ("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 CE for Healthcare Providers (HCPs), 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.

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

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

The FDA recently announced a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee to be held on April 19, 2023. The committee will discuss post-marketing requirements 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 will focus on a clinical trial designed to address these objectives. We intend to participate in this meeting.

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 annually 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 an annual 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. As a result of a projected decrease in need for Schedule II opioids in 2023 and in an attempt to further reduce the risk of diversion, the DEA is lowering the supply of Schedule II opioids, which includes an average decrease in oxycodone and tapentadol, of approximately 6%.

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 CMS of medically-assisted treatment options. In addition, the SUPPORT Act requires HHS to report to Congress on existing barriers to access to abuse-deterrent opioid formulations by Medicare Part C and D beneficiaries.

Healthcare Fraud and Abuse Laws and Compliance Requirements

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

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

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

The civil False Claims Act and similar state laws impose liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The *qui tam* provisions of the False Claims Act and similar state laws allow a private individual to bring civil actions on behalf of the federal or state government and to share in any monetary recovery. The Federal Physician Payments

Sunshine Act and similar state laws impose reporting requirements for various types of payments to physicians, other licensed healthcare practicioners 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.

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, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (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 unconsistutional, 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, although they have been suspended by the Coronavirus Aid, Relief and Economic Security, or CARES, Act, until March 31, 2022. From April through June 2022, a 1% reduction was in effect. As of July 2, 2022, the 2% cut resumed.

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

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

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 require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. The Inflation Reduction Act of 2022 also caps Medicare

beneficiaries' annual out-of-pocket drug expenses. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 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 Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

Other Regulatory Requirements

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

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

Our commitment to serving as a responsible corporate citizen, through the advancement of our mission, expansion of our product portfolio, intentional business decisions and dedication to corporate social responsibility (CSR) activities, is longstanding. We have focused on implementing corporate governance and risk-mitigation best practices, investing in the development of our culture and people, engaging with our broader communities in meaningful ways and introducing operational efficiencies to reduce our environmental impact. As a reflection of this commitment, our annual Corporate Scorecard has included metrics relating to our performance relative to specific ESG initiatives.

In February 2023, we published our inaugural ESG report on our corporate website highlighting our ESG accomplishments to date and focus on advancing the oversight, evolution, and reporting of our ESG program. The information contained in our ESG report is not a part of, nor is it incorporated by reference in, this Form 10-K.

Collegium Culture, Employee Engagement and Management of Human Capital Resources

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 safety and wellness; talent acquisition and retention; employee engagement, development, and training; diversity and inclusion; and compensation and pay equity.

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.

As one reflection of our Core Values, we are dedicated to being a responsible corporate citizen. We and our employees strive to make a positive impact in the communities where we live and work by fostering a culture of philanthropy, service, and mentorship, supporting the wellness of our communities, and working for equitable access to education and educational resources. In addition, we have a charitable matching gift program, which enables employees to make matched charitable donations to any registered 501(c)(3) charity. We have also established a service initiative, which includes financial donations supporting local and national nonprofits with a focus on STEM initiatives and community service. In 2022, we donated over $350,000 and approximately 180 hours of service in support of these charitable initiatives.

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. These programs include benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice, where possible, so they can customize their benefits to meet their needs and the needs of their families.

Employee Engagement

None of our employees are represented by a labor organization or under any collective bargaining arrangements. We consider our employee relations to be good. We were named a 2022 National Top Place to Work for the second consecutive year following recognition in the Boston Globe's Top Places to Work Massachusetts in 2021 and the Boston Business Journal's Best Places to Work in 2020. These recognitions are based on anonymous employee surveys, and we believe these recognitions reflect our mission, Core Values and dedication to employees' well-being.

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. We offer a comprehensive and competitive benefit package to all full-time employees including medical, dental and vision benefits; flexible spending account; life and disability insurance; paid parental and caregiver leave; a 401(k) with a dollar-for-dollar matching contribution on the first 5% contributed by the employee; an employee stock purchase plan; a hybrid workweek that allows most employees to work from home up to two days each week; charitable matching up to $1,000 per employee per calendar year for donations to registered 501(c)(3) charities; tutoring for employees'children; a company-wide shut down during the last week of the year; complementary access to the gym in our headquarters and a fully stocked snack and drink room available to employees at our headquarters. In addition, through our Collegium Cares Program, employees can award points to colleagues for demonstrating our Core Values and Leadership Behaviors, which can be exchanged for rewards.

In 2022, we had 90 new hires and, as of December 2022, our voluntary turnover rate was 28.3% in the home office and 38.8% in the field.

Employee Training and Development

We believe that 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. All employees work with their managers to create annual Individual Development Plans with specific objectives and resource actions. We encourage our employees to develop breadth and depth of experience, build transferable skills, broaden perspectives and hone technical skill sets. While career promotion is driven by business needs and sustained strong performance and capabilities, we have identified and articulated Leadership Behaviors that drive career development within the organization, and our people managers provide feedback to all employees that is tied to demonstration of these skills.

Our comprehensive performance review process ensures our employees are on track with their development throughout the year and provides an opportunity for managers to identify talented individuals for our Emerging Leaders Program. This is an annual initiative comprising specialized assessments and training to prepare employees for management and leadership positions throughout the business and reaffirms our commitment to excellence in our industry.

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.

Consistent with this commitment, we established our DEI Council comprised of a cross-functional team of employees and executives in June 2020. The DEI Council focuses on shaping and implementing our DEI strategy and routinely reviews our recruitment and hiring practices, with the intention of improving diversity at all levels within our organization. Additionally, we are implementing a 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 2022, we had a total of 207 employees with representation with respect to gender and self-reported race and ethnicity as follows:

Ethnicity	#	%
Asian (Not Hispanic or Latino)	14	6.8%
Black or African American (Not Hispanic or Latino)	12	5.8%
Hispanic or Latino	5	2.4%
Prefer Not to Disclose	4	1.9%
Two or More Races (Not Hispanic or Latino)	3	1.4%
White (Not Hispanic or Latino)	169	81.7%

Gender	#	%
Female	102	49.3%
Male	105	50.7%

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.

Environmental Impact

We recognize that our duty of care extends beyond people to the planet we all share. We are taking action to minimize our environmental impact through several initiatives, such as implementing in-office processes to minimize the use of consumables, investing in clean-in-place manufacturing systems, and exploring options to reduce the impact of our sales fleet, to name a few.

Moreover, we continue to review and update our vendor performance management and other operational policies as part of our commitment to environmental sustainability. This practice enables us to minimize resource use and waste generation, optimize the use of raw materials and undertake continuous improvement in environmental performance, with an emphasis on recycling packaging materials and implementing sustainability opportunities in our vendor supply chains.

We are developing an action plan to ensure we are actively monitoring our use of resources throughout the value chain. We are working to review and understand the financial implications of our environmental risks, setting baselines and tracking resources with a focus on reducing our impacts, while maintaining transparency about future climate risks and the material impacts on our company.

We conduct our operations in compliance with applicable laws, directives, and regulations. Our current material handling policies and management systems include procedures for assessing compliance with applicable laws and regulations and reporting incidents of non-compliance to applicable governmental authorities.

Our Executive Officers

The following table lists the positions, names and ages of our executive officers as of February 23, 2023:

Name	Age	Position(s)
Joseph Ciaffoni	51	Director, President and Chief Executive Officer
Colleen Tupper	47	Executive Vice President and Chief Financial Officer
Scott Dreyer	50	Executive Vice President and Chief Commercial Officer
Shirley Kuhlmann	39	Executive Vice President, General Counsel and Chief Administrative Officer
Thomas Smith	62	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 his 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, PA. 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 and future product candidates, if approved, that we may develop or acquire in the future;
- We have substantial outstanding indebtedness, which may adversely affect our business, financial condition and results of operations;
- If we cannot continue successfully commercializing our products, 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 future product candidates which we may develop, 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, and our future product candidates may contain, controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies;
- 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 numbers 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 has been, and may continue to be, adversely affected by certain events or circumstances outside our control, including the effects of the COVID-19 pandemic 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, and clinical trials of any future product candidates we may develop or 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;
- 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 and future product candidates, if approved, that we may develop or acquire in the future. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

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

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

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

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

As of December 31, 2022, we had a U.S. federal net operating loss ("NOL") carryforward of approximately $229.8 million and state NOL carryovers of approximately $252.6 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 $4.2 million, and state tax credits of approximately $0.8 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. Refer to Note 17, *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 $575.0 million in principal was outstanding as of December 31, 2022. 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 Conertible 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 flow from operations to service our indebtedness, which will reduce the amount of cash available for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other purposes;
- limiting our ability to obtain additional financing;
- limiting our flexibility to plan for, or react to, changes in our business;
- 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, including any such downturn related to the impact of the COVID-19 pandemic.

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 bear interest at a rate based on LIBOR, subject to a LIBOR floor of 1.20%. LIBOR tends to fluctuate based on general short-term interest rates, rates set by the U.S. Federal Reserve and other central banks, the supply of and demand for credit in the London interbank market and general economic conditions. 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 LIBOR 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.

The Financial Conduct Authority (“FCA”), the regulatory supervisor of USD LIBOR’s administrator (“IBA”), has announced the future cessation or loss of representativeness of overnight/Spot Next, 1-month, 3-month, 6-month and 12-month USD LIBOR tenor settings. As a result, most USD tenors of LIBOR will cease on December 31, 2023. Following

such date, subject to an earlier opt-in triggered by the collateral agent or us, amounts outstanding under our 2022 Loan Agreement are expected to bear interest at a rate based on the Secured Overnight Financing Rate ("SOFR"), a new index calculated by reference to short-term repurchase agreements backed by U.S. Treasury securities, in place of LIBOR. Currently, it is not possible to predict the effect of any discontinuance, modification or other reforms to LIBOR, or the establishment of alternative reference rates such as SOFR, or any other reference rate, will have on us or our borrowing costs.

Risks Related to our Products

If we cannot continue successfully commercializing our products, 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.

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; 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 an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim.

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

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could 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 future product candidates which we may develop, we may lose valuable assets or be unable to compete effectively in our market.

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

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

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

We have been, and may continue to be, forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets, 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.

Additionally, our sales, marketing and distribution capabilities may continue to be hindered as a result of the COVID-19 outbreak. As the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. Notwithstanding the fact that the Department of Health and Human Services is planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term. We have, and will continue to, equip our personnel with the tools and resources needed to effectively continue their sales and marketing efforts in a manner that complies with all relevant regulations, whether in person or from a remote setting. We face the risk, however, that limitations on activities within the healthcare sector and on economic activity generally will impede our ability to continue successfully commercializing our products.

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

Some of our products contain, and our future product candidates may contain, controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as Schedule II controlled substances under the CSA and regulations of the DEA 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, see 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 development and commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

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

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

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could prevent or delay marketing approval of future product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell our products for which we obtain marketing approval. For example, several states, including New York, have 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 require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. The Inflation Reduction Act of 2022 also caps Medicare beneficiaries' annual out-of-pocket drug expenses. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 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 Inflation Reduction Act of 2022 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. See 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 payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue and maintain profitability.

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

Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to 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 payers may not be willing to pay a premium for abuse-deterrent formulations of opioid.

Federal laws have been enacted to address the national epidemics of prescription opioid abuse and illicit opioid use, including the Comprehensive Addiction and Recovery Act and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. These laws are described in more detail 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. 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. For more information, refer to Note 12, *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.

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 completed the activities required to transition 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 cost, to qualify these sources. Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and Nucynta ER, exposes us to the following risks, any of which could impact commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products including the COVID-19 pandemic, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment;
- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and/or 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 development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require our products to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. 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, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

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

Because we currently rely on a sole supplier 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. For example, we presently depend upon a single supplier for the active pharmaceutical ingredient for the Nucynta Products (tapentadol) and Symproic, and two active pharmaceutical ingredient suppliers for Xtampza ER and Belbuca. 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 the COVID-19 pandemic and geopolitical turmoil, such as the Ukrainian War. 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 proceed with our planned clinical trials, obtain regulatory approval for commercial marketing and build commercial supplies. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply.

We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors 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, 2022. 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, including as a result of the COVID-19 pandemic, 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. In addition, due to unprecedented and significant disruptions in the processing of product returns by wholesale pharmaceutical distributors, as further disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations," we formally denied a significant portion of unprocessed product claims under our return policy. We subsequently received payment for only a portion of the denied claims and vigorously pursued collections of the full amount of these short-pay receivables. Although we were able to formally settle a portion of the unprocessed product claims and receive payment therefor, payment for a significant portion of the unprocessed product claims has not been and is not expected to be received. There can be no assurance that similar disruptions in the wholesaler distribution network will not occur in the future or if they do, that we will be able to successfully manage such disruptions.

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

Our opioid products are subject to a comprehensive regulatory scheme, including post-marketing requirements ("PMRs") to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium ("OPC"). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of 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. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

We have historically relied on third parties to conduct our non-clinical and clinical trials, and may continue to rely upon third parties for any product candidates we develop or acquire in the future. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect.

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

Risks Related to Our Business and Strategy

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 has been, and we may in the future continue to be, adversely affected by certain events or circumstances outside our control, including the COVID-19 pandemic and geopolitical turmoil.

Our business has been, and we may in the future continue to be, adversely affected by certain events or circumstances outside our control. For example, the COVID-19 pandemic has, and may continue to have, a substantial impact on the delivery of healthcare services in the United States. As the COVID-19 pandemic unfolded, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. We believe that the disruptions caused by COVID-19 may continue and, despite the Department of Health and Human Services planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations.

In addition, other 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, social unrest, political instability, 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.

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 alleged 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 all 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 will be dismissed, with prejudice.

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

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

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

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

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

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

Risks Related to Our Common Stock

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

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors described in these "Risk Factors," some of which are beyond our control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations. 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, 2022, there were outstanding options to purchase an aggregate of 1,683,805 shares of our common stock at a weighted average exercise price of $18.84 per share, of which options to purchase 1,545,610 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. On January 1, 2023, our Board of Directors authorized a new share repurchase program for the repurchase of up to $100 million of shares of our common stock at any time or times through December 31, 2023 (the "2023 Repurchase Program"). Under the 2023 Repurchase Program, we will be permitted 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. Although a substantial number of shares were repurchased pursuant to the Prior Repurchase Program, any future share repurchases under the 2023 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 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 12, *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 is publicly traded on the NASDAQ Global Select Market under the symbol "COLL" since May 7, 2015. Prior to May 7, 2015, there was no public trading market for our common stock.

Holders

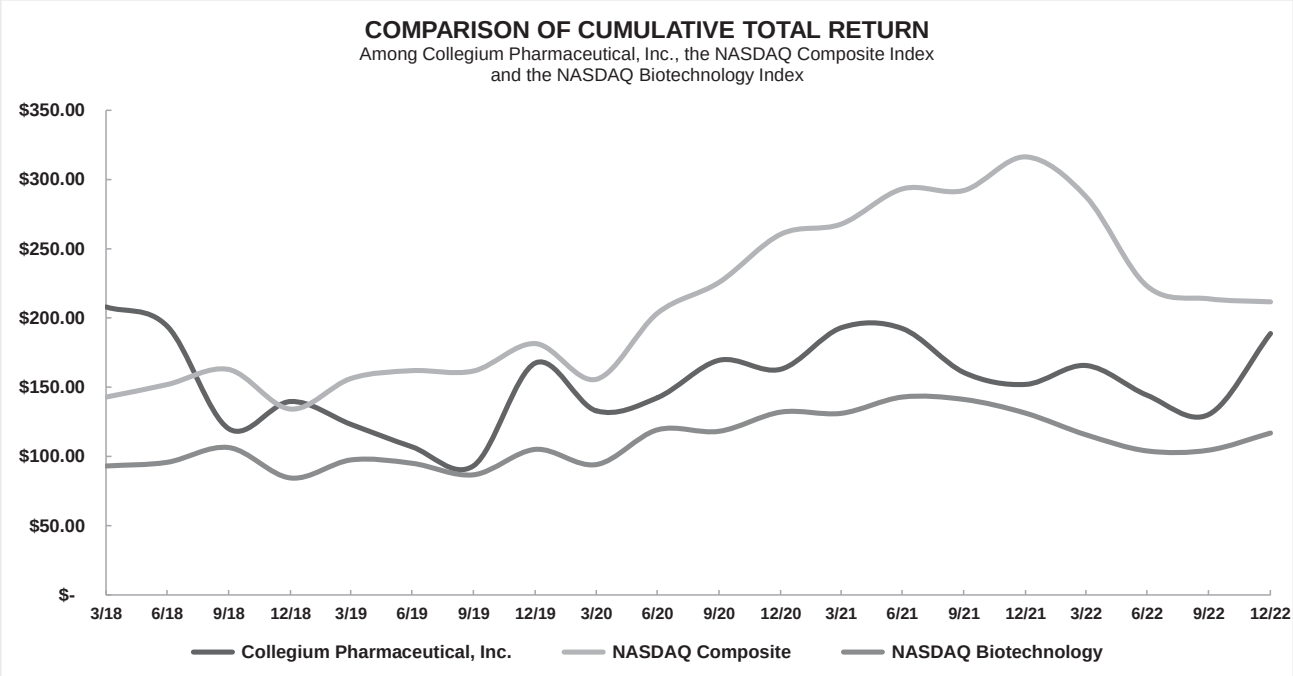
As of January 31, 2023, there were 15 holders of record of our common stock. The number of holders of record does not include beneficial owners whose shares are held by nominees in street name.

Dividends

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

Stock Performance Graph

The following graph shows a comparison from May 7, 2015, the date on which our common stock first began trading on the NASDAQ Global Select Market, of the total cumulative shareholder return on an assumed investment of $100.00 in cash in our common stock as compared to the same investment in the NASDAQ Composite Index and the NASDAQ Biotechnology Index, all through December 31, 2022. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and NASDAQ Biotechnology Index assume reinvestment of dividends, however no dividends have been declared on our common stock to date.



$100 investment in stock or index	May 7, 2015	December 31, 2022
Collegium Pharmaceutical, Inc. (COLL)	$ 100.00	$ 188.77
NASDAQ Composite Index (IXIC)	$ 100.00	$ 211.63
NASDAQ Biotechnology Index (NBI)	$ 100.00	$ 116.98

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 August 2021 (the "Prior 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, 2022:

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
October 1, 2022 through October 31, 2022	206,525	$ 17.48	205,600	$ 42,122
November 1, 2022 through November 30, 2022	206,668	19.63	206,161	38,076
December 1, 2022 through December 31, 2022	904	21.85	—	38,076
Total	414,097 (2)	$ 18.56	411,761 (2)	$ 38,076

(1) The Prior Repurchase Program was announced on August 16, 2021. The Prior Repurchase Program provided for the repurchase of up to $100 million of outstanding shares of our common stock at any time or times through December 31, 2022. The Prior Repurchase Program expired December 31, 2022 with approximately $38.1 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 FDA in April 2016 for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. We commercially launched Xtampza ER in June 2016.

The Nucynta Products are extended-release ("ER") and immediate-release ("IR") formulations of tapentadol. Nucynta ER is indicated for the management of pain severe enough to require daily, around the clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. We began shipping and recognizing product sales on the Nucynta Products in January 2018 and began marketing the Nucynta Products in February 2018.

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, pursuant to an Agreement and Plan of Merger, dated as of February 14, 2022, by and among us, Bristol Acquisition Company Inc., our wholly owned subsidiary, and BDSI (the "BDSI Acquisition"). Upon closing, we acquired the Belbuca, Symproic, and Elyxyb products. We began shipping and recognizing product sales related to Belbuca, Symproic, and Elyxyb in March 2022.

Belbuca is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment 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. Elyxyb was approved by the FDA in May 2020 for the acute treatment of migraine with or without aura in adults. We discontinued commercialization of Elyxyb in the fourth quarter of 2022 and transferred that product, together with related assets and liabilities, to a third party in the first quarter of 2023.

We believe the addition of Belbuca and Symproic to our portfolio strategically aligns with our mission to build a leading, diversified specialty pharmaceutical company committed to improving the lives of people suffering from serious medical conditions.

Outlook

We incurred net losses in each year since inception until 2020. In the year ended December 31, 2022, we also incurred a net loss. Substantially all our net losses resulted from costs incurred in connection with selling, general and administrative costs associated with our operations and research and development programs, and we expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities.

The BDSI Acquisition diversified and expanded our business by adding Belbuca and Symproic to our highly differentiated pain portfolio. We expect the addition of these products to continue to strengthen our financial position

through increased revenue scale and accelerated cash flow generation. While we incurred significant transaction costs and other acquisition related expenses during the year ended December 31, 2022 to complete the BDSI Acquisition and to integrate BDSI's operations, we do not expect to incur additional acquisition related expenses related to the BDSI Acquisition moving forward. In addition, we expect the step-up basis in inventory to impact our results of operations until all acquired inventory is sold, which we expect to occur within 12 to 18 months following the Acquisition Date.

We believe that our cash and cash equivalents at December 31, 2022, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

As the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, our business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods, which in turn may account for fewer patients beginning therapy with our products, and labor disruptions that impacted pain offices, which in turn impacted our access to, and quality of interactions with, such offices. Notwithstanding the fact that the Department of Health and Human Services is planning for the federal public health emergency for COVID-19 to expire in May 2023, we expect the trends that emerged as a result of the pandemic to persist in the near to medium term.

Financial Operations Overview

Product Revenues

Product revenues through the year ended December 31, 2022 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, 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 10, *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"), and the term notes (the "2020 Term Loan") and convertible notes (the "2026 Convertible Notes") issued in February 2020 in connection with the Nucynta Acquisition. 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. Historically, interest expense also related to a term loan facility with Silicon Valley Bank ("SVB") in connection with the Nucynta Commercialization Agreement. However, in January 2020, we prepaid the outstanding principal, accrued interest, and required prepayment fees on the SVB term loan and recognized an immaterial loss on extinguishment as a component of interest expense.

Interest Income

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

Provision for Income Taxes

The provision for income taxes reflects expense or tax benefit for federal and state income taxes. During the year ended December 31, 2022, we recognized a tax benefit, partially offset by state income tax expense. The provision for 2022 income taxes primarily consisted of state income tax for states for which our state-level NOLs did not fully offset state-level taxable income. During the year ended December 31, 2021, we removed the valuation allowance on the substantial majority of our deferred tax assets, resulting in a tax benefit in 2021 partially offset by state tax expense.

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 unsaleable 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 on Form 10-K, we believe the following accounting policies to be most critical to the significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

Product Revenue

Our only source of revenue to date has been generated by sales of our products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies and others for the treatment of patients ("end users"). 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 (1) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (2) product returns, including return estimates for our products; and (3) trade allowances and chargebacks, including fees for distribution service fees, prompt pay discounts, and chargebacks. We estimate the amount of variable consideration that should be included in revenue under the expected value method for all sales deductions other than trade allowances, which are estimated under the most likely amount method. These provisions reflect our best estimates of the amount of revenue to which we are entitled based on the terms of our contracts.

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

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 judgement 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. 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, 2022, our intangible assets included those acquired in connection with the BDSI Acquisition and the Nucynta Intangible Asset. There have been no triggering events that indicate that the carrying value is not recoverable from undiscounted cash flows other than Elyxyb, which was subject to an impairment event in the fourth quarter of 2022 when commercialization of the product was discontinued.

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.

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 $5.3 million as of December 31, 2022.

Significant judgment is required in making these assessments to maintain or reverse our valuation allowances, and, to the extent our future expectations change we would have to assess the recoverability of these deferred tax assets at that time.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2022 compared to the year ended December 31, 2021. For a discussion of the year ended December 31, 2021 compared to the year ended December 31, 2020, 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, 2021.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes the results of our operations for the years ended December 31, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Product revenues, net	$ 463,933	$ 276,868
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	118,190	59,070
Intangible asset amortization and impairment	136,255	67,181
Total cost of products revenues	254,445	126,251
Gross profit	209,488	150,617
Operating expenses		
Research and development	3,983	9,451
Selling, general and administrative	172,186	118,960
Restructuring	—	4,578
Total operating expenses	176,169	132,989
Income from operations	33,319	17,628
Interest expense	(63,213)	(21,014)
Interest income	1,047	12
Loss before income taxes	(28,847)	(3,374)
Benefit from income taxes	(3,845)	(74,891)
Net (loss) income	$ (25,002)	$ 71,517

Product revenues, net

Product revenues, net were $463.9 million for the year ended December 31, 2022 (“2022”), compared to $276.9 million for the year ended December 31, 2021 (“2021”), representing a $187.0 million increase. The $187.0 million increase is primarily due to increases in revenue for products acquired from BDSI of $140.6 million, including $126.5 million for Belbuca, as well as increases in revenue for Xtampza ER and the Nucynta Products of $35.1 million and $11.3 million, respectively.

The increase in revenue for products acquired from BDSI was due to the acquisition of these products in March 2022.

The increase in revenue for Xtampza ER of $35.1 million is primarily due to an increase in gross price and lower gross-to-net adjustments primarily related to rebates and provisions for returns, including revisions in the estimate of variable consideration associated with unprocessed returns claims, resulting in a $8.1 million increase in comparative revenue, partially offset by decreased sales volume.

The increase in revenue for the Nucynta Products of $11.3 million is primarily due to an increase in gross price and lower provisions for returns, including revisions in the estimate of variable consideration associated with unprocessed returns claims, resulting in a $3.4 million comparative decrease in revenue, partially offset by decreased sales volume and higher rebates.

Cost of product revenues

Cost of product revenues (excluding intangible asset amortization) was $118.2 million for 2022, compared to $59.1 million for 2021. The $59.1 million increase was primarily related to the step-up basis in inventory acquired from BDSI which resulted in higher cost of product revenues when sold in 2022 of $39.6 million, combined with an increase in

royalties and cost of product revenues for additional products acquired from BDSI. This increase was partially offset by lower cost of product revenues associated with the Nucynta Products and Xtampza ER, which was primarily related to a decrease in sales volume.

Intangible asset amortization and impairment was $136.3 million for 2022, compared to $67.2 million for 2021. The $69.1 million increase in amortization expense was due to the BDSI Acquisition, in which $435.0 million of consideration was allocated to our acquired intangible assets, Belbuca, Symproic, and Elyxyb. The intangible assets are amortized on a straight-line basis over the respective estimated useful lives. In addition to amortization expense, impairment expense of $4.8 million was recognized in 2022 related to Elyxyb which was impaired in the fourth quarter of 2022 following our decision to discontinue commercialization of this product.

Operating Expenses

Research and development expenses were $4.0 million for 2022, compared to $9.5 million for 2021. The $5.5 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 $172.2 million for 2022, compared to $119.0 million for 2021. The $53.2 million increase was primarily related to:

- an increase in acquisition related expenses classified as selling, general and administrative of $31.3 million which primarily consisted of financial advisory, banking, legal, and regulatory fees, other consulting fees, employee-related severance expenses, BDSI directors and officers insurance, and miscellaneous other acquisition related expenses incurred;
- an increase in sales, marketing, and consulting expenses of $10.7 million, primarily due to expenses incurred to support the commercialization of products acquired from BDSI in 2022, including Belbuca and Symproic, as well as for supporting the commercial launch of Elyxyb prior to its discontinuation in the fourth quarter of 2022;
- an increase in salaries, wages, and benefits of $4.0 million, primarily due to higher expense for corporate bonuses and incentive compensation due to improved company performance in 2022 compared to 2021;
- an increase in regulatory fees of $2.7 million primarily due to fees incurred for products acquired from BDSI in 2022 following the BDSI Acquisition;
- an increase in trainings, conferences, and meetings expenses of $1.9 million primarily due to certain annual internal meetings resuming in 2022 for the first time since the onset of the COVID-19 pandemic;
- an increase in product taxes and fees of $1.7 million due to incurring product taxes and fees for products acquired from BDSI in 2022; and
- an increase in insurance expense of $1.4 million, primarily due to higher premiums.

Restructuring expenses were zero for 2022, compared to $4.6 million for 2021. The decrease in restructuring expenses is due to the reduction of our workforce, primarily our salesforce, in 2021. The arrangement included the payment of a cash severance benefit near the time of separation, together with continued medical benefits and related services. Refer to Note 2, *Summary of Significant Accounting Policies*, for more information.

Interest expense and Interest income

Interest expense was $63.2 million for 2022, compared to $21.0 million for 2021. The $42.2 million increase was primarily due to the 2022 Loan Agreement that we entered into in connection with the BDSI Acquisition, which substantially increased our indebtedness, along with higher interest rates impacting our variable rate term loan debt.

Interest income was $1.0 million for 2022, compared to $12,000 for 2021. The $1.0 million increase was primarily due to an increase in interest rates earned on money market funds and a higher overall balance invested in money market funds in 2022 compared to 2021.

Taxes

Benefit from income taxes was $3.8 million for 2022, compared to $74.9 million in 2021. The $71.1 million decrease in benefit was primarily due to 2021 including a deferred tax benefit of $78.0 million due to the removal of the valuation allowance on the substantial majority of our deferred tax assets. In 2022, we recognized a deferred tax benefit, partially

offset by state income tax expense. The provision for income taxes in 2022 primarily consistent 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 13.3% and 2,220.0% for 2022 and 2021, respectively.

Liquidity and Capital Resources

Sources of Liquidity

We incurred net losses in each year since inception until 2020. In the year ended December 31, 2022, we also incurred a net loss. Historically, we have funded such losses through private placements and/or public offerings of our preferred stock, common stock, and convertible notes, and commercial bank debt. 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 are required to pay $100.0 million in principal payments during the first year of the 2022 Term Loan and the remaining $550.0 million balance is required to be paid in equal quarterly installments over the remaining three years of the term note. As of December 31, 2022, the outstanding principal balance of the 2022 Term Loan was $575.0 million, of which $162.5 million in principal payments are due within the next 12 months. As of December 31, 2022, the outstanding principal balance of the convertible notes was $143.8 million which is not due until 2026. As of December 31, 2022, and December 31, 2021, we had $173.7 million and $186.4 million in cash and cash equivalents, respectively.

We believe that our cash and cash equivalents at December 31, 2022, 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 the material borrowing arrangements and equity offerings.

2020 Term Loan

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, we, together with our 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 provides for a $200.0 million secured term loan, the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

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, we entered into an Amended and Restated Loan Agreement by and among us, and Pharmakon (the "2022 Loan Agreement"). The 2022 Loan Agreement provided for the $650.0 million secured 2022 Term Loan, the proceeds of which were used to repay our 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 $173,000 were expensed. In connection with the 2022 Loan Agreement, we paid loan commitment and other fees to the lender of $19.8 million, which together with preexisting debt issuance costs and note discounts of $2.0 million 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 our material domestic subsidiaries. The 2022 Term Loan is also secured by substantially all of our assets and those of our material domestic subsidiaries. The 2022 Term Loan bears interest at a rate based upon the London Interbank Offered Rate ("LIBOR") (subject to a LIBOR floor of 1.20%), plus a margin of 7.5% per annum. As of December 31, 2022, the interest rate was 11.2%. We are required to repay the 2022 Term Loan by paying $100.0 million in principal payments during the first year and the remaining $550.0 million balance will amortize in equal quarterly installments

over the remaining three years. The outstanding principal balance for the 2022 Term Loan as of December 31, 2022 is $575.0 million, including $162.5 million of obligations due in the first twelve months after period end.

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 our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business. Failure to comply with these covenants would constitute an event of default under the 2022 Loan Agreement, notwithstanding our ability to meet our 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. As of December 31, 2022, we were in compliance with all of our covenants.

2026 Convertible Notes

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

The 2026 Convertible Notes are senior, unsecured obligations and will accrue interest at a rate of 2.625% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate is 34.2618 shares of common stock per $1,000 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price will be subject to adjustment upon the occurrence of certain events. The outstanding principal balance for the 2026 Convertible Notes as of December 31, 2022 is $143.8 million. There are no principal repayment obligations due in the first twelve months after period end.

2029 Convertible Notes

On February 13, 2023, we issued 2.875% convertible senior notes due in 2029 in the aggregate principal amount of $241.5 million (the “2029 Convertible Notes”). Contemporaneously with the pricing of the notes in the offering, we entered into separate privately negotiated transactions with certain holders of the 2026 Convertible Notes to repurchase $117.4 million aggregate principal amount of the 2026 Convertible Notes for an aggregate of approximately $140.1 million of cash, which includes accrued and unpaid interest on the 2026 Convertible Notes to be repurchased. Refer to Note 20, *Subsequent Events,* for more information.

Cash flows

In this section, we discuss cash flows for the year ended December 31, 2022 compared to the year ended December 31, 2021. For a discussion of the year ended December 31, 2021 compared to the year ended December 31, 2020, 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, 2021.

	Years Ended December 31,	
	2022	2021
Net cash provided by operating activities	$ 124,230	$ 103,557
Net cash used in investing activities	(573,691)	(1,944)
Net cash provided by (used in) financing activities	436,723	(89,303)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (12,738)	$ 12,310

Operating activities. Cash provided by operating activities was $124.2 million in 2022, compared to $103.6 million in 2021. The $20.6 million increase in cash provided by operating activities was primarily due to the impact of higher non-cash items included in net loss, including higher intangible asset amortization as a result of the BDSI Acquisition, and the effect of deferred taxes. This increase was partially offset by lower net income, primarily due to acquisition related expenses, as well as changes in working capital. The change in working capital is primarily due to the effect of working capital balances acquired from BDSI, inclusive of the step-up basis in inventory acquired, as well as accrued rebates, returns, and discounts.

Investing activities. Cash used in investing activities was $573.7 million in 2022, compared to $1.9 million in 2021. The $571.8 million increase in cash used in investing activities was primarily due to the use of $572.1 million for the BDSI Acquisition, net of cash acquired, which closed in 2022.

Financing activities. Cash provided by financing activities was $436.7 million in 2022, compared to cash used in financing activities of $89.3 million in 2021. The $526.0 million increase was primarily due to the repayment of the outstanding balance of the 2020 Term Loan in connection with the BDSI Acquisition and establishment of the 2022 Term Loan, which was accounted for as a debt modification, resulting in $517.7 million in proceeds from the term note modification, partially offset by $75.0 million in repayments of the 2022 Term Loan, combined with $50.0 million in repayments of the 2020 Term Loan in 2021. The remainder of the increase in financing activities was primarily due to $33.8 million less in repurchases of common stock in 2022.

Funding requirements

We believe that our cash and cash equivalents as of December 31, 2022, 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.

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

Our forecast that our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we

currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

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

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

Contractual Obligations

Our contractual obligations as of December 31, 2022 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 13, *Debt.* For further detail regarding our operating lease obligations, refer to Note 14, *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, 2022 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 use these non-GAAP financial measures to understand, manage and evaluate our business as we believe they provide additional information on the performance of our business. We believe that the presentation of these non-GAAP financial measures, taken in conjunction with our results under GAAP, provide analysts, investors, lenders and other third parties insight into our view and assessment of our ongoing operating performance. In addition, we believe that the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing our performance and results from period to period. We report these non-GAAP financial measures to portray the results of our operations prior to considering certain income statement elements. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

In our quarterly and annual reports, earnings press releases and conference calls, we may discuss the following financial measures that are not calculated in accordance with GAAP, to supplement our consolidated financial statements presented on a GAAP basis.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income (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 (loss), which is the nearest GAAP equivalent, such as:

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

Adjusted EBITDA for the years ended December 31, 2022 and 2021 was as follows:

	Years Ended December 31,	
	2022	2021
GAAP net (loss) income	$ (25,002)	$ 71,517
Adjustments:		
Interest expense	63,213	21,014
Interest income	(1,047)	(12)
Benefit from income taxes	(3,845)	(74,891)
Depreciation	2,684	1,736
Amortization	131,469	67,181
Impairment expense	4,786	—
Stock-based compensation expense	22,874	24,255
Restructuring	—	4,578
Litigation settlements	—	2,935
Acquisition related expenses	31,297	—
Recognition of step-up basis in inventory	39,584	—
Total adjustments	$ 291,015	$ 46,796
Adjusted EBITDA	$ 266,013	$ 118,313

Adjusted EBITDA was $266.0 million for 2022 compared to $118.3 million for 2021. The $147.7 million increase was primarily due to higher revenue and gross profit before excluded costs, partially offset by higher adjusted operating expenses, as discussed below.

The following is a summary of 2022 quarterly Adjusted EBITDA:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
GAAP net (loss) income	$ (13,069)	$ (5,191)	$ 457	$ (7,199)
Adjustments:				
Interest expense	5,831	17,761	19,046	20,575
Interest income	(4)	(5)	(11)	(1,027)
(Benefit from) provision for income taxes	(2,773)	(1,455)	975	(592)
Depreciation	715	656	488	825
Amortization	18,923	37,501	37,552	37,493
Impairment expense	—	—	—	4,786
Stock-based compensation expense	6,135	5,692	5,377	5,670
Acquisition related expenses	27,167	3,579	463	88
Recognition of step-up basis in inventory	603	12,638	10,519	15,824
Total adjustments	$ 56,597	$ 76,367	$ 74,409	$ 83,642
Adjusted EBITDA	$ 43,528	$ 71,176	$ 74,866	$ 76,443

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, 2022 and 2021 were as follows:

	Years Ended December 31,	
	2022	2021
GAAP operating expenses	$ 176,169	$ 132,989
Adjustments:		
Stock-based compensation	22,874	24,255
Restructuring	—	4,578
Litigation settlements	—	2,935
Acquisition related expenses	31,297	—
Total adjustments	$ 54,171	$ 31,768
Adjusted operating expenses	$ 121,998	$ 101,221

Adjusted operating expenses were $122.0 million for 2022 compared to $101.2 million for 2021. The $20.8 million increase was primarily driven by higher selling, general and administrative expenses, excluding stock-based compensation and acquisition related expenses, including:

- an increase in sales, marketing, and consulting expenses of $10.7 million, primarily due to expenses incurred to support the commercialization of products acquired from BDSI in 2022, including Belbuca and Symproic, as well as for supporting the commercial launch of Elyxyb prior to its discontinuation in the fourth quarter of 2022;
- an increase in salaries, wages, and benefits (excluding stock-based compensation) of $3.5 million, primarily due to higher expense for corporate bonuses and incentive compensation due to improved company performance in 2022 compared to 2021;
- an increase in regulatory fees of $2.7 million primarily due to fees incurred for products acquired from BDSI in 2022 following the BDSI Acquisition;
- an increase in trainings, conferences, and meetings expenses of $1.9 million primarily due to certain annual internal meetings resuming in 2022 for the first time since the onset of the COVID-19 pandemic;

- an increase in product taxes and fees of $1.7 million due to incurring product taxes and fees for products acquired from BDSI in 2022; and
- an increase in insurance expense of $1.4 million, primarily due to higher premiums.

The following is a summary of 2022 quarterly adjusted operating expenses:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
GAAP operating expenses	$ 58,511	$ 41,254	$ 38,372	$ 38,032
Adjustments:				
Stock-based compensation	6,135	5,692	5,377	5,670
Acquisition related expenses	27,167	3,579	463	88
Total adjustments	33,302	9,271	5,840	5,758
Adjusted operating expenses	$ 25,209	$ 31,983	$ 32,532	$ 32,274

Adjusted Net Income and Adjusted Earnings Per Share

Adjusted net income is a non-GAAP financial measure that represents GAAP net income 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, 2022 and 2021 were as follows:

	Years Ended December 31,	
	2022	2021
GAAP net (loss) income	$ (25,002)	$ 71,517
Adjustments:		
Non-cash interest expense	8,285	3,406
Amortization	131,469	67,181
Impairment expense	4,786	—
Stock-based compensation expense	22,874	24,255
Restructuring	—	4,578
Litigation settlements	—	2,935
Acquisition related expenses	31,297	—
Recognition of step-up basis in inventory	39,584	—
Discrete deferred tax benefit from valuation allowance release	—	(62,649)
Income tax effect of above adjustments (1)	(60,553)	(9,071)
Total adjustments	$ 177,742	$ 30,635
Non-GAAP adjusted net income	$ 152,740	$ 102,152
Adjusted weighted-average shares — diluted (2)	39,531,814	41,045,805
Adjusted earnings per share (2)	$ 3.96	$ 2.58

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate of 26% to the adjustments that have a tax effect. As such, the non-GAAP effective tax rates for the years ended December 31, 2022 and 2021 were 25.4% and 22.8%, 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, for periods where non-GAAP adjusted income (loss) was in an income position, adjusted earnings per share includes 4,925,134 shares related to the assumed conversion of the convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income, as well as other potentially dilutive securities to the extent that they are not antidilutive.

The following is a summary of 2022 quarterly adjusted net income and adjusted earnings per share:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
GAAP net (loss) income	$ (13,069)	$ (5,191)	$ 457	$ (7,199)
Adjustments:				
Non-cash interest expense	913	2,522	2,467	2,383
Amortization	18,923	37,501	37,552	37,493
Impairment expense	—	—	—	4,786
Stock-based compensation expense	6,135	5,692	5,377	5,670
Acquisition related expenses	27,167	3,579	463	88
Recognition of step-up basis in inventory	603	12,638	10,519	15,824
Discrete deferred tax benefit from valuation allowance release	—	—	—	—
Income tax effect of above adjustments (1)	(13,671)	(15,737)	(14,290)	(16,855)
Total adjustments	$ 40,070	$ 46,195	$ 42,088	$ 49,389
Non-GAAP adjusted net income	$ 27,001	$ 41,004	$ 42,545	$ 42,190
Adjusted weighted-average shares — diluted (2)	39,241,622	39,256,685	39,495,453	39,644,115
Adjusted earnings per share (2)	$ 0.71	$ 1.07	$ 1.10	$ 1.09

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate of 26% to the adjustments that have a tax effect. As such, the non-GAAP effective tax rates for the three months ended March 31, June 30, September 30, and December 31, 2022 were 25.4%, 25.4%, 25.3%, 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, for periods where non-GAAP adjusted income (loss) was in an income position, adjusted earnings per share includes 4,925,134 shares related to the assumed conversion of the convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income, as well as other potentially dilutive securities to the extent that they are not antidilutive.

The following is a summary of 2021 quarterly adjusted net income and adjusted earnings per share:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
GAAP net income (loss)	$ 15,662	$ 72,843	$ 8,046	$ (25,034)
Adjustments:				
Non-cash interest expense	919	875	833	779
Amortization	16,795	16,795	16,796	16,795
Stock-based compensation expense	6,879	6,516	5,948	4,912
Restructuring	—	—	—	4,578
Litigation settlements	—	—	—	2,935
Discrete deferred tax benefit from valuation allowance release	—	(62,649)	—	—
Income tax effect of above adjustments (1)	(5,997)	10,270	(5,899)	(7,445)
Total adjustments	$ 18,596	$ (28,193)	$ 17,678	$ 22,554
Non-GAAP adjusted net income (loss)	$ 34,258	$ 44,650	$ 25,724	$ (2,480)
Adjusted weighted-average shares — diluted (2)	41,160,092	41,286,853	41,186,308	34,123,309
Adjusted earnings (loss) per share (2)	$ 0.86	$ 1.10	$ 0.65	$ (0.07)

(1) The income tax effect of the adjustments was calculated by applying our blended federal and state statutory rate of 26% to the adjustments that have a tax effect. As such, the non-GAAP effective tax rates for the three months ended March 31, June 30, September 30, and December 31, 2021 were 24.4%, 26.7%, 25.0%, and 24.8%, 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, for periods where non-GAAP

adjusted income (loss) was in an income position, adjusted earnings per share includes 4,925,134 shares related to the assumed conversion of the convertible notes and the associated cash interest expense added-back to non-GAAP adjusted net income, as well as 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 money market funds and the 2022 Term Loan.

As of December 31, 2022, our cash and cash equivalents included money market funds of $172.6 million. Our money market funds are short-term highly liquid investments, however, due to the short-term duration and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

The 2022 Term Loan has an underlying rate that is indexed to the 3-month LIBOR rate (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, 2022 of $575.0 million and the applicable interest rate, a hypothetical 1% increase or decrease in interest rates would increase or decrease future interest expense by approximately $5.8 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, 2022.

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, 2022.

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. During the fourth quarter of 2022, we completed the integration of BDSI into our internal control over financial reporting. Except for this change, there has been no other changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2022 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, 2022, 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, 2022, 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, 2022, of the Company and our report dated February 23, 2023, 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 23, 2023

Item 9B. Other Information

Not applicable.

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 2023 Annual Meeting of the Shareholders.

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

Item 11. Executive Compensation

The information required by this Item 11 is incorporated herein by reference from our definitive proxy statement for the 2023 Annual Meeting of Shareholders.

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

The information required by this Item 12 is incorporated herein by reference from our definitive proxy statement for the 2023 Annual Meeting of Shareholders.

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

The information required by this Item 13 is incorporated herein by reference from our definitive proxy statement for the 2023 Annual Meeting of Shareholders.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 is incorporated herein by reference from our definitive proxy statement for the 2023 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Consolidated Financial Statements

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

Consolidated Financial Statement Schedules

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

Exhibits

Exhibit Number	Exhibit Description
2.1†	Agreement and Plan of Merger, dated July 10, 2014, by and between Collegium Pharmaceutical, Inc., a Delaware corporation, and Collegium Pharmaceutical, Inc., a Virginia corporation.(1)
2.2†	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. (16)
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†	Warrant to Purchase Stock, dated November 8, 2018, issued by Collegium Pharmaceutical, Inc. to Assertio Therapeutics, Inc.(4)
4.2†	Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee. (5)
4.3†	First Supplemental Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee. (5)
4.4†	Form of certificate representing the 2.625% Convertible Senior Notes due 2026 (included as Exhibit A to Exhibit 4.3). (5)
4.5	Indenture, dated as of February 10, 2023, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.(11)
4.6	Form of certificate representing the 2.875% Convertible Senior Notes due 2029 (included as Exhibit A to Exhibit 4.5).(11)
4.7	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed herewith).
10.1†	Office Lease agreement by and between Campanelli-Trigate 100 TCD Stoughton, LLC, and Collegium Pharmaceutical, Inc as of March 23, 2018. (6)
10.2+†	2015 Employee Stock Purchase Plan.(7)
10.3+†	Performance Bonus Plan. (8)
10.4(a)+†	Amended and Restated 2014 Stock Incentive Plan. (7)
10.4(b)+†	Form of Incentive Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. (7)
10.4(c)+†	Form of Non-Qualified Stock Option Agreement under the Amended and Restated 2014 Stock Incentive Plan. (7)
10.4(d)+†	Form of Restricted Stock Award Agreement under the Amended and Restated 2014 Stock Incentive Plan. (7)
10.4(e)+†	Form of Performance Share Unit Agreement under the Amended and Restated 2014 Stock Incentive Plan. (9)
10.5†	Form of Indemnification Agreement. (8)
10.6+†	Amended & Restated Employment Agreement, dated December 27, 2020, by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni.(10)
10.7+†	Amended & Restated Employment Agreement, dated December 27, 2020, by and between Shirley Kuhlmann and Collegium Pharmaceutical, Inc. (10)
10.8+†	Amended & Restated Employment Agreement, dated December 27, 2020, by and between Collegium Pharmaceutical, Inc. and Scott Dreyer.(10)
10.9+†	Amended & Restated Employment Agreement, effective as of December 27, 2020, by and between Richard Malamut, M.D. and Collegium Pharmaceutical, Inc.(10)
10.10†	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)
10.11†	Consent Agreement, dated January 30, 2020, by and among Grünenthal GmbH, Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc.(12)
10.12†	Settlement Agreement, dated September 29, 2020, by and among Collegium Pharmaceutical, Inc. and Teva Pharmaceuticals USA, Inc.(13)
10.13+†	Employment Agreement, dated May 24, 2021, by and between Colleen Tupper and Collegium Pharmaceutical, Inc.(14)
10.14†	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. (17)
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.

10.16†	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). (15)
10.17+†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Joseph Ciaffoni. (15)
10.18+†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Colleen Tupper. (15)
10.19+†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Shirley Kuhlmann. (15)
10.20+†	Amendment to Employment Agreement, dated January 20, 2022 by and between Collegium Pharmaceutical, Inc. and Scott Dreyer. (15)
10.21+†	Employment Agreement, dated March 23, 2022 by and between Collegium Pharmaceutical, Inc. and Thomas Smith. (15)
21.1	Subsidiaries of Collegium Pharmaceutical, Inc.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
31.1	Certifying Statement of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certifying Statement of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifying Statement of the Chief Executive Officer pursuant to Section 1350 of Title 18 of the United States Code.
32.2	Certifying Statement of the Chief Financial Officer pursuant to Section 1350 of Title 18 of the United States Code.
101	The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2022, formatted in Inline XBRL: (i) Consolidated Balance Sheets as of December 31, 2022, and 2021, (ii) Consolidated Statements of Operations for the years ended December 31, 2022, 2021 and 2020, (iii) Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2022, 2021 and 2020, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021 and 2020, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

†Previously filed.

+Indicates management contract or compensatory plan.

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

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

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

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

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

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

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

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

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

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

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

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

(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 Commission on May 7, 2020.

(13) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission 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 Commission August 5, 2021.

(15) 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 Commission May 10, 2022.

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

(17) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on March 23, 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 23, 2023
/s/ Colleen Tupper Colleen Tupper	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2023
/s/ Michael T. Heffernan, R.Ph. Michael T. Heffernan, R.Ph.	Chairman of the Board	February 23, 2023
/s/ Rita Balice-Gordon, Ph.D. Rita Balice-Gordon, Ph.D.	Director	February 23, 2023
/s/ Garen G. Bohlin Garen G. Bohlin	Director	February 23, 2023
/s/ John A. Fallon, M.D. John A. Fallon, M.D.	Director	February 23, 2023
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	February 23, 2023
/s/ Gwen Melincoff Gwen Melincoff	Director	February 23, 2023
/s/ Gino Santini Gino Santini	Director	February 23, 2023
/s/ Neil McFarlane Neil McFarlane	Director	February 23, 2023

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.

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COLLEGIUM PHARMACEUTICAL, INC.
Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Collegium Pharmaceutical, Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 23, 2023, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for convertible debt in 2021 due to the adoption of ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, using the modified retrospective approach.

Basis for Opinion

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

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

Critical Audit Matters

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

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) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period. 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 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 and the refund liability (the "return adjustments") included the following, among others:

- We tested the effectiveness of controls over the measurement and recognition of return adjustments, including management's controls over product returns and revenue data.
- We evaluated the Company's methodology and significant assumptions made in developing the return adjustments.
- We tested the completeness and accuracy of the data underlying the measurement of return adjustments.
- We tested the mathematical accuracy of management's underlying calculation of return adjustments.
- We tested the reasonableness of management's estimate through corroboration with management outside of accounting and finance and evaluated evidence related to return adjustments.
- We evaluated management's ability to accurately forecast product return activity by performing a retrospective review, comparing prior period product return estimates to actual product returns processed in the subsequent year to identify potential bias or unanticipated trends in the determination of the refund liability.
- We developed independent estimates of the return adjustments using historical sales and returns activity, product dating and expiration dates, and other information.

Business Combinations - Refer to Note 4 to the financial statements

Critical Audit Matter Description

During the year ended December 31, 2022, the Company acquired BioDelivery Sciences International, Inc ("BDSI") for $669.4 million and accounted for the transaction as a business combination. Accordingly, the purchase price was allocated to the assets acquired and liabilities assumed based on their respective fair values, including identifiable intangible assets and inventory of $435.0 million and $77.4 million, respectively. Management estimated the fair value of these assets using valuation techniques, including income-based models, which required the use of significant estimates and assumptions related to revenue forecasts, future profit margins, and the selection of appropriate discount rates.

We identified the valuation of acquired intangible assets and inventory as a critical audit matter. Given that the determination of the fair value of the acquired intangible assets and inventory requires significant estimates and assumptions by management, performing audit procedures to evaluate the reasonableness of these estimates and assumptions required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the revenue forecasts, future profit margins, and the selection of the discount rates for the acquired intangible assets and inventory included the following, among others:

- We tested the effectiveness of controls over the valuation of the acquired intangible assets and inventory, including management's controls over revenue forecasts, future profit margins, and selection of the discount rates.

- We assessed the reasonableness of management's revenue and profit margin forecasts by performing the following:
    - We compared the forecasts to historical results of the acquired business.
    - We compared the forecasts to internal forecasts and other information obtained while performing the audit.
    - We performed a sensitivity analysis to determine the impact of the assumptions under different scenarios.
    - We compared the revenue growth rates and profit margins to available external information.
- With the assistance of our fair value specialists, we performed the following:
    - We evaluated the reasonableness of the valuation methodologies selected and the mathematical accuracy of the calculation.
    - We tested the source information underlying the determination of the discount rates, tested the mathematical accuracy of the calculations and compared those to the amounts selected by management.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 23, 2023

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, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 173,688	$ 186,426
Accounts receivable, net	183,119	105,844
Inventory	46,501	17,394
Prepaid expenses and other current assets	16,681	5,879
Total current assets	419,989	315,543
Property and equipment, net	19,521	19,491
Operating lease assets	6,861	7,644
Intangible assets, net	567,468	268,723
Restricted cash	2,547	2,547
Deferred tax assets	23,950	78,042
Other noncurrent assets	100	87
Goodwill	133,695	—
Total assets	$ 1,174,131	$ 692,077
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 3,494	$ 4,189
Accrued expenses	36,129	29,214
Accrued rebates, returns and discounts	230,491	196,996
Current portion of term notes payable	162,500	48,353
Current portion of operating lease liabilities	1,112	814
Total current liabilities	433,726	279,566
Term notes payable, net of current portion	397,578	61,666
Convertible senior notes	140,873	139,966
Operating lease liabilities, net of current portion	7,112	7,951
Total liabilities	979,289	489,149
Commitments and contingencies (refer to Note 12)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000; 37,084,759 issued and 33,848,936 outstanding shares at December 31, 2022 and 35,806,119 issued and 33,655,402 outstanding shares at December 31, 2021	37	36
Additional paid-in capital	538,073	502,095
Treasury stock, at cost; 3,235,823 shares at December 31, 2022 and 2,150,717 shares at December 31, 2021	(61,924)	(42,861)
Accumulated deficit	(281,344)	(256,342)
Total shareholders’ equity	194,842	202,928
Total liabilities and shareholders’ equity	$ 1,174,131	$ 692,077

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,		
	2022	**2021**	**2020**
Product revenues, net	$ 463,933	$ 276,868	$ 310,016
Cost of product revenues			
Cost of product revenues (excluding intangible asset amortization)	118,190	59,070	69,500
Intangible asset amortization and impairment	136,255	67,181	60,680
Total cost of products revenues	254,445	126,251	130,180
Gross profit	209,488	150,617	179,836
Operating expenses			
Research and development	3,983	9,451	9,772
Selling, general and administrative	172,186	118,960	113,832
Restructuring	—	4,578	—
Total operating expenses	176,169	132,989	123,604
Income from operations	33,319	17,628	56,232
Interest expense	(63,213)	(21,014)	(28,882)
Interest income	1,047	12	232
(Loss) income before income taxes	(28,847)	(3,374)	27,582
(Benefit from) provision for income taxes	(3,845)	(74,891)	830
Net (loss) income	$ (25,002)	$ 71,517	$ 26,752
(Loss) earnings per share — basic	$ (0.74)	$ 2.05	$ 0.78
Weighted-average shares — basic	33,829,495	34,936,817	34,407,959
(Loss) earnings per share — diluted	$ (0.74)	$ 1.86	$ 0.76
Weighted-average shares — diluted	33,829,495	41,045,805	35,151,353

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	Treasury Stock		Accumulated	Total Shareholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Equity
Balance at December 31, 2019	33,678,840	$ 34	$ 447,297	—	$ —	$ (359,899)	$ 87,432
Exercise of common stock options	637,924	1	6,656	—	—	—	6,657
Issuance for employee stock purchase plan	67,512	—	758	—	—	—	758
Vesting of RSUs	335,524	—	—	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(107,746)	—	(2,255)	—	—	—	(2,255)
Stock-based compensation	—	—	21,910	—	—	—	21,910
Equity component of 2020 Convertible Notes, net of issuance costs of $1,773	—	—	44,777	—	—	—	44,777
Net income	—	—	—	—	—	26,752	26,752
Balance at December 31, 2020	34,612,054	$ 35	$ 519,143	—	$ —	$ (333,147)	$ 186,031
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 at 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 at December 31, 2022	37,084,759	$ 37	$ 538,073	(3,235,823)	$ (61,924)	$ (281,344)	$ 194,842

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,		
	2022	**2021**	**2020**
Operating activities			
Net (loss) income	$ (25,002)	$ 71,517	$ 26,752
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Amortization and impairment expense	136,255	67,181	60,680
Depreciation expense	2,684	1,736	870
Deferred income taxes	(8,391)	(78,042)	—
Stock-based compensation expense	22,874	24,255	21,910
Non-cash lease expense	238	18	57
Non-cash interest expense for amortization of debt discount and issuance costs	8,285	3,406	8,972
Changes in operating assets and liabilities:			
Accounts receivable	(21,780)	(22,524)	(10,367)
Inventory	48,274	(2,296)	(8,270)
Prepaid expenses and other assets	(4,606)	(1,086)	(1,598)
Accounts payable	(707)	(5,827)	3,769
Accrued expenses	(11,131)	4,777	(7,838)
Accrued rebates, returns and discounts	(22,766)	40,442	(995)
Operating lease assets and liabilities	3	—	—
Net cash provided by operating activities	124,230	103,557	93,942
Investing activities			
Purchase of intangible asset	—	—	(368,226)
Purchases of property and equipment	(1,622)	(1,944)	(5,546)
Acquisition of BDSI (net of cash acquired)	(572,069)	—	—
Net cash used in investing activities	(573,691)	(1,944)	(373,772)
Financing activities			
Proceeds from issuances of common stock from employee stock purchase plans	337	755	758
Proceeds from the exercise of stock options	11,811	11,952	6,577
Payments made for employee stock tax withholdings	(4,044)	(4,149)	(2,255)
Repurchases of common stock	(14,063)	(47,861)	—
Proceeds from issuance of term note, net of issuance costs of $2,456	—	—	192,117
Proceeds from convertible senior notes, net of issuance costs of $5,473	—	—	138,277
Repayment of term notes	(75,000)	(50,000)	(37,500)
Proceeds from term note modification	517,682	—	—
Repayment of term loan	—	—	(11,500)
Net cash provided by (used in) financing activities	436,723	(89,303)	286,474
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,738)	12,310	6,644
Cash, cash equivalents and restricted cash at beginning of year	188,973	176,663	170,019
Cash, cash equivalents and restricted cash at end of year	$ 176,235	$ 188,973	$ 176,663
Reconciliation of cash, cash equivalents and restricted cash to the Consolidated Balance Sheets:			
Cash and cash equivalents	$ 173,688	$ 186,426	$ 174,116
Restricted cash	2,547	2,547	2,547
Total cash, cash equivalents and restricted cash	$ 176,235	$ 188,973	$ 176,663
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 52,528	$ 17,608	$ 18,967
Cash paid for income taxes	$ 10,400	$ 3,005	$ 483
Supplemental disclosure of non-cash activities			
Acquisition of property and equipment in accounts payable and accrued expenses	$ —	$ 72	$ 293
Accrued royalties discharged upon closing of asset acquisition	$ —	$ —	$ 1,145
Inventory used in the construction and installation of property and equipment	$ —	$ 516	$ 2,299
Receivable from stock option exercises in other current assets	$ —	$ —	$ 80

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

COLLEGIUM PHARMACEUTICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

1. NATURE OF BUSINESS

Organization

Collegium Pharmaceutical, Inc. (the "Company" 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. As the COVID-19 pandemic unfolded, and governmental and societal reactions to it evolved, the Company's business was impacted by several trends, including depressed pain patient office visits compared to pre-COVID periods. The Company believes the disruptions caused by COVID-19 will continue and there remains substantial uncertainty as to when such disruptions will cease.

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 unsaleable 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
Level 2 inputs: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs: Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

There were no transfers between Levels 1, 2 and 3 during the years ended December 31, 2022 and 2021.

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at December 31, 2022 and 2021.

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
December 31, 2022				
Money market funds, included in cash equivalents	$ 172,590	$ 172,590	$ —	$ —
December 31, 2021				
Money market funds, included in cash equivalents	$ 45,078	$ 45,078	$ —	$ —

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, 2022, the convertible senior notes had a fair value of approximately $138,359 and a net carrying value of $140,873.

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, 2022, the carrying amount of the term notes reasonably approximated the estimated fair value.

As of December 31, 2022, and 2021, the carrying amounts of the cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, 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, 2022, 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, 2022. These customers comprised 37%, 33%, and 28% of the accounts receivable balance as of December 31, 2022 and 46%, 33%, and 20% as of December 31, 2021.

The same customers comprised 10% or more of the Company's revenue during the year ended December 31, 2022. These customers comprised 33%, 32%, and 31% of revenue during the year ended December 31, 2022; 35%, 31%, and 29% during the year ended December 31, 2021; and 34%, 31%, and 31% during the year ended December 31, 2020.

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, 2022 or 2021. The Company has no financial instruments with off balance sheet risk of loss.

Cash and Cash Equivalents

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

Restricted Cash

Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months. As of December 31, 2022 and 2021, the Company had restricted cash of $2,547, which represents cash held in a depository account at a financial institution to collateralize conditional standby letters of credit for the Company's corporate credit card program, its lease of its corporate headquarters, and its leases of vehicles for its field-based employees.

Inventory

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

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 has capitalized $46,501 of inventory as of December 31, 2022. The Company expects to use the inventory over its operating cycle.

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.

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, 2022 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.

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.

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 $11,743, $4,186 and $5,368 in the years ended December 31, 2022, 2021, and 2020 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, 2022, 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 (loss) attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted earnings per share is computed by dividing the net income (loss) attributable to common shareholders 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*, 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 13, *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 as of December 31, 2022 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 May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.* This ASU clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021 and may be applied prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company adopted this standard effective January 1, 2022 and the adoption did not have a material impact on the Company's consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers.* This ASU amends Accounting Standards Codification ("ASC") 805 to add contract assets and contract liabilities to the list of exceptions to the recognition and measurement principles that apply to business combinations and to require that an entity (acquirer) recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 606. As a result of the amendments made by the ASU, it is expected that an acquirer will generally recognize and measure acquired contract assets and contract liabilities in a manner consistent with how the acquiree recognized and measured them in its pre-acquisition financial statements. The ASU's amendments are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The amendments should be applied prospectively to business combinations occurring on or after the effective date of the amendments. Early adoption of the amendments is permitted, including adoption in an interim period. An entity that early adopts in an interim period should apply the amendments (i) retrospectively to all business combinations for which the acquisition date occurs on or after the beginning of the fiscal year that includes the

interim period of early application and (ii) prospectively to all business combinations that occur on or after the date of initial application. The Company adopted this standard effective January 1, 2022 and the adoption did not have a material impact on the Company's consolidated financial statements.

In 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848)*: *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, to ease the potential burden in accounting for reference rate reform. The amendments in ASU 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. The 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. As the United Kingdom's Financial Conduct Authority announced that the intended cessation date of LIBOR in the United States will be June 30, 2023, the Company expects to be impacted by reference reform in the next twelve months as the Company's contracts and transactions are transitioned to another reference rate, however, the impact of such transition is not yet known. Upon the transition of the Company's contracts and transactions to new reference rates in connection with reference rate reform, the Company will prospectively apply the standard and disclose the effect on its consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

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 for the treatment of patients ("end users").

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

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.

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.

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.

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 for returns to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period. 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 revenue, net of $38,329, with offsetting reductions in accounts receivable or increases in the refund liability for future 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 is constrained) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period. 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. In particular, resolution of the unprocessed return claims includes the risk of concession for those that are outside of the Company's return policy.

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.

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, 2022, 2021, and 2020, respectively:

	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2019	$ 129,901	$ 27,648	$ 14,020
Provision related to current period sales	326,280	10,900	75,554
Changes in estimate related to prior period sales	(539)	—	(403)
Credits/payments made	(322,867)	(14,769)	(70,116)
Balance at December 31, 2020	$ 132,775	$ 23,779	$ 19,055
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 at 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 at December 31, 2022	$ 156,937	$ 73,554	$ 22,058

(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, 2022, 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,		
	2022	2021	2020
Belbuca	$ 126,461	$ —	$ —
Xtampza ER	138,804	103,708	127,984
Nucynta IR	112,058	102,222	116,318
Nucynta ER	72,418	70,938	65,714
Symproic	12,267	—	—
Other	1,925	—	—
Total product revenues, net	$ 463,933	$ 276,868	$ 310,016

The Company began recognizing revenue from net product sales of Belbuca, Symproic, and Elyxyb 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 the Belbuca, Symproic, and Elyxyb products.

Upon completion of the BDSI Acquisition, management leveraged 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 the 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 preliminary purchase price allocation is based on estimates, assumptions, valuations and other studies which have not yet been finalized. Prior to the finalization of the purchase price allocation, if information becomes available that would indicate it is probable that unknown events had occurred and the amounts can be reasonably estimated, such items will be included in the final purchase price allocation and may change the carrying value of goodwill. The Company is finalizing its valuation of acquired deferred tax assets and anticipates finalizing the purchase price allocation as the information necessary to complete the analysis is obtained, but no later than one year after the Acquisition Date. During the year ended December 31, 2022, the subsequent adjustments within the measurement period to the preliminary purchase price allocation did not have a significant impact on earnings. The Company recorded measurement period adjustments to increase inventory by $14,300, decrease intangible assets by $10,000, increase accrued rebates, returns and discounts by $3,916, increase prepaid expenses and other current assets by $888, decrease accrued expenses by $502, and increase deferred tax liabilities by $3,957, with a net offsetting increase to goodwill of $2,183.

The following tables set forth the preliminary allocation of the BDSI Acquisition purchase price to the estimated fair value of the net assets acquired at the Acquisition Date (in thousands):

	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 expenses	18,115
Accrued rebates, returns and discounts	56,261
Operating lease liabilities	481
Deferred tax liabilities	62,482
Total liabilities	$ 137,351
Total identifiable net assets acquired	535,736
Goodwill	133,695
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 is amortizing the identifiable intangible assets on a straight-line basis over their respective useful lives (refer to Note 10, *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 13, *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. LICENSE 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.

Dr. Reddy's acquired product rights

Prior to the BDSI Acquisition, BDSI and Dr. Reddy's Laboratories Limited ("DRL"), entered into an asset purchase agreement (the "Elyxyb Asset Purchase Agreement") for the acquisition by BDSI from DRL of certain patents, trademarks, regulatory approvals and other rights related to Elyxyb and its commercialization in the United States and Canada (the "DRL Territory").

Pursuant to the terms of the Elyxyb Asset Purchase Agreement, a $9,000 payment was due to DRL on August 3, 2022. In addition, up to an additional $9,000 of payments are due to DRL upon achievement of certain regulatory milestones as well as for quarterly earn-out payments on potential sales of the Elyxyb Product in the DRL Territory that range from high single digits to the low double digits (subject to reduction in certain circumstances) of net sales based on volume of sales. DRL will also be entitled to one-time payments upon the achievement of six escalating sales milestones, which range from $4,000 to be paid upon the achievement of $50,000 in net sales in a calendar year to $100,000 to be paid upon the achievement of $1,000,000 in net sales in a calendar year up to a total of $262,000.

During the three months ended December 31, 2022, the Company discontinued the commercialization of Elyxyb. Refer to Note 10, *Goodwill and Intangible Assets*, for more information.

In February 2023, the Company entered into an agreement with Scilex to transfer to Scilex all assets, rights, and obligations necessary to commercialize Elyxyb in the United States and Canada (the "Elyxyb Sale Agreement"). Refer to Note 20, *Subsequent Events*, for more information.

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,		
	2022	2021	2020
Numerator:			
Net (loss) income	$ (25,002)	$ 71,517	$ 26,752
Adjustment for interest expense recognized on convertible senior notes:	—	4,675	—
Net (loss) income — diluted	$ (25,002)	$ 76,192	$ 26,752
Denominator:			
Weighted-average shares outstanding — basic	33,829,495	34,936,817	34,407,959
Effect of dilutive securities:			
Stock options	—	504,699	431,524
Restricted stock units	—	461,471	271,542
Performance share units	—	85,229	27,002
Employee stock purchase plan	—	1,198	567
Warrants	—	131,257	12,759
Convertible senior notes	—	4,925,134	—
Weighted average shares outstanding — diluted	33,829,495	41,045,805	35,151,353
(Loss) earnings per share — basic	$ (0.74)	$ 2.05	$ 0.78
(Loss) earnings per share — diluted	$ (0.74)	$ 1.86	$ 0.76

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 in cash, shares or a combination of the two. 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,		
	2022	2021	2020
Stock options	1,683,805	1,202,403	2,294,961
Restricted stock units	2,047,571	22,605	4,809
Performance share units	447,770	242,714	211,618
Convertible senior notes	4,925,134	—	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. INVENTORY

Inventory consisted of the following:

	Years Ended December 31,	
	2022	2021
Raw materials	$ 5,600	$ 3,685
Work in process	24,672	1,007
Finished goods	16,229	12,702
Total inventory	$ 46,501	$ 17,394

During the year ended December 31, 2022, the expenses related to excess and obsolete inventory that were recorded as a component of cost of products revenues were $1,814. Expenses related to excess and obsolete inventory were immaterial for the years ended December 31, 2021 and 2020.

During the years ended December 31, 2022, 2021, and 2020, inventory used in the construction and installation of property and equipment was zero, $516, and $2,299, respectively.

8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	Years Ended December 31,	
	2022	2021
Prepaid regulatory fees	$ 5,614	$ 3,602
Prepaid income taxes	5,138	—
Prepaid co-pay program incentives	1,907	—
Prepaid insurance	960	864
Other current assets	57	27
Other prepaid expenses	3,005	1,386
Prepaid expenses and other current assets	$ 16,681	$ 5,879

9. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	Years Ended December 31,	
	2022	2021
Computers and office equipment	$ 2,491	$ 1,547
Laboratory equipment	436	1,340
Furniture and fixtures	1,133	1,079
Manufacturing equipment	20,910	14,498
Leasehold improvements	874	541
Construction-in-process	—	5,182
Total property and equipment	25,844	24,187
Less: accumulated deprecation	(6,323)	(4,696)
Property and equipment, net	$ 19,521	$ 19,491

Depreciation expense related to property and equipment amounted to $2,684, $1,736 and $870 for the years ended December 31, 2022, 2021, and 2020, respectively. During the years ended December 31, 2022, 2021, and 2020 the Company disposed of fully depreciated assets of $1,040, $96 and $102, respectively. Any gains or losses from the retirement, sale or disposal of property and equipment during the years ended December 31, 2022, 2021, and 2020 were immaterial.

10. 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 at December 31, 2021	$ —
Goodwill resulting from BDSI Acquisition	133,695
Balance at December 31, 2022	$ 133,695

The following table sets forth the cost, accumulated amortization, and carrying amount of intangible assets as of December 31, 2022 and 2021:

	Amortization Period (Years)	As of December 31, 2022			As of December 31, 2021		
		Cost	Accumulated Amortization	Carrying Amount	Cost	Accumulated Amortization	Carrying Amount
Belbuca	4.8	$ 360,000	$ (58,428)	$ 301,572	$ —	$ —	$ —
Nucynta Products	8.0	521,170	(319,628)	201,542	521,170	(252,447)	268,723
Symproic	9.6	70,000	(5,646)	64,354	—	—	—
Elyxyb	—	5,000	(5,000)	—	—	—	—
Total intangibles		$ 956,170	$ (388,702)	$ 567,468	$ 521,170	$ (252,447)	$ 268,723

The following table presents amortization and impairment expense recognized in cost of product revenues for the years ended December 31, 2022, 2021, and 2020:

	Years Ended December 31,		
	2022	2021	2021
Belbuca	$ 58,428	$ —	$ —
Nucynta Products	67,181	67,181	60,680
Symproic	5,646	—	—
Elyxyb (1)	5,000	—	—
Total amortization and impairment expense	$ 136,255	$ 67,181	$ 60,680

(1) 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 expense were recognized. In addition, contract termination costs related to the

discontinuation were immaterial and expensed upon the termination of the contracts. The expected completion date of the remaining exit and other activities associated with the discontuation of Elyxyb is March 31, 2023.

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. Refer to Note 20, *Subsequent Events*, for more information.

As of December 31, 2022, the remaining amortization expense expected to be recognized is as follows:

Years ended December 31,	Belbuca	Nucynta Products	Symproic	Total
2023	$ 75,393	$ 67,181	$ 7,285	$ 149,859
2024	75,393	67,181	7,285	149,859
2025	75,393	67,180	7,285	149,858
2026	75,393	—	7,285	82,678
2027	—	—	7,285	7,285
Thereafter	—	—	27,929	27,929
Remaining amortization expense	$ 301,572	$ 201,542	$ 64,354	$ 567,468

11. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	As of December 31,	
	2022	2021
Accrued royalties	$ 13,770	$ 9,930
Accrued bonuses	6,347	2,634
Accrued product taxes and fees	4,352	2,570
Accrued sales and marketing	2,130	697
Accrued audit and legal	1,957	3,623
Accrued incentive compensation	1,507	851
Accrued interest	1,410	1,415
Accrued payroll and related benefits	1,208	807
Accrued income taxes	—	622
Accrued restructuring expenses	—	3,222
Accrued other operating costs	3,448	2,843
Total accrued expenses	$ 36,129	$ 29,214

12. 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

The Company filed the NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Orange Book, in this case OxyContin. The 505(b)(2) process requires that the Company certify to the FDA that the Company does not infringe any of the patents listed for OxyContin in the Orange Book, or that the patents are invalid. The process also requires that the Company notify Purdue Pharma, L.P ("Purdue"), as the holder of the NDA, and any other Orange Book-listed patent owners that it has made such a certification. On February 11, 2015, the Company made the required certification documenting why Xtampza ER does not infringe any of

the 11 Orange Book-listed patents for OxyContin, five of which have been invalidated in court proceedings, and provided the required notice to Purdue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, Purdue had the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

In response to these actions, Purdue sued the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

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

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

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

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

A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the '933, '497, and '717 patents. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment that the Company filed. Specifically, the Court ruled that the Xtampza ER formulation does not infringe the '497 and '717 patents. On September 18, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. On September 20, 2019, the matter was stayed pending further order of the Court.

On September 1, 2020, the Bankruptcy Court entered an Order Granting Motions for Relief from the Automatic Stay, lifting the automatic stays in both the District of Massachusetts and PTAB proceedings. The Company appealed the Bankruptcy Court's Order, in part, and that appeal is stayed, on consent by Purdue, pending the outcome of any appeal of the 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. The Company opposed Purdue's motion. On November 19, 2021, the PTAB (i) denied Purdue's motion to terminate the PGR and (ii) issued its Final Written Decision, finding that claims 1-17 of the '961 patent were invalid for lack of written description and anticipation. On December 17, 2021, Purdue filed a Request for Director Review. That request was denied on February 7, 2022. On February 16, 2022, Purdue filed a Federal Circuit notice of appeal. On April 12, 2022, the Company filed a Motion to

Dismiss the Appeal as Untimely. On May 20, 2022, the Federal Circuit denied the Motion to Dismiss and directed the parties to address jurisdiction during merits briefing.

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, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. The Company responded to Purdue's complaint asserting the '434 patent with a motion to dismiss. On May 21, 2021, and in response to the Company's motion to dismiss, Purdue filed an amended complaint asserting the '434 patent. 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 October 5, 2021, the Court held a claim construction hearing for the '961 patent and the '434 patent. On November 17, 2022, the Court set (i) the fact discovery deadline for May 4, 2023; and (ii) expert witness depositions to conclude by August 24, 2023. 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 '933, '919, '434, and '961 patents. The parties agreed, however, that litigation concerning the '961 patent is stayed pending resolution of Purdue's Federal Circuit appeal of the PTAB decision invalidating the claims of the '961 patent. 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 District of Delaware. Specifically, Purdue argues that the Company's sale of immediate-release and extended-release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

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

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

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

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 United States District Court for the Southern District of New York, captioned *Stein v. BioDelivery Sciences International, Inc., et al.*, No. 1:22-cv-01600, 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, captioned *Sanford v. BioDelivery Sciences International, Inc., et al*., No. 1:22-cv-01676 ("*Sanford* Action"), and *Higley v. BioDelivery Sciences International, Inc., et al.*, No. 1:22-cv-01658 ("*Higley* Action"). On March 2, 2022 and March 5, 2022, two additional cases were filed by purported individual stockholders of BDSI in the United States District Court for the Eastern District of New York, captioned *Justice II v. BioDelivery Sciences International, Inc., et al.*, No. 1:22-cv-01145 ("*Justice* Action") and *Zomber v. BioDelivery Sciences International, Inc., et al.*, No. 1:22-cv-01220 ("*Zomber* Action"; together with the *Stein*, *Sanford*, *Higley*, and *Justice* 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 by allegedly failing to disclose purportedly material information relating to the sale process leading to the Merger, BDSI's financial projections, and the analyses performed by Moelis & Company LLC in connection with the Merger. 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. Additionally, the *Stein, Higley, Justice*, and *Zomber* complaints assert violations of Section 14(d) of the Exchange Act and Rule 14d-9 promulgated thereunder. 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, on February 24, 2022, February 28, 2022, and March 7, 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"). On March 4, 2022, March 9, 2022, and March 11, 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").

On April 14, 2022, plaintiff in the *Higley* Action filed a notice of voluntary dismissal of the complaint. On May 15, 2022, plaintiff in the *Zomber* Action filed a notice of voluntary dismissal of the complaint. And, on June 24, 2022, plaintiff in the *Justice* Action filed a notice of voluntary dismissal of the complaint. In the remaining *Stein* and *Sanford* Actions, on July 20, 2022, the respective Courts entered an Order for plaintiff to serve a summons and complaint by August 3, 2022. On July 28, 2022, plaintiff in the *Sanford* Action filed a partial voluntary dismissal of the individual named defendants but not BDSI from that action and filed a waiver of service as to BDSI. On October 26, 2022, plaintiff in the *Sanford* Action filed a notice of voluntary dismissal of the complaint as to Defendant BDSI as well. To date, the complaint in the *Stein* Action has not been served on, nor was service waived by, any of the named defendants in that action.

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.

As set forth in the Supplemental Disclosures, nothing therein shall be deemed an admission of the legal necessity or materiality under applicable law of the Supplemental Disclosures. To the contrary, the Company and BDSI specifically deny all allegations that any of the Supplemental Disclosures, or any other additional disclosures, were or are required. The Company plans to defend the Merger Litigations 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, healthcare providers, and other entities brought suit against manufacturers, wholesale distributors, and pharmacies alleging a variety of claims related to opioid marketing and distribution practices. In late 2017, the U.S. Judicial Panel on Multidistrict Litigation ordered the consolidation of what were then a few hundred cases pending around the country in federal court against opioid manufacturers and distributors into a Multi-District Litigation ("MDL") in the Northern District of Ohio. The Company was named as a defendant in a small subset of the MDL cases. Of the 21 MDL cases that named the Company as a defendant, the allegations against it were previously dismissed or withdrawn in 13 cases as of December 31, 2021. As explained below, the remaining eight MDL cases that named the Company were dismissed as of April 19, 2022. In addition, the Company had been previously dismissed from three non-MDL cases filed in Pennsylvania and Arkansas state courts.

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

- In Pennsylvania, six lawsuits naming the Company were consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors. These included lawsuits filed between May 2018 and July 2019 on behalf of Bucks County, Clinton County, Mercer County, Warrington Township, Warminster Township, and the City of Lock Haven, each of Pennsylvania, alleging claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws.

- In Massachusetts, there were lawsuits by the City of Worcester, the City of Salem, the City of Framingham, the Town of Lynnfield, the City of Springfield, the City of Haverhill, the City of Gloucester, the Town of Canton, the Town of Wakefield, the City of Chicopee, the Town of Natick, the City of Cambridge and the Town of Randolph, all of which were consolidated before the Business Litigation Session of the Superior Court. The actions alleged a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, Section 11, unjust enrichment and civil conspiracy.

On December 24, 2021, the Company entered into a settlement framework with Scott+Scott Attorneys at Law, LLP, the law firm representing plaintiffs in each of the 27 cases, including the 8 remaining MDL cases and 19 state court cases described above. Pursuant to the terms of the settlement framework, which were later memorialized in a final settlement agreement, the Company agreed to pay $2,750 in exchange for the dismissal, with prejudice, of each plaintiff's lawsuit against the Company and a release of claims related to such lawsuits. The settlement agreement was executed by the Company and all 27 plaintiffs, and the amounts subject to the settlement agreement were paid.

The Company entered into this settlement to efficiently resolve this litigation and does not admit any liability or acknowledge any wrongdoing in connection with the settlement agreement.

The parties have submitted appropriate motions to dismiss the Company with prejudice for each of the 27 cases. All were granted, thereby dismissing the Company, with prejudice, from all 27 cases.

Ongoing BDSI Litigation Matters

BDSI's ongoing litigations with Aquestive Therapeutics, Inc. (formerly MonoSol Rx, "Aquestive") and Indivior PLC (formerly RB Pharmaceuticals Limited, "Indivior") are provided below.

Litigation related to BUNAVAIL

On October 29, 2013, 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 against BDSI relating to its BUNAVAIL product in the United States District Court for the Eastern District of North Carolina ("EDNC") for alleged patent infringement. BUNAVAIL is a drug approved for the maintenance treatment of opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL, which has never been disclosed publicly, infringes its U.S. Patent No. 8,475,832 (the "'832 Patent"). On May 21, 2014, the Court granted BDSI's motion to dismiss.

On September 22, 2014, the RB Plaintiffs filed an action against BDSI (and BDSI's commercial partner) relating to BDSI's BUNAVAIL product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 (the "'167 Patent").

On December 12, 2014, BDSI filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against its commercial partner. On October 28, 2014, BDSI filed multiple IPR petitions on certain claims of the '167 Patent. The USPTO instituted three of the four IPR petitions. The PTAB upheld the claims and denied collateral estoppel applied to the PTAB decisions in March 2016. BDSI appealed to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the PTAB.

On June 19, 2018, BDSI filed a motion to remand the case for further consideration by the PTAB in view of intervening authority. On July 31, 2018, the Federal Circuit vacated the decisions, and remanded the '167 Patent IPRs for further consideration on the merits.

On February 7, 2019, the PTAB issued three decisions on remand vacating institution of the three previously instituted IPRs of the '167 patent. BDSI timely appealed the PTAB decisions, and that appeal was ultimately denied.

On May 18, 2021, the RB Plaintiffs filed an amended complaint dropping BDSI's commercial partner from the action it began on September 22, 2014. On June 1, 2021, BDSI answered the amended complaint asserting counterclaims of non-infringement, invalidity, and unenforceability. On December 16, 2021, the parties completed claim construction briefing on the disputed claim terms of the '167 patent. The Court has not set a date for the claim construction hearing, or for a subsequent trial. 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.

Litigation related to BELBUCA

On January 13, 2017, Aquestive filed a complaint in the United States District Court for the District of New Jersey alleging BELBUCA infringes the '167 Patent. In lieu of answering the complaint, BDSI filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC. On July 25, 2017, the New Jersey Court administratively terminated the case pending the parties' submission of a joint stipulation of transfer because the District of New Jersey was an inappropriate venue. This case was later transferred to the Delaware District Court. On October 31, 2017, BDSI filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC.

On October 16, 2018, denying the motion to dismiss as moot, the Delaware District Court granted BDSI's motion to transfer the case to the EDNC. On November 20, 2018, BDSI moved the EDNC to dismiss the complaint for patent infringement for failure to state a claim for relief.

On August 6, 2019, the EDNC granted BDSI's motion to dismiss, and dismissed the complaint without prejudice. On or about November 11, 2019, Aquestive refiled a complaint in the EDNC against BDSI alleging that BELBUCA infringes the '167 Patent. On January 13, 2020, in lieu of answering the complaint, BDSI filed a motion to dismiss the complaint. After that motion was denied, BDSI answered the complaint on April 16, 2020. Aquestive moved to dismiss BDSI's counterclaim of unenforceability, but the court denied that motion.

On December 16, 2021, the parties completed claim construction briefing on the disputed claim terms of the '167 patent. The Court has not set a date for the claim construction hearing, or for a subsequent trial. 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.

Chemo Research, S.L

On March 1, 2019, BDSI filed a complaint for patent infringement in United States 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 its Orange Book-listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 ("'866 patent") and 9,655,843, ("'843 patent") both expiring in July of 2027, and U.S. Patent No. 9,901,539 ("'539 patent") expiring December of 2032 (collectively, "the BEMA patents"). This complaint follows a receipt by BDSI on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it has 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. Because BDSI initiated a patent infringement suit asserting the patents identified in the Notice Letter within 45 days after receipt, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. On March 15, 2019, BDSI filed a complaint against the Chemo Defendants in the Federal District Court for the District of New Jersey asserting the same claims for patent infringement made in the Delaware lawsuit. On April 19, 2019, Defendants filed an answer to the Delaware complaint wherein they denied infringement of the '866, '843 and '539 patents and asserted counterclaims seeking declaratory relief concerning the alleged invalidity and non-infringement of such patents.

On April 25, 2019, BDSI voluntarily dismissed the New Jersey lawsuit given Defendants' consent to jurisdiction in Delaware.

The trial to adjudicate issues concerning the validity of the Orange Book-listed patents covering BELBUCA was held from March 1-3, 2021. Chemo did not participate in the bench trial. Instead, on February 26, 2021, Chemo agreed to be bound by the decision of the Court with respect to the validity of the BEMA patents from the March 1-3, 2021 trial with Alvogen. On December 20, 2021, the Court issued an opinion upholding the validity of certain claims in BDSI's '866 patent, which expires in 2027, and certain claims in the '539 patent, which expires in 2032, to which Chemo is bound. This holding was affirmed on appeal by the Federal Circuit on December 21, 2022. The bench trial to adjudicate issues concerning the Chemo Defendants' infringement of the Orange Book patents was set to commence on April 25, 2022. On March 30, 2022, the Court vacated the trial and has not yet set a new trial date.

On August 1, 2022, BDSI received a second Paragraph IV certification notice letter from Chemo indicating that Chemo has 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 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 district 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.

The Company plans to litigate these cases 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.

Alvogen

On September 7, 2018, BDSI filed a complaint for patent infringement in United States 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 infringes BDSI's Orange Book-listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539, expiring in December of 2032 (collectively, "the BEMA patents"). This complaint followed receipt by BDSI on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an ANDA with the FDA for a generic version of BELBUCA Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because BDSI initiated a patent infringement suit asserting the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid.

The Court scheduled a bench trial to adjudicate issues concerning the validity of the BEMA patents. A three-day bench trial against Alvogen was conducted commencing on March 1, 2021.

On December 20, 2021, the Court issued an opinion upholding the validity of certain claims in BDSI's '866 patent, which expires in 2027, and certain claims in the '539 patent, which expires in 2032. Alvogen conceded infringement of those claims prior to the trial. The Court entered final judgment on January 21, 2022. The final judgment entered in this case upholding the validity of claims of the '866 and '539 Orange Book-listed patents extends the effective date of any final approval by the FDA of Alvogen's ANDA until December 21, 2032, which is the expiration date of the '539 patent, and enjoins Alvogen and those acting in concert with Alvogen from commercially manufacturing, using, selling, or offering for sale Alvogen's ANDA products until December 21, 2032. Alvogen filed a motion to stay certain provisions of the final judgment in the Court. 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 entered on January 21, 2022. Separately, BDSI has filed a cross-appeal to the Federal Circuit seeking to reverse the Court's opinion that claims 3 and 10 of the '866 patent and claims 8, 9 and 20 of the '843 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 November 1, 2022, the Federal Circuit held oral argument on the parties' appeal and issued its decision on December 21, 2022. In that decision, the Federal Circuit affirmed the district court judgment that certain claims of the '866 and '539 patent were not invalid as obvious. The Federal Circuit also vacated the district court's judgment that certain claims of the '866 and '843 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.

Opioid-Related Request and Subpoenas

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

On December 16, 2021, the Company entered into an Assurance of Discontinuance with the Massachusetts Attorney General (the "AoD"). Pursuant to the AoD, the Company provided certain assurances and agreed to pay the Massachusetts Attorney General $185, including $65 relating to that office's costs of investigation, in exchange for closure of the investigation and a release of claims pertaining to the subject matter of the investigation. The Company is currently cooperating with each of the foregoing states in their respective investigations.

13. 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 Pharmakon (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. The 2022 Term Loan bears interest at a rate based upon the London Interbank Offered Rate ("LIBOR") (subject to a LIBOR floor of 1.20%), plus a margin of 7.5% per annum. As of December 31, 2022, the interest rate was 11.2%. The Company is required to repay the 2022 Term Loan by paying $100,000 in principal payments during the first year and the remaining $550,000 balance will amortize 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.

During the years ended December 31, 2022, 2021, and 2020, the Company recognized interest expense of $58,533, $16,339, and $19,034, respectively.

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

Years ended December 31,	Principal Payments
2023	$ 162,500
2024	183,333
2025	183,333
2026	45,834
Total before unamortized discount and issuance costs	$ 575,000
Less: unamortized discount and issuance costs	(14,922)
Total term notes	$ 560,078

2026 Convertible Notes

On February 13, 2020, the Company issued 2.625% convertible senior notes due in 2026 (the "2026 Convertible Notes" or "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 Nucynta Acquisition, and the proceeds of the convertible notes were used to finance a portion of the purchase price payable pursuant to the Nucynta Purchase Agreement. Some of the Company's existing investors participated in the convertible notes offering.

The Company may, at its option, settle the convertible notes in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock. Accordingly, the Company originally accounted for the liability component (the "Liability Component") and the embedded derivative conversion option (the "Equity Component") of the convertible notes separately by allocating the proceeds between the Liability Component and the Equity Component. In connection with the issuance of the convertible notes, the Company incurred approximately $5,473 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs between the Liability Component and the Equity Component based on the allocation of the proceeds. Of the total debt issuance costs, $1,773 was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $3,700 was allocated to the Liability Component and recorded as a debt discount of the convertible notes. The portion allocated to the Liability Component was expected to be amortized to interest expense using the effective interest method over six years.

Prior to the adoption of ASU 2020-06 on January 1, 2021, the initial carrying amount of the Liability Component of $97,200 was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible borrowing rate for similar debt. The Equity Component of the convertible notes of $46,550 was recognized as a debt discount. The excess of the principal amount of the Liability Component over its carrying amount was expected to be amortized to interest expense using the effective interest method over six years.

Subsequent to the adoption of ASU 2020-06 on January 1, 2021, which the Company elected to adopt using the modified retrospective method, the Company removed the impact of recognizing the Equity Component of the senior convertible notes (at issuance and the subsequent accounting impact of additional interest expense from debt discount amortization).

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

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

(1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2020, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
(2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") in which the "trading price" per $1 principal amount of the 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 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, 2022, none of the above circumstances had occurred and as such, the convertible notes could not have been converted.

The Company may not redeem the convertible notes prior to February 15, 2023. On or after February 15, 2023, the Company may redeem the convertible notes, in whole and not in part, at a cash redemption price equal to the principal amount of the 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 convertible note for redemption will constitute a make-whole fundamental change with respect to that convertible note, in which case the conversion rate applicable to the conversion of that convertible note, if it is converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

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

As of December 31, 2022, the convertible notes outstanding consisted of the following:

Principal	$	143,750
Less: unamortized issuance costs		(2,877)
Net carrying amount	$	140,873

The Company determined the expected life of the convertible notes was equal to its six-year term. The effective interest rate on the convertible notes was 3.26%. As of December 31, 2022, 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, 2022, 2021, and 2020:

	Years Ended December 31,		
	2022	2021	2020
Contractual interest expense	$ 3,773	$ 3,773	$ 3,323
Amortization of debt discount	—	—	5,628
Amortization of debt issuance costs	907	902	447
Total interest expense	$ 4,680	$ 4,675	$ 9,398

As of December 31, 2022, the future minimum payments on the convertible notes were as follows:

Years ended December 31,	Future Minimum Payments
2023	$ 3,773
2024	3,773
2025	3,773
2026	145,638
Total minimum payments	$ 156,957
Less: interest	(13,207)
Less: unamortized issuance costs	(2,877)
Convertible senior notes	$ 140,873

14. LEASES

Operating Lease Arrangements

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

In January 2016, the Company entered a non-cancellable contract with the contract manufacturing organization ("CMO") of Xtampza ER. The contract term continued through December 2022 and was automatically renewed for successive two-year terms as neither party gave written notice of termination two-years in advance. Pursuant to the terms of the agreement, since 2016 the CMO has reserved 3,267 square feet of existing manufacturing space for a dedicated manufacturing suite for Xtampza ER, which was put into service in the year ended December 31, 2020. As the Company can direct the use of the dedicated manufacturing suite and obtain substantially all the economic benefits of the dedicated space, the Company determined that the arrangement was an embedded operating lease. The Company expects the lease term to continue at least through December 2026 and separated the agreement's lease and non-lease components in determining the operating lease assets and liabilities. The Company determined its best estimate of stand-alone prices for each of the lease and nonlease components by considering observable information including gross margins expected to be recovered from the Company's service provider and terms of similar lease contracts.

In connection with the BDSI Acquisition, the Company acquired an operating lease for the former headquarters of BDSI pursuant to which the Company leases 11,628 of rentable square feet of space in Raleigh, North Carolina (the "BDSI Lease"). The BDSI Lease continues through July 2023. The Company does not expect to renew or extend the lease beyond its contractual expiration in July 2023.

As of December 31, 2022, the Company had operating lease assets of $6,861 and operating lease liabilities of $8,224 primarily related to operating lease agreements for its corporate headquarters.

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, 2022, 2021, and 2020 are as follows:

	Years Ended December 31,		
	2022	2021	2020
Lease Cost			
Operating lease cost	$ 1,805	$ 1,305	$ 1,305
Short-term lease cost	993	1,492	1,312
Variable lease cost	331	292	331
Total lease cost	$ 3,129	$ 3,089	$ 2,948

The lease term and discount rate for operating leases for the years ended December 31, 2022 and 2021 are as follows:

	Years Ended December 31,	
	2022	2021
Lease Term and Discount Rate:		
Weighted-average remaining lease term — operating leases (years)	6.6	7.6
Weighted-average discount rate — operating leases	6.2 %	6.1 %

Other information related to operating leases for the years ended December 31, 2022, 2021, and 2020 is as follows:

	Years Ended December 31,		
	2022	2021	2020
Other Information:			
Cash paid for amounts included in the measurement of operating leases liabilities	$ 1,568	$ 1,286	$ 1,249
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, 2022, are as follows:

2023	$ 1,585
2024	1,398
2025	1,436
2026	1,474
2027	1,489
Thereafter	2,697
Total minimum lease payments	$ 10,079
Less: Present value discount	1,855
Present value of lease liabilities	$ 8,224

15. 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, 2022, there were 1,920,793 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 our plans are funded through the issuance of new shares. Refer to Note 16, *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 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, 2022, there were no outstanding warrants remaining.

Share Repurchases

In August 2021, the Company's Board of Directors authorized a repurchase program for 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. Shares repurchased under the Prior Repurchase Program were returned to the Company's pool of authorized but unissued shares available for reissuance. The timing and amount of any such repurchases were determined based on share price, market conditions, legal requirements, and other relevant factors.

In October 2021, the Company's Board of Directors authorized an 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 "ASR Agreement"), the Company paid $25,000 on November 15, 2021, and 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 was 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 separate transactions (1) a repurchase of common stock in a treasury stock transaction recorded on November 15, 2021 and (2) a forward contract indexed to the Company's own common stock which settled on January 7, 2022. The forward contract for the purchase of the remaining $5,000, representing remaining shares to be delivered by the investment bank under the ASR Agreement, was recorded as a reduction to stockholders' equity as of December 31, 2021.

Forward contracts to repurchase a variable number of the Company's equity shares that require physical settlement are accounted for in conformity with guidance in ASC 815-10-15. Under ASC 815-10-15-74, contracts issued or held by a

company that are both (1) indexed to its own stock and (2) classified in stockholders' equity in its statement of financial position are not considered to be derivative instruments. Based on the transaction structure, the Company concluded that the forward purchase contract portion of the Company's ASR Agreement satisfied these criteria and accordingly was classified as an equity instrument. In accordance with ASC 260-10-55-88, the above-noted treasury stock acquisition resulted in an immediate reduction of 1,026,694 shares from the outstanding shares 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 contract, 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 forward was outstanding. The forward contract was no longer outstanding as of 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 and the cost of repurchased shares were recorded as treasury stock in the Consolidated Balance Sheet. The Prior Repurchase Program expired on December 31, 2022.

In January 2023, the Company's Board of Directors authorized the 2023 Share Repurchase Program for the repurchase of up to $100,000 of the Company's common stock through December 31, 2023. The 2023 Share 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 the share repurchase program.

16. 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.

In December 2020, the Company's Board of Directors approved a modification of PSUs that were originally granted to the Company's senior management team in January 2019. The modification replaced the original performance criteria for the 2020, 2021 and cumulative performance periods from being based on Xtampza 2020, 2021 and three-year cumulative revenue goals to being based on TSR for 2020, 2021 and the corresponding two-year cumulative period. The PSUs achieved based on 2019 Xtampza revenues goals were not changed as part of the modification. The Company accounted for this modification under ASC 718, and, per guidance, determined the modification created incremental value as the fair value of these awards was increased upon modification. The increase in fair value resulted in an accelerated recognition of stock-based compensation expense on the modification date of $906. The total expense for these PSUs in years ended December 31, 2022, 2021, and 2020 was zero, $289 and $950, respectively.

A summary of the Company's performance share units activity for the year ended December 31, 2022 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2021	353,100	$ 31.77
Granted	241,550	24.12
Vested	(126,081)	29.12
Forfeited	(22,104)	29.60
Performance adjustment	1,305	28.96
Outstanding at December 31, 2022	447,770	$ 28.71

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, 2022, 2021, and 2020 was $24.12, $35.15, and $28.49, respectively.

For the years ended December 31, 2022, 2021, and 2020, the stock-based compensation expense for PSUs was $5,398, $4,817, and $3,551, respectively.

As of December 31, 2022, the unrecognized compensation cost related to performance share units was $4,242 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, 2022 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2021	1,620,023	$ 22.48
Granted	1,372,247	17.53
Vested	(573,204)	21.89
Forfeited	(371,495)	20.57
Outstanding at December 31, 2022	2,047,571	$ 19.67

The weighted-average grant date fair value of RSUs granted for the years ended December 31, 2022, 2021 and 2020 was $17.53, $24.23 and $21.35. The total fair value of RSUs vested (measured on the date of vesting) for the years ended December 31, 2022, 2021 and 2020 was $10,166, $11,165 and $6,992 respectively.

As of December 31, 2022, the unrecognized compensation cost related to restricted stock units was $26,742 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, 2022, 2021, and 2020 was $12,547, $8,526, and $5,989, respectively.

Stock Options

A summary of the Company's stock option activity for the year ended December 31, 2022 and related information is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	2,728,169	$ 18.33	5.8	$ 6,070
Exercised	(742,348)	15.93		
Cancelled	(302,016)	21.35		
Outstanding at December 31, 2022	1,683,805	$ 18.84	5.5	$ 7,953
Exercisable at December 31, 2022	1,545,610	$ 18.82	5.4	$ 7,394

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,		
	2022	2021	2020
Risk-free interest rate	— %	0.7 %	1.3 %
Volatility	— %	67.2 %	66.2 %
Expected term (years)	—	6.0	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 weighted-average grant date fair value of stock options granted for the years ended December 31, 2022, 2021, and 2020 was zero, $12.60 and $12.78 respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2022, 2021, and 2020 was $3,943, $6,456 and $7,516, respectively.

As of December 31, 2022, the unrecognized compensation cost related to outstanding options was $1,322 and is expected to be recognized as expense over approximately 1.1 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 (1) the first day of the purchase period or (2) the last day of the purchase period. During the year ended December 31, 2022, 22,627 shares of common stock were purchased for total proceeds of $337. As of December 31, 2022, there were 1,932,173 shares of common stock authorized for issuance pursuant to the employee stock purchase plan. The expense for the years ended December 31, 2022, 2021 and 2020 was $117, $224 and $342 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,		
	2022	2021	2020
Research and development	$ 1,591	$ 3,422	$ 3,909
Selling, general and administrative	21,283	20,833	18,001
Total stock-based compensation expense	$ 22,874	$ 24,255	$ 21,910

17. INCOME TAXES

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

	Years Ended December 31,		
	2022	2021	2020
Current provision:			
Federal	$ 166	$ —	$ —
State	4,540	3,142	830
	4,706	3,142	830
Deferred benefit:			
Federal	$ (4,631)	$ (61,445)	$ —
State	(3,920)	(16,588)	—
	(8,551)	(78,033)	—
(Benefit from) provision for income taxes	$ (3,845)	$ (74,891)	$ 830

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,		
	2022	2021	2020
Federal income tax expense at statutory rate	21.0 %	21.0 %	21.0 %
(Increase) decrease income tax (benefit) resulting from:			
State income tax, net of federal benefit	5.0	2.9	5.1
Permanent differences	(1.9)	(3.9)	1.1
Stock compensation	(5.1)	(18.8)	(3.0)
Research and development credit	0.7	16.3	(1.1)
Transaction costs	(4.4)	—	—
Change in tax rates and other	(2.0)	—	—
Change in valuation allowance	—	2,202.5	(20.1)
Effective income tax rate	13.3 %	2,220.0 %	3.0 %

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,	
	2022	2021
Deferred tax assets:		
U.S. and state net operating loss carryforwards	$ 56,982	$ 31,400
Research and development credits	5,036	5,470
Operating lease liabilities	2,131	2,321
Returns and discounts	19,423	23,072
Stock-based compensation	6,776	7,838
Accruals and other	5,228	2,210
163(j) Carryforward	3,647	—
Capitalized R&D	929	—
Intangible assets	23,592	12,699
Gross deferred tax assets:	123,744	85,010
Valuation allowance	(5,254)	(1,966)
Total deferred tax assets:	118,490	83,044
Deferred tax liabilities:		
Debt discount	(406)	—
Operating lease assets	(1,778)	(2,024)
Inventory	(3,918)	—
Intangible assets	(84,167)	—
Property and equipment	(4,271)	(2,978)
Total deferred tax liabilities:	(94,540)	(5,002)
Net deferred tax assets	$ 23,950	$ 78,042

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, 2022. The valuation allowance was $5,254 and $1,966 as of December 31, 2022 and 2021, respectively. The change in the 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.

As of December 31, 2022, 2021, and 2020, the Company had gross U.S. federal net operating loss carryforwards of $229,797, $119,280, and $226,824, respectively, which may be available to offset future income tax liabilities. The Tax Cuts and Jobs Act of 2017 ("TCJA") will generally allow losses incurred after 2017 to be carried over indefinitely but will generally limit the NOL deduction to the lesser of the NOL carryover or 80% of a corporation's taxable income (subject to Internal Revenue Code Sections 382 and 383). Also, there will be no carryback for losses incurred after 2017. Losses incurred prior to 2018 will generally be deductible to the extent of the lesser of a corporation's NOL carryover or 100% of a corporation's taxable income (subject to Internal Revenue Code Section 382 and 383) and be available for twenty years from the period the loss was generated.

As of December 31, 2022, 2021, and 2020, the Company also had gross U.S. state net operating loss carryforwards of $252,597, $103,044, and $170,280, respectively, which may be available to offset future income tax liabilities and expire at various dates through 2037.

As of December 31, 2022, 2021 and 2020, the Company had federal research and development tax credit carryforwards of approximately $4,231, $4,503, and $4,623, respectively, available to reduce future tax liabilities which expire at

various dates through 2037 and some are indefinite lived. As of December 31, 2022, 2021 and 2020 the Company had state research and development tax credit carryforwards of approximately $832, $955, and $1,150, respectively, available to reduce future tax liabilities which expire at various dates through 2037.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. The net operating losses acquired in the BDSI acquisition, totaling $234,675 are subject to limitation.

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. In addition, 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.

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, 2022. 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,		
	2022	2021	2020
Gross UTB Balance at January 1	$ 654	$ 586	$ 578
Additions based on tax positions related to the current year	—	67	36
Additions for tax positions related to acquisitions	10,930	—	—
(Reductions) additions for tax positions of prior years	(184)	1	(28)
Gross UTB Balance at December 31	$ 11,400	$ 654	$ 586
Net UTB impacting the effective tax rate at December 31 excluding valuation allowance impacts, if any	$ 11,368	$ 500	$ 560

18. 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, 2022, 2021 and 2020 was $1,315, $1,236, and $1,260 respectively.

19. UNAUDITED QUARTERLY OPERATING RESULTS

The following is a summary of unaudited quarterly results of operations for the years ended December 31, 2022 and 2021:

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

Year Ended December 31, 2021	First Quarter	Second Quarter	Third Quarter	Fourth Quarter (1)
Product revenues, net	$ 87,721	$ 82,942	$ 78,843	$ 27,362
Cost of product revenues				
Cost of product revenues (excluding intangible asset amortization)	15,328	15,908	15,934	11,900
Intangible asset amortization and impairment	16,795	16,795	16,796	16,795
Total cost of products revenues	32,123	32,703	32,730	28,695
Gross profit	55,598	50,239	46,113	(1,333)
Operating expenses				
Research and development	2,930	3,462	1,450	1,609
Selling, general and administrative	31,476	30,368	30,514	26,602
Restructuring	—	—	—	4,578
Total operating expenses	34,406	33,830	31,964	32,789
Income (loss) from operations	21,192	16,409	14,149	(34,122)
Interest expense	(5,721)	(5,421)	(5,115)	(4,757)
Interest income	3	3	3	3
Income (loss) before income taxes	15,474	10,991	9,037	(38,876)
(Benefit from) provision for income taxes	(188)	(61,852)	991	(13,842)
Net income (loss)	$ 15,662	$ 72,843	$ 8,046	$ (25,034)
Earnings (loss) per share — basic	$ 0.45	$ 2.06	$ 0.23	$ (0.73)
Weighted-average shares — basic	34,951,740	35,302,608	35,373,909	34,123,309
Earnings (loss) per share — diluted	$ 0.41	$ 1.79	$ 0.22	$ (0.73)
Weighted-average shares — diluted	41,160,092	41,286,853	36,261,174	34,123,309

(1) In the fourth quarter of 2021, product revenues, net included a $38,329 product revenue adjustment related to returns adjustments, of which $13,787 related to Xtampza revenue and $24,542 related to Nucynta Products revenue. In addition, selling general and administrative operating expense includes $2,935 of expense related to litigation settlements.

20. SUBSEQUENT EVENTS

2029 Convertible Notes

On February 10, 2023, the Company issued $241,500 principal amount of its 2.875% Convertible Senior Notes due 2029. The 2029 Convertible Notes issued on February 10, 2023 include $31,500 principal amount of notes issued pursuant to the full exercise by the initial purchasers of such optional purchase.

The 2029 Convertible Notes will be the Company's senior, unsecured obligations and will be (i) equal in right of payment with the Company's existing and future senior, unsecured indebtedness, including its existing 2.625% convertible senior notes due 2026; (ii) senior in right of payment to the Company's future indebtedness that is expressly subordinated to the notes; (iii) effectively subordinated to the Company's existing and future secured indebtedness, including borrowings under the Company's secured term loan agreement, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company's subsidiaries.

The 2029 Convertible Notes will accrue interest at a rate of 2.875% per annum, 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. The Company will settle conversions by

paying or delivering, as applicable, cash, shares of its common stock or a combination of cash and shares of its common stock, at the Company's election. The initial conversion rate is 27.3553 shares of common stock per $1,000 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 will be subject to customary adjustments upon the occurrence of certain events.

Contemporaneously with the pricing of the notes in the offering, Collegium entered into separate privately negotiated transactions with certain holders of the 2026 Convertible Notes to repurchase $117,400 aggregate principal amount of the 2026 notes for an aggregate of approximately $140,100 of cash, which includes accrued and unpaid interest on the 2026 Convertible Notes to be repurchased.

Tranfser of Elyxyb Rights and Obligations to Scilex

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.

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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

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-237200 on Form S-3 and Registration Statement Nos. 333-207744, 333-218767, 333-225498, 333-233092, 333-245649, 333-258752, and 333-266778 on Form S-8 of our reports dated February 23, 2023, 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, 2022.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 23, 2023

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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 23, 2023

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 23, 2023

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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph Ciaffoni, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Date: February 23, 2023

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, 2022 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 her 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 23, 2023