UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

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 001-36306

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2834**	**20-8179278**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
(201) 326-5300

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common stock, $0.001 par value per share	EGRX	The Nasdaq Global Market

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

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 o No x

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 x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted 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 x No o

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 definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	
☐	☒	☐	☐	☐

Emerging growth company ☐

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

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. x

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was approximately $437,105,101 computed by reference to the last reported sale price of $42.80 per share as reported by The Nasdaq Global Market, as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2021. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares outstanding of the registrant's common stock, $0.001 par value per share, as of February 28, 2022 was 12,697,101 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2022 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2021, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

Eagle Pharmaceuticals, Inc.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan,", "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "project," "continue," "potential," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- the potential benefits and commercial potential of our approved products, including rapidly infused bendamustine RTD, or Bendeka, Ryanodex® (dantrolene sodium), or Ryanodex, and bendamustine ready-to-dilute, or RTD, 500ml solution, or Belrapzo, TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride, PEMFEXY™, and vasopressin, for approved indications and any expanded uses;
- the commercial potential of additional indications for our products;
- sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for our products or for additional indications or in additional territories;
- future expansion of our commercial organization and transition to third-parties in certain jurisdictions to perform sales, marketing and distribution functions;
- the initiation, timing, design, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our plans to research, develop and commercialize our products and product candidates and our ability to successfully commercialize our products and product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the impact of the ongoing coronavirus 2019, or COVID-19, pandemic on our business and operations, results of operations and financial performance including: disruption in the sales of our marketed products; delays, interruptions or other adverse effects to clinical trials and patient enrollment, or interruptions to key clinical trial activities such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers or others; delays in regulatory review; manufacturing and supply chain interruptions; and the adverse effects on healthcare systems and disruption of the global economy overall;
- the diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals and doctor offices serving as locations for administration of our products, including Bendeka and hospital staff supporting the conduct of such administration;
- the rate and degree of market acceptance of our products;
- our ability to significantly grow our commercial sales and marketing organization, whether alone or with potential future collaborators;
- the performance of our strategic collaborators and success of our current strategic collaborations;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing drugs that are or become available;
- the retention of key scientific or management personnel;
- our ability to obtain additional funding for our operations;

- our ability to obtain, maintain, protect and enhance intellectual property rights and proprietary technologies and operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- our ability to prevent or minimize the effects of litigation; and
- our expectations regarding anticipated future costs, operating expenses and capital requirements.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties, assumptions and other factors described under the "Risk Factors" section and elsewhere in this Annual Report, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements as predictions of future events. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

NOTE REGARDING COMPANY REFERENCES

References to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation, together with its subsidiaries. References to "Eagle Biologics" mean Eagle Biologics, Inc. and references to "Eagle Research Labs" means Eagle Research Labs Limited.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the ® or TM symbols, but such references are not intended to indicate in any way that the Company will not assert, to the fullest extent under applicable law, its rights or the rights of the applicable licensor to these trademarks and trade names. The Company does not intend its use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of the Company by, any other entity.

SUMMARY RISK FACTORS

Our business faces significant risks and uncertainties of which investors should be aware before making a decision to invest in our common stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors set forth under the caption "Risk Factors" in Item 1A in Part I of this Annual Report on Form 10-K. Some of the more significant risks include the following:

a. If we cannot sustain profitability, our business, prospects, operating results and financial condition would be materially harmed.
b. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
c. If we are unable to successfully conduct our sales and marketing capabilities or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.
d. If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs.
e. We may sell additional equity or incur additional debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.
f. We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized.
g. Current and future legislation and regulations may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain for our products.
h. If we are unable to differentiate our products or product candidates from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the ability to successfully commercialize our product candidates would be adversely affected.
i. Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.
j. Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.
k. Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and which may delay or prevent the review or approval of our product candidates; in addition, an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.
l. Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community.
m. A substantial portion of our total revenues is derived from sales of a limited number of products.
n. The COVID-19 pandemic has adversely impacted, and may continue to adversely impact, our business, including the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities.
o. We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
p. We rely on limited sources of supply for our products and product candidates, and any disruption in the chain of supply may impact production and sales of our products and cause delay in developing and commercializing our product candidates.
q. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
r. Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could negatively affect our operating results and business..
s. If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.
t. Our stock price may continue to fluctuate significantly.
u. There is no assurance that our share repurchase program will result in repurchases of our common stock or enhance stockholder value.
v. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

w. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

EAGLE PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

For the fiscal year ended December 31, 2021

PART I

Item 1. Business

Company Overview

Organization

We are a pharmaceutical company registered at and with principal offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. We also have a research and development facility in Cambridge, Massachusetts and an office space in Palm Beach Gardens, Florida.

Business

We are a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. We are committed to developing innovative medicines that result in meaningful improvements in patients' lives. Our commercialized products include RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM®, and PEMFEXY™ and our oncology and CNS/metabolic critical care pipeline includes product candidates we believe have the potential to address underserved therapeutic areas across multiple disease states.

Recent Developments

PEMFEXY

On February 1, 2022, we announced the commercial availability of our novel product PEMFEXY™ (pemetrexed for injection) in the United States. A branded alternative to ALIMTA®, PEMFEXY is a ready-to-use liquid with a unique J-code approved to treat nonsquamous non-small cell lung cancer and mesothelioma.

Prevously, in February 2020, Eagle received final approval from the U.S. Food and Drug Administration, or FDA, of our New Drug Application, or NDA, for PEMFEXY, following the settlement agreement of patent litigation with Eli Lilly and Company (NYSE: LLY) in December 2019. The agreement provided for a release of all claims by the parties and allowed for an initial entry of PEMFEXY into the market (equivalent to approximately a three-week supply of ALIMTA utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022. Under the settlement agreement, we will pay a royalty equal to one percent of the net sales of PEMFEXY during the royalty term, which will end no later than May 24, 2022.

Landiolol

On January 31, 2022, we announced that AOP Orphan Pharmaceuticals GmbH, or AOP Orphan, a privately owned Austrian company devoted to the treatment of rare and special diseases, had engaged with the FDA to obtain alignment on the content and format of the pre-clinical and clinical data required to support a NDA seeking approval of Landiolol. Previously, in August 2021, we entered into a licensing agreement with AOP Orphan for the commercial rights to Landiolol in the United States. Landiolol is a novel therapeutic product candidate that is expected to be developed for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter. See License Agreements - AOP Orphan License Agreement, below.

Vasopressin

On January 18, 2022, we announced the commercial availability of our recently approved product, vasopressin, an A-rated generic alternative to Vasostrict®, with 180 days of marketing exclusivity. The commercial launch follows the FDA's approval in December 2021 of our abbreviated new drug application, or ANDA, for vasopressin, a product that is indicated for use to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

TREAKISYM

Our bendamustine franchise continues to grow, including the launch of the TREAKISYM ready-todilute, or RTD, formulation by Symbio in Japan in the first quarter of 2021. In addition, Symbio is expected to seek approval in Japan of the rapid infusion, or RI, (50ml) liquid formulation.

Fulvestrant

Based on discussions with the FDA, we reformulated and plan to commence human pilot studies of our fulvestrant product candidate for the treatment of HR+/HER- advanced breast cancer shortly.

CAL02
We are preparing to begin clinical trials for CAL02, a novel approach to the treatment of severe bacterial pneumonia, later in 2022.

Executive Officer Transitions

On September 27, 2021, our board of directors appointed Scott Tarriff as our President and Michael Moran as our Executive Vice President, Chief Commercial Officer. In addition, David Pernock, our former President and Chief Operating Officer since January 2017, was appointed as Executive Vice President, Operations.

On December 27, 2021, Judith Ng-Cashin, M.D., ceased to serve as our Executive Vice President, Chief Medical Officer. We are currently in search for a replacement.

On December 31, 2021, David Pernock, ceased to serve as our Executive Vice President, Operations.

Other Events
On January 26, 2022, Tyme Technologies, Inc., or Tyme, announced the discontinuation of the Phase 2 clinical trial of SM-88 with methoxsalen, phenytoin, and sirolimus in patients with metastatic pancreatic cancer. On February 11, 2022, Tyme stated SM-88 is being evaluated in a Phase 2clinical trial evaluating SM-88 in breast cancer (HR+/HER2-), as well as continuing enrollment of a Phase 2 study in high-risk metastatic sarcomas. Previously, in January 2020, we and Tyme had announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer.

Share Repurchase Program

In March 2020, our board of directors approved our current share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of $160.0 million of our outstanding common stock. As of December 31, 2021, we have repurchased an aggregate of 4,111,622 shares of common stock for an aggregate of $228.1 million pursuant to our share repurchase programs in effect since August 2016.

COVID-19 Business Update

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on our business, such as remote working policies, facilitating management's daily communication to address employee and business concerns and providing frequent updates to the Board. We anticipate that the COVID-19 pandemic may have an impact on the clinical development timeline for EA-114, our fulvestrant product candidate. We anticipate that the COVID-19 pandemic will continue to delay our supply chain and marketing and sales efforts for certain of our products, including Bendeka, although it is not currently expected that any further disruption would be material. The COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and have specifically led to a continuing reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. While we have experienced variable financial impacts to date, the ongoing COVID-19 pandemic, including government measures taken in response thereto, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic, could materially adversely affect our business, financial condition, results of operations and growth prospects. We continue to closely monitor the COVID-19 pandemic as we evaluate and evolve our business plans and response strategy. The impact of the COVID-19 pandemic on our business and financial condition is more fully described below in Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations - Trends and Uncertainties. See also Item 1A – Risk Factors - The COVID-19 pandemic could adversely impact our business, including the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities.

Our Competitive Strengths
Our Purpose

We believe that many currently available critical care and oncology injectable drugs and biopharmaceuticals have suboptimal characteristics that do not meet the needs of patients, physicians, nurses or pharmacists. These characteristics can impact safety, shelf life, convenience, waste, cost, and ease of use by practitioners and pharmacy staff. For instance, existing drugs may be packaged inefficiently or come in formulations that require reconstitution or dilution, or which are otherwise difficult or inconvenient to prepare, and which could expose workers to cytotoxic compounds and can result in dosing errors. This can also

lead to wasted quantities of drug, inefficiencies in staff time and constrained work flow, reduced shelf life and the need for multiple dosing of individual patients to complete treatment. Likewise the viscosity of many biologic products requires them to be delivered intravenously often in time consuming and sometimes painful treatments for patients. We believe there is a large and unmet market for developing injectable drugs that address the specific needs of patients, physicians, nurses and pharmacists to simplify their use, reduce waste and lower healthcare costs.

We have and continue to engage physicians, nurses, pharmacists and key opinion leaders, to identify specific products where the characteristics described above present opportunities for product improvement. We evaluate the product opportunities presented by the stakeholders and determine whether or not they conform to our research and development planning. A key aspect of our evaluation is the intellectual property landscape for each product opportunity, including our ability to avoid infringing existing patents and the potential patentability of our modified version of the drug. We utilize our experienced team of formulators with extensive experience with injectable pharmaceuticals, and a track record of success in product development, regulatory relations, and quality assurance to develop improved products.

Because our products are differentiated from the branded reference drugs, we believe we are able to avoid infringing existing patents covering the branded reference drug allowing us to enter the existing market before applicable generic drugs, which may be subject to protracted patent litigation that delays market entry. Protracted litigation is a significant barrier to entry for competitors seeking approval of an ANDA referencing the branded reference product, and our early entry into the market leads to less price erosion due to constrained competition. Our patent holdings include over 30 owned or exclusively-licensed U.S. issued patents and over 10 filed U.S. patent applications, as well as several patents and patent applications that have been filed in various worldwide territories, that we believe protect or will protect, as applicable the market value of our current portfolio of products. We believe that other potential barriers to entry for our competitors consist of the following:

- our early entry into the market allows us to influence usage patterns when fewer, if any, competitors exist and allows us to market our products as improved versions of the branded reference drug prior to or concurrent with any generic entry, thereby giving us the opportunity to capture significant market share at this early stage. We believe that such early entry into the market will limit later conversions into generic versions of the branded reference drugs, allowing us to maintain market share and favorable pricing;
- the potential for seven years of exclusivity upon approval of a 505(b)(2) NDA that receives orphan drug status; and
- the potential for three years of regulatory exclusivity for our future product candidates upon approval, if any, of a 505(b)(2) NDA supported by new clinical investigations (other than bioequivalence and bioavailability studies) essential to approval of the application.

Our product portfolio is focused around our external partnerships (e.g., Teva, Symbio and Tyme); our vasopressin and Pemfexy products, with commercial launches for each product in early 2022; our Ryanodex related development projects; and our Fulvestrant project that is expected to yield a new approach to drug delivery.

We believe that we can leverage our formulation and development expertise to achieve improved product attributes in terms of potential for longer stability, shorter infusion times, less waste and/or ease and safety of use for healthcare professionals and achieve longer commercial duration compared to generic competitors. We believe that our products may offer certain benefits as compared to existing injectable drugs which may include one or more of the following:

- improved safety through elimination of reconstitution in the pharmacy or in the acute care setting;
- reduction in the number of injections required;
- reduction in the volume of drug needed to be injected, potentially expanding the application to additional medical situations;
- reduction in the amount of diluent required to administer the drug;
- reduction in drug waste;
- reduction in drug infusion time; and
- potential label expansion to include additional indications.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company. Our strategy to achieve this goal includes:

*Strengthen our product portfolio.*We intend to continue to strengthen our product portfolio with continued investment in research and development activities and other business development opportunities. We will continue to develop our current

product portfolio and leverage our expertise to identify new products with suboptimal characteristics that present us with significant opportunity for revenue generation. In addition to our internal efforts, we plan to opportunistically in-license or acquire product candidates that meet our rigorous evaluation process, fit our therapeutic areas of focus and match our commercial, regulatory and development expertise. Any in-licensing or product acquisitions are excepted to be funded through cash and cash equivalents, in combination with issuances of our common stock, borrowings under our Credit Agreement or other debt arrangements, or other means. See “Liquidity and Capital Resources.”

Retain commercial rights in the United States and selectively partner outside of the United States. In general, we believe that we can cost-effectively commercialize our products in the United States internally or through a contracted sales force and selected commercial arrangements, and thereby retain the commercial value of these products. We have established a small, contract specialty sales force focusing on group purchasing organizations, or GPOs, hospital systems and key stakeholders in acute care settings, primarily hospitals. Outside of the United States, we may utilize partners for the commercialization of our products.

Continue to build a robust intellectual property portfolio. Our patent estate includes over 30 owned or exclusively-licensed U.S. issued patents and over 10 filed U.S. patent applications, as well as several that have been filed in various worldwide territories, that protect or will protect, as applicable the market value of our approved and pipeline products. We intend to continue to build our patent portfolio by filing for patent protection on new developments with respect to our product candidates that will not infringe patents that cover the branded reference drugs. We expect that these will, if issued, allow us to list our own patents in the Orange Book, to which potential competitors will be required to certify upon submission of their applications referencing our products, if approved.

Our Products and Product Portfolio

Belrapzo, Bendeka (Licensed to Teva) and Treakisym (Licensed to SymBio) for Chronic Lymphocytic Leukemia and Non-Hodgkin's Lymphoma

Overview

Bendamustine is an alkylating agent approved for use in chronic lymphocytic leukemia, or CLL, and indolent B-cell non-hodgkin’s lymphoma, or NHL, that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen (which we refer to herein as the NHL indication).

U.S. Marketed Bendamustine Products

Teva currently markets its lyophilized bendamustine product under the trade name Treanda®. Teva ceased distribution of Treanda® liquid on March 30, 2016.

Limitations of Marketed Bendamustine Products

Treanda® is a lyophilized powder that requires reconstitution in water prior to use. A 500 mL intravenous (IV) administration is used over 30 or 60 minutes for CLL and NHL patients, respectively. The product is sold in single use vials creating an opportunity for product waste in certain applications.

Eagle's Solution: Belrapzo and Bendeka

The Belrapzo and Bendeka liquid formulations eliminate the need to reconstitute the drug prior to use, relative to the lyophilized presentation of Treanda®. As a result, we believe that relative to the lyophilized presentation of Treanda® there is less potential for dosing errors, less exposure to cytotoxic powders and a more efficient work flow.

Additionally, admixtures prepared with Bendeka contain lower sodium as compared with Treanda® which could be of benefit to the predominantly elderly, renally impaired and cardiovascular compromised patients. Also, Bendeka is available in a multi-use vial, which allows infusion centers and hospitals to avoid needless waste of unused drug remaining after procedures with single use vials.

Belrapzo

On May 15, 2018, the FDA granted final approval for Belrapzo, a ready-to-dilute, or RTD, multi-dose liquid with extended drug stability for use with a 500mL IV infusion bag.

License agreement with Cephalon

Bendeka is the same RTD, multi-dose liquid formulation as Belrapzo, with extended drug stability, but for use with a 50 mL IV infusion bag, which enables it to be administered in a shorter time-period than current drugs on the market and represents a label expansion from Belrapzo. We received orphan drug designation for Bendeka for CLL and NHL in July 2014. We entered into the Cephalon License to market this product. *See License Agreements - Cephalon License Agreement, below.*

License agreement with SymBio

On September 20, 2017, we entered into a product collaboration and license agreement, effective as of September 19, 2017 (the "SymBio License Agreement"), with SymBio Pharmaceuticals Limited, or SymBio, for the rights to develop and commercialize our bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product in Japan. SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma, or MCL, and as a first line treatment of low-grade NHL and MCL. Under the SymBio License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Ryanodex® for Malignant Hyperthermia

Overview

Dantrolene was first introduced to the U.S. market in 1979 and is currently the only drug approved to treat a rare genetic disorder called malignant hyperthermia, or MH. There are only estimated to be 500 to 800 cases of MH in the United States each year, qualifying dantrolene for orphan drug designation. This disease is triggered when a patient with this genetic predisposition has a surgical procedure and is exposed to certain inhaled anesthetics or the muscle relaxant, succinylcholine. When this exposure occurs, a metabolic response can be triggered in the patient resulting in an episode of MH that can be fatal if not treated immediately. Because dantrolene is the only approved drug available to treat MH, the Joint Commission on Accreditation of Healthcare Organizations, or the Joint Commission, requires that all hospitals stock vials of this product at all times, generally in the operating room area.

Currently-Preexisitng Dantrolene Products for MH

The two preexisting injectable dantrolene drugs on the market for the treatment of MH, Dantrium® and Revonto®, are offered in a vial containing 20mg of lyophilized powder that requires mixing with 60mL of sterile water.

Limitations of Dantrium® and Revonto®

When an MH crisis occurs during surgery, the surgical procedure is immediately discontinued and the anesthesiologist and others in the operating room quickly begin reconstituting dantrolene, often at the same time as performing other resuscitative efforts, in order to administer the drug to the patient as an IV push. Based on recommendations from the Malignant Hyperthermia Association of the United States, or MHAUS, the recognized authority on treating MH in the United States, the recommended dose is 2.5mg/kg or higher. It is critically important that the drug be administered as rapidly as possible, as MH symptoms include tachycardia, elevated blood pressure, raised CO_2 levels and very high body temperature levels. If not treated immediately, the disease can be fatal.

Because of the dosing required in adult patients to reverse the MH symptoms and the current formulations of Dantrium® and Revonto®, it is often necessary to reconstitute 10 to 20 vials of dantrolene. As the current formulations are also poorly water soluble, this process generally takes up to 15 to 20 minutes at a point when time is critical and the patient is extremely unstable. Furthermore, the volume of diluent required to reconstitute Dantrium® and Revonto® means that the adult patient receives a significant volume of fluid (600mL to 1,200mL) as an IV infusion, which on occasion can result in detrimental secondary physiological consequences for the patient, such as pulmonary edema and extravasation, which can lead to tissue necrosis.

Eagle's Solution: Ryanodex®

We have developed a differentiated formulation of dantrolene sodium that was approved by the FDA in July 2014 and is currently sold under the brand name, Ryanodex®, for the treatment of MH. The presentation is a 5ml vial containing 250mg of dantrolene sodium in lyophilized powder form.

We believe that the immediate benefits of our Ryanodex® formulation are clinically significant in critical care situations. Specifically, Ryanodex® reduces the amount of time to reconstitute and administer dantrolene from 15 to 20 minutes with Dantrium® and Revonto®, to 1 minute, as the anesthesiologist are able to mix and administer a dose of 250mg from a single vial of Ryanodex® in contrast to mixing and administering up to 12 or more vials of Dantrium® or Revonto®. A recent retrospective study conducted by MHAUS demonstrated that every 15-minute delay in treating MH resulted in a 7.8% increase in patient complications.

EP-4104 Ryanodex®* (dantrolene sodium) for the treatment of organophosphate exposure *(Nerve Agents)

Organophosphates are a class of chemicals that include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophospates may result in severe consequences, including brain damage and death. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent, or NA, exposure. If approved, Ryanodex would represent the first product available for this indication.

Limitations of Current Therapies

While the standard treatment of atropine and oxime is essential after exposure to a nerve agent, these drugs are not neuroprotective. There are currently no FDA-approved products that treat acute intoxication with organophospates that may result in severe consequences, including brain damage and death.

Eagle's Solution: Ryanodex

Ryanodex's presentation would initially be an injectable suspension. We believe that Ryanodex may provide significant benefits over the current standard of care, which may not be readily available in most settings.

EP-4104 Clinical Development and Regulatory Status

In May 2019, we announced positive results of our study to evaluate the neuroprotective effects of Ryanodex secondary to NA exposure, conducted with the United States Army Medical Research Institute of Chemical Defense, the nation's leading science and technology laboratory in the area of medical chemical countermeasures research and development. The study results showed a p-value of 0.04 or less compared to the control group in six critical areas of the brain. We believe these results demonstrate the neuroprotective effects of Ryanodex. It has been hypothesized that nerve agent poisoning triggers intracellular calcium release in the body. The study data supports the proposed mechanism of action of Ryanodex, which modulates intracellular calcium in different organs including the brain.

On December 16, 2019, we announced that the FDA granted orphan drug designation, or ODD, for Ryanodex® (dantrolene sodium) for the treatment of organophosphate exposure. On August 8, 2020, we submitted a Special Protocol Assessment, or SPA, to the FDA for Ryanodex for the treatment of brain damage secondary to nerve agent exposure. We are initiating dose ranging studies in another animal model using IV administration using an intermuscular formulation of EA-111. We expect the preliminary results from these studies, if positive, will allow us to update our SPA with the FDA. If approved, Ryanodex would represent the first product available for this indication..

PEMFEXY™ for Lung Cancer

PEMFEXY is an IV-administered cancer agent indicated for locally advanced or metastatic non-small cell lung cancer and mesothelioma. We have developed PEMFEXY as a ready-to-use/dilute liquid form of pemetrexed that is available in a 25mg/mL per vial. Because our product is available in liquid form, product reconstitution is not required, making EP-5101 a preferred formulation under the Joint Commission guidelines.

Currently-Marketed Pemetrexed Product

The branded form of a pemetrexed product is marketed by Eli Lilly and Company, or Lilly, as Alimta. Alimta is approved for use to treat non-small cell lung cancer and mesothelioma. Alimta's lyophilized formulation utilizes pemetrexed disodium. The product presentations for Alimta are 100mg and 500mg single use vials containing lyophilized powder that must be reconstituted before patient administration. Once mixed, Alimta must be used within 24 hours due to product stability concerns. According to Lilly, worldwide sales of Alimta for the 2020 calendar year were approximately $2.3 billion.

Limitations of Alimta

Alimta, a lyophilized pemetrexed disodium formulation requiring reconstitution, adds time to administration, presents cytotoxic safety issues for healthcare professionals administering the drug and the potential for dosing errors. Because reconstitution of Alimta is generally not performed until the patient has cleared all tests necessary to receive the drug, this process contributes to a significant amount of time spent by such patients in infusion clinics. Additionally, this method of administration limits the number of patients that may be treated on any given day by such clinics. Furthermore, as with any oncology drug, cytotoxic vapors released through reconstitution can be potentially harmful to pharmacists, physicians and nurses. Moreover, dosing errors may occur during reconstitution, as incorrect amounts of diluent may be used. As a result, lyophilized formulations are less preferred by the Joint Commission as compared to an RTD product.

Eagle's Solution: PEMFEXY™

PEMFEXY is an RTD liquid formulation of pemetrexed. As an RTD liquid formulation, PEMFEXY will not require additional time for reconstitution and may avoid certain safety concerns to healthcare professionals, including reducing exposure to the drug's cytotoxic vapors during reconstitution by healthcare providers, and potential dosing errors during mixing. This could allow for a more efficient work flow within the infusion clinic and may result in an opportunity to reduce office staff and see more patients each day.

PEMFEXY™ Development and Regulatory Status

We submitted an NDA for PEMFEXY on December 30, 2016 for use in non-small cell lung cancer and mesothelioma. On October 27, 2017, we were granted tentative approval for PEMFEXY by the FDA. On December 13, 2019, we reached a settlement agreement with Lilly related to Pemfexy. The agreement provided for a release of all claims by the parties and allowed for an initial entry of Pemfexy into the market on February 1, 2022 and a subsequent uncapped entry on April 1, 2022. On February 10, 2020, we received final approval from the FDA for Pemfexy. Following such approval, on February 1, 2022 we announced the commercial availability of Pemfexy in the United States.

EA-114 (fulvestrant) for Breast Cancer

Fulvestrant is an injectable estrogen receptor antagonist. It is used for the treatment of hormone receptor positive advanced breast cancer for post-menopausal women whose disease has progressed following treatment with prior endocrine therapy.

Currently-Marketed Fulvestrant Products

The branded form of fulvestrant is Faslodex, a 500mg injectable product marketed by AstraZeneca plc. Worldwide sales of Faslodex were $1 billion in 2018, which included U.S. sales of $537 million.

Limitations of Faslodex

Faslodex is administered in two deep intramuscular injections of high viscosity product per dose of treatment (5 ml each) over 1-2 minutes into each buttock. The procedure is painful and Faslodex injection reactions have been associated with peripheral nerve adverse reactions, including risk of damaging the sciatic nerve.

Eagle's Solution: EA-114

On August 5, 2019, we announced a clinical development plan to support the submission of a NDA for our fulvestrant formulation. Our original formulation of fulvestrant was studied in a clinical trial conducted in 2018 in healthy post-menopausal women. A detailed review of the study data led to the hypothesis that the unique properties of our formulation would potentially allow for greater inhibition of estrogen receptors. Based on this hypothesis, we completed additional work designed to further

enhance our proprietary drug formulation. We met with the FDA and mutually agreed to a clinical program that could provide an efficient approval pathway for our fulvestrant formulation. The main goal of the clinical research program was to determine if the unique properties of our fulvestrant formulation would result in greater inhibition of estrogen receptors, potentially leading to improved efficacy outcomes, including lower disease progression rates, compared to current treatment options.

On December 9, 2019, we announced that we had commenced dosing in a pilot clinical study to assess the unique characteristics of our fulvestrant product candidate, which has the potential to enhance estrogen receptorER, inhibition and improve patient outcomes.

Based on discussions with the FDA, we reformulated and plan to commence human pilot studies of our fulvestrant product candidate for the treatment of HR+/HER- advanced breast cancer shortly.

Other Opportunities

We are pursuing several additional potential products and product indications that address broad indications such as oncology, emergency medicine, infectious diseases and others. We intend to use our novel and well-developed methods to identify ideal development candidates and to commercialize improved formulations of widely prescribed therapeutics.

Sales and Marketing

Other than products subject to existing commercialization arrangements, we commercialize our product portfolio in the United States and Japan with our commercial organization. Ryanodex and Belrapzo are marketed by our internal commercial team consisting of 44 direct sales representatives, support staff and management.

Major Customer

We are dependent on our commercial partner, Teva, to market and sell Bendeka. As a result, our future revenues are highly dependent on our collaboration and distribution arrangement with Teva.

Teva markets Bendeka through the Cephalon License. Pursuant to that license agreement, Teva pays us a royalty based on net sales of the product and also purchases the product from us. A disruption in this arrangement caused by, among other things, a supply disruption, loss of exclusivity or the launch of a superior product would have a material adverse effect on our financial position, results of operations and cash flows.

The total revenues and accounts receivables broken down by major customers as a percentage of the total are as follows:

	Year Ended December 31,		
	2021	**2020**	**2019**
Net revenues			
Cephalon, Inc. (Teva) - See Revenue Recognition	66 %	67 %	77 %
Other	34 %	33 %	23 %
	100 %	100 %	100 %

Manufacturing

We do not own any manufacturing facilities. The manufacture of sterile injectables is highly reliant on very complex sterile techniques and personnel aseptic techniques which present significant challenges and requires specialized expertise. Further, sterile processes have a high level of scrutiny by regulatory agencies. Consequently, we utilize a network of third party manufacturers for production of our products. All manufacturers are monitored and evaluated by our quality department to assess compliance with regulatory requirements and our internal quality standards and benchmarks.

Intellectual Property and Exclusivity

We strive to protect and enhance the proprietary technologies that we believe are important to our business. We seek to obtain and maintain patents for any patentable aspects of our products or product candidates, their methods of use and any other inventions that are important to our business model and maintaining a competitive advantage over generic competitors. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially

important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the fields targeted by our products and product candidates.

Patents and Patent Applications

We are the exclusive licensee under our license with Lyotropic to a family of patents and applications that relate to low volume formulations of dantrolene, and methods of treatment using dantrolene. There are eight issued U.S. patents, and several pending U.S. patent applications, along with foreign counterparts that include both issued patents and pending applications. The issued U.S. patents cover low volume formulations of dantrolene in reconstitutable and in ready to use liquid form. We expect that the issued patents will expire no later than July 1, 2025.

We are the sole owner of over 10 issued patents, several pending U.S. patent applications, and multiple patents and/or corresponding foreign filings for patent applications in a number of jurisdictions covering various formulations and methods of use of bendamustine. We are currently prosecuting these applications, which, if issued, would expire between 2031 and 2033.

We are the owner of U.S. Patent No. 8,431,539 expiring July 20, 2031 and covering daptomycin.

We also have a patent portfolio of issued and/or pending U.S. patent applications and corresponding foreign patent application in a range of countries that cover our biologics platform technologies. We are the sole owner of U.S. Patent Nos. 9,833,513, 9,913,905 and 9,925,263 expiring between 2034 and 2036.

Trade Secrets and Proprietary Information

Trade secrets play an important role in protecting our products and provide protection beyond patents and regulatory exclusivity. The scale-up and commercial manufacture of our products involves processes, custom equipment, and in-process and release analytical techniques that we believe are unique to us. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures, individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors or any future collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring third parties with whom we contract for services related to our products, including manufacturing services to agree to terms in our agreements with such third parties that protect our confidential and trade secret information. We also require our employees, consultants and other advisors to execute proprietary information and confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

License Agreements

License Agreement with Lyotropic Therapeutics, Inc.

In October 2008, we entered into a license and sublicense agreement with Lyotropic Therapeutics, Inc., or Lyotropic, under which we were granted an exclusive license under Lyotropic's intellectual property rights relating to dantrolene, and an exclusive worldwide sublicense under certain nanocrystal technology relating to a formulation of dantrolene licensed by Alkermes, Inc. (as successor in interest to Elan Pharma International Limited), or Alkermes, to Lyotropic under an August 2004 license agreement between Alkermes and Lyotropic.

Development and License Agreement with Robert One, LLC (bendamustine)

In March 2008 we entered into a development and license agreement with Robert One, LLC, or Robert One in which Robert One assigned to us certain patents relating to bendamustine and four additional 505(b)(2) products and/or ANDA products under development, or the Robert One (bendamustine) Subject Products, and granted us an exclusive, sub-licensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One (bendamustine) Subject Products worldwide (excluding China) with respect to bendamustine and other 505(b)(2) product applications and in North America with respect to ANDA product applications.

Under the terms of this agreement, no further milestone payments are due to Robert One. We are required to make royalty payments based on gross profits of sales of the Robert One (bendamustine) Subject Products by us and our affiliates in the Territory (i) at 10%, pursuant to an amendment in 2013, for bendamustine products and (ii) at 50% for products, other than bendamustine products, that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), and (iii) at 30% with respect to products, other than bendamustine products, that are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each Robert One (bendamustine) Subject Product and the expiration of the last valid claim covering such Robert One (bendamustine) Subject Product, subject to certain reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such Robert One (bendamustine) Subject Product in a country in the territory.

Development and License Agreement with Robert One, LLC (pemetrexed)

In February 2009 we entered into a development and license agreement with Robert One, in which Robert One assigned to us certain patents relating to pemetrexed and four additional 505(b)(2) products and/or ANDA products under development ("the Robert One 2009 Subject Products") and granted us an exclusive, sub-licensable, license under Robert One's intellectual property rights to develop make, use, sell and import Robert One 2009 Subject Products worldwide (excluding China) with respect to pemetrexed and other 505(b)(2) product applications and in North America with respect to ANDA product applications.

Under the terms of this Agreement no further milestone payments are due to Robert One. We are required to make royalty payments based on gross profits of sales of the Robert One 2009 Subject Product by us and our affiliates in the Territory (i) at 25% for pemetrexed parental formulation (ii) at 50% for Robert One 2009 Subject Products other than pemetrexed that achieve regulatory approval and are commercialized on the basis of a 505(b)(2) application (provided that we are entitled to recoup all of our expenses related to the development of a product commercialized under a 505(b)(2) application prior to splitting the profits we receive from such product), and (iii) at 30% with respect to Robert One 2009 Subject Products other than pemetrexed that are commercialized on the basis of an ANDA application. Our royalty obligations continue on a product-by-product basis until the later of ten years after the first commercial sale of each Robert One 2009 Subject Product and the expiration of the last valid claim covering such Robert One 2009 Subject Product, subject to certain reductions in the event that there is no valid patent claim covering the manufacture, use, import or sale of such Robert One 2009 Subject Product in a country in the territory.

Cephalon License Agreement

On February 13, 2015, we submitted an NDA to the FDA for Bendeka which was approved by the FDA on December 8, 2015. Also, on February 13, 2015, we entered into the Cephalon License with Cephalon, for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Subsequently, with our consent, Cephalon assigned to Teva Pharmaceuticals International GmbH, or TPIG, all of Cephalon’s rights and obligations under the Cephalon License. TPIG is responsible for preforming Cephalon’s obligations and has Cephalon’s rights under the agreement.. Pursuant to the terms of the Cephalon License, TPIG is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. Additionally, under the terms of the Cephalon License, we received an upfront cash payment of $30 million, a $15 million milestone payment in January 2016 in connection with the FDA approval of Bendeka in December 2015, a $40 million milestone in the fourth quarter of 2016 in connection with the receipt of the J-Code for Bendeka and in the first quarter of 2017, Bendeka reached $500 million in cumulative net sales, triggering an additional $25 million sales-based milestone payment. In addition, the royalty payments of 20% of net sales of the product that we were entitled to receive increased to 25% on receipt of

the J-Code. In connection with the Cephalon License, we have entered into a supply agreement with TPIG, pursuant to which we are responsible for supplying product to TPIG.

On April 13, 2019, we and Teva entered into an amendment to the Cephalon License, amending the terms of the License Agreement to increase the U.S. royalty paid to us and re-allocate certain litigation expenses. Pursuant to the Amendment, beginning on October 1, 2019,our royalty payment increased from 25% to 30% of Bendeka net United States sales. The royalty rate increased by one percentage point on October 1, 2020, and will continue to increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The Amendment also extends the U.S. royalty term for Bendeka until it is no longer sold in the United States. The previous royalty term was set to expire in 2025. The extended term coincides with the bendamustine patents with expiries through 2033. Pursuant to the amendment, we will continue to be responsible for the manufacture of Bendeka for the U.S. market for so long as it is sold in the United States. Pursuant to the amendment, we have also agreed to assume a portion of Bendeka-related patent litigation expenses.

In March 2019, we received an upfront cash payment of $9.0 million upon execution of an amendment to the Cephalon License to terminate Teva’s obligation to pay future milestones and royalties on Bendeka sales outside of the U.S.

Cephalon Settlement

On February 13, 2015, we entered into the Cephalon Settlement Agreement with Cephalon, in connection with the Cephalon License, pursuant to which the parties agreed to settle the pending patent infringement claims against each other regarding Cephalon's US Patent No. 8,791,270, under which we agreed to enter into a Consent Judgment regarding the ‘270 patent. As part of the Cephalon Settlement Agreement, Cephalon has agreed to waive its orphan drug exclusivities for the treatment of patients with CLL and patients with NHL.

SymBio Product Collaboration and License Agreement

On September 20, 2017, we entered into the SymBio License with SymBio for the rights to develop and commercialize EP-3101 and Bendeka, or collectively, the Products, in Japan. Under the SymBio License, SymBio is responsible for all development of the Products in Japan and for obtaining and maintaining all regulatory approvals of the Products in Japan. SymBio bears all costs of development of the Products in Japan except that, if Japanese regulatory authorities require a certain clinical study to be conducted as a condition for approving one of the Products in Japan, we would share 50% of the out-of-pocket costs of that clinical study up to a specified dollar amount as a reduction to future royalty payments. Based on our assessment of the probability of additional costs, we have not deferred revenue on the SymBio License. SymBio will also be responsible, at its sole cost, for all marketing, promotion, distribution and sales of the Products in Japan and is obligated to launch the Products and meet certain minimum detailing, promotion and marketing commitments in connection with commercialization of the Products in Japan.

SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma, or MCL, and as a first line treatment of low-grade NHL and MCL. Under the SymBio License, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Pursuant to the terms of the SymBio License, we and SymBio will enter into a separate supply agreement, under which we will be responsible for manufacturing and supplying the Products to SymBio for development and commercialization in Japan. After a period of time following launch of a Product, SymBio will have the right to assume the responsibility for manufacturing of the Products in and for Japan. Under the SymBio License, we will retain the right to control the prosecution, maintenance and enforcement of our patents covering the Products, both inside and outside of Japan.

Under the SymBio License, we earned an upfront non-refundable cash payment of $12.5 million in the third quarter of 2017 and a $5.0 million milestone payment in the third quarter of 2020 when SymBio, received regulatory approval for TREAKISYM from the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan. We are eligible to receive a milestone payment upon achievement of certain cumulative net sales of the Products in Japan. We will also receive tiered, low double-digit royalties on net sales of the Products in Japan for so long as there are patents covering the Products in Japan or regulatory exclusivity for the Products in Japan. Potential payments to us could reach $10 to $25 million per year in royalties and milestones.

On September 23, 2020, we announced that SymBio had received approval for Treakisym RTD liquid formulation in Japan. The approval covered all indications for which TREAKISYM is currently approved (low-grade non-Hodgkin's lymphoma, mantle cell lymphoma, and chronic lymphocytic leukemia). Approval for the additional indication of relapsed-refractory diffuse large B cell lymphoma currently under review by the PMDA, which could create another large market opportunity beyond the current indications.

Combioxin License Agreement

In August 2021, we entered into a license agreement with Combioxin, SA, or Combioxin, under which we were granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 clinical trial development for the treatment of severe pneumonia in combination with traditional antibacterial drugs. We are solely responsible for the development, regulatory, manufacturing and commercialization activities of CAL02. Combioxin will assist us in transitioning the manufacturing and supply of CAL02 to the Company.

Under the terms of the agreement, we made an upfront payment of $10 million. We may pay to Combioxin up to $105 million upon achievement of certain development, regulatory and sales based milestone payments plus royalty payments at royalty rates ranging in low double digit percentages on the net sales of all products sold, subject to certain adjustments as provided in the agreement. The Company is also obligated to make certain payments based upon amounts received by sublicensees under the agreement.

License agreement with AOP Orphan License Agreement

In August 2021, we entered into a licensing agreement with AOP Orphan, a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, Landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We will support the submission of a NDA by AOP Orphan to the FDA seeking approval for Landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.

Under the terms of the agreement, we made an upfront payment of $5 million. We may pay to AOP Orphan additional amounts upon achievement of certain regulatory milestone payments plus profit share payments, subject to certain adjustments as provided in the agreement. We also entered into a supply agreement at the same time as the licensing agreement.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than products that we are currently selling through partners or developing or that we may develop, which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payors. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product portfolio in our target commercial markets.

Government Regulation

FDA Approval Process for Drugs

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act, or FDCA, and in the case of biologics, the Public Health Service Act, or PHSA, and other federal and state statutes and regulations, govern, among other things, 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 FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of product from the market, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new unapproved drug biologic or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice, or cGLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, 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, or cGCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA or BLA.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including cGLPs. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

Phase 1: In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

Phase 2: Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

Phase 3: Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an application is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most applications is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved application is also subject to annual product and establishment user fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under PDUFA the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the application contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A tentative approval is issued to a 505(b)(2) NDA if the sponsor must await the expiration of an Orange Book listed patent covering the reference product. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA or BLA approval, the FDA may require a Risk Evaluation and Mitigation Strategies ("REMS") program to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS program is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS program may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate

healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS program can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing supplements as it does in reviewing original applications.

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, including standards and regulations for direct to consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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 with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls 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 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 outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

In addition, the distribution of prescription pharmaceuticals is subject to the Drug Supply Chain Security Act requirements for medicine identification, tracing and verification, among others, that are designed to detect and remove counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. A growing majority of states also impose certain drug pedigree requirements on the sale and distribution of prescription drugs.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. 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 a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Act established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or

NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacological action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws and Compliance Requirements

In the United States, the research, manufacturing, distribution, marketing, sale and promotion of drug products and medical devices are subject to numerous regulations by various federal, state and local authorities in addition to the FDA including, but not limited to, the U.S. Federal Communications Commission, the U.S. Department of Justice, the U.S. Department of Health and Human Services, or HHS, and its various enforcement divisions, such as the Centers for Medicare & Medicaid Services, or CMS, the Office of Inspector General, or OIG, the Office for Human Research Protections, or OHRP, and the Office of Research Integrity, or ORI, state Attorneys General, state Medicaid Fraud Control Units, or MFCUs, and other state and local government agencies. Healthcare laws and regulations that may govern our business include the following.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, including a prescription drug manufacturer, or a party acting on its behalf, from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce in return for either the referral of an individual, or the purchase, recommendation, leasing, ordering or furnishing of a good, facility, item, or service, for which payment may be made in whole or in part under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted broadly to apply to, among other things, arrangements between pharmaceutical manufacturers, on one hand, and prescribers, purchasers, and formulary managers, on the other. The term "remuneration" expressly includes kickbacks, bribes or rebates and also has been broadly interpreted to include anything of value, including for example, gifts, discounts, 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. There are a number of statutory exceptions and regulatory safe harbors, which are narrowly drawn, protecting certain business arrangements from prosecution. Failure to meet all of the requirements of a particular applicable statutory exception or safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability in all cases. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, among other things, amended the intent standard under the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The ACA also provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below). Further, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state laws may be broader in scope in that some of these state laws extend to all payors and may not contain safe harbors.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval by the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The "*qui tam*" provisions of the federal civil False Claims Act allow a private individual to bring a civil action on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and potentially to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the federal civil False Claims Act. Many of these state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the federal government. There are many potential bases for liability under the federal civil False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, and improper promotion of off-label uses not expressly approved by the FDA in a drug's label. Our future activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several additional federal civil and criminal statutes that prohibit healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute 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. Like the federal Anti-Kickback Statute, the ACA amended certain of these federal criminal statutes such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to

have committed a violation.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA and its implementing regulations established uniform standards for certain "covered entities," which are certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity, as well as their covered subcontractors, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included the Health Information Technology for Economic and Clinical Health Act, or HITECH, which expanded certain of HIPAA's privacy and security standards. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, federal transparency laws, including the federal Physician Payments Sunshine Act created under Section 6002 of the ACA and its implementing regulations require that certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors), generally, with some exceptions, other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations must also report annually to the CMS certain ownership and investment interests held by physicians (as defined above) and their immediate family members.

There are also an increasing number of analogous state laws that require manufacturers to file reports with states on pricing and marketing information, such as tracking and reporting of gifts, compensations, other remuneration and items of value provided to health care professionals and health care entities. Many of these laws contain ambiguities as to what is required to comply with the laws. Several states have also enacted legislation requiring pharmaceutical companies to, among other things, establish and implement commercial compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. Certain state laws also regulate manufacturers' use of identifiable data. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including significant administrative, criminal and civil monetary penalties, damages, fines, imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government healthcare programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We are unable to predict whether we would be subject to actions under these laws or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance.

To the extent that any of our products are sold in a foreign country, we also may be subject to similar foreign laws and regulations, which may include, for instance, the U.S. Foreign Corrupt Practices Act, the U.K. Anti-Bribery Act, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Third-Party Payor Coverage and Reimbursement

The commercial success of our approved product portfolio, as well as our pre-clinical and clinical product portfolio, if and when approved, will depend, in part, upon the availability of coverage and adequate reimbursement from third-party payors at the federal, state and private levels. Patients who are prescribed treatments for their conditions and providers performing the

prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Sales of our product portfolio will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our product portfolio will be paid by health maintenance, managed care, pharmacy benefit, and/or similar healthcare management organizations, or are reimbursed by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other third-party payors. The market for our product portfolio will depend significantly on access to third-party payors' formularies, or lists of treatments for which third-party payors provide coverage and reimbursement.

Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Further, coverage and reimbursement for therapeutic products can differ significantly from payor to payor. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payor scrutiny. We expect that the pharmaceutical industry will experience continued pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative and administrative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as healthcare legislative and administrative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. 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 product portfolio and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Reform

In the United States and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that will likely affect our future operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs, improve access, and improve quality.

By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry included, among others, 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 statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extension products;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 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, unless the drug is subject to discounts under the 340B drug discount program;
- 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;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- new requirements under the federal Physician Payments Sunshine Act for manufacturers to report information related to payments and other transfers of value made to physicians, as defined by such law, and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members; and,
- a new requirement to annually report certain drug samples that manufacturers and distributors provide to licensed practitioners, or to pharmacies of hospitals or other healthcare entities.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling,, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact ACA.

Other healthcare legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, following passage of subsequent legislation, will remain in effect through 2031, except for a temporary suspension from

We expect that additional state and federal healthcare reform measures will be adopted in the future. For example, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration’s proposals. The FDA also released a final rule and related guidance in September 2020 implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new

safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any additional healthcare reform measures could further constrain our business and/or limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product portfolio or additional pricing pressures. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 government agencies 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.

Data Privacy and Security Laws

In the ordinary course of our business, we may process personal or sensitive data. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, or CCPA, the European Union's General Data Protection Regulation 2016/679, or EU GDPR, the EU GDPR as it forms part of United Kingdom, or UK, law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR, and the ePrivacy Directive. In addition, several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collection, use, and disclosure of personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for certain data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020, CPRA, effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches that are subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. U.S. federal and state consumer protection laws require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate

purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

Human Capital Management

As of December 31, 2021, we had a total of 102 employees. None of our employees are represented by a labor union or subject to a collective bargaining agreement. We have not experienced any work stoppage and consider our relations with our employees to be good.

We have built an internal commercial team consisting of 36 direct sales representatives, support staff and management who are a part of our independent commercial organization.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and future employees, advisors and consultants. In addition to competitive base salaries, the other competitive benefits that we provide to employees include equity and cash incentive plans, retirement benefits, and paid vacation. The principal purposes of these employee benefits are to attract, retain, reward and motivate our personnel and to provide long-term incentives that align the interests of employees with the interests of our stockholders.

Corporate Information

We were incorporated in Delaware in January 2007. Our principal executive offices are located at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677, and our telephone number is (201) 326-5300.

Available Information

Our corporate website address is www.eagleus.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only. We make 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 available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or SEC. You can access our filings through the SEC's internet site: www.sec.gov.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Investors should consider carefully the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K, as well as our other public filings with the Securities and Exchange Commission. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall. In addition to the risk factors identified under the captions below, the operation and results of our business are subject to risks and uncertainties identified elsewhere in this Annual Report on Form 10-K as well as general risks and uncertainties such as those relating to general economic conditions and demand in the market for our products.

Risks Related to Our Financial Condition and Need for Additional Capital

An investment in our securities involves a high degree of risk. Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities.

The COVID-19 pandemic has adversely impacted, and may continue to adversely impact, our business, including the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities.

The ongoing COVID-19 pandemic has adversely impacted, and may continue to adversely impact, our business. In mid-March 2020, we implemented work-from-home policies which are still in place for the majority of our employees. Our work-from-home policies may negatively impact productivity or disrupt our business, the magnitude of which will continue to depend, in part, on the length of this continued remote working arrangement and other limitations on our ability to conduct our business in the ordinary course. During the second quarter of 2021, we developed and implemented plans to resume in-person work practices while adhering to relevant health authority guidance. The effects of government actions and our policies and those of third parties to reduce the spread and ameliorate the impact of COVID-19 may negatively impact productivity and our ability to market and sell our products, cause disruptions to our supply chain and ongoing and future clinical trials and impair our ability to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

The marketing, sale and commercialization of our products have been adversely impacted and may continue to be adversely impacted by COVID-19 and actions taken to slow its spread and ameliorate its impact. We saw a variable impact on our product revenues in 2020 due to the COVID-19 pandemic and also experienced variable impacts on our business and financial condition as a result of the pandemic. We are expecting the impact on our near-term financial results to continue for the duration of the pandemic. Other parts of our business have been, and continue to be, impacted by the outbreak. For example, patients have postponed and we expect will continue to postpone visits to healthcare provider facilities, certain healthcare providers have temporarily closed their offices or are restricting patient visits, healthcare provider employees may become generally unavailable and there could be disruptions in the operations of payors, distributors, logistics providers and other third parties that are necessary for our products to be prescribed, reimbursed and administered to patients. For example, we have continued to observe a reduction in the number of Bendeka patients visiting infusion centers, hospitals and clinics for intravenous administration of Bendeka due to interruptions in healthcare services, and the patients' inability to visit administration sites and desire to avoid contact with infected individuals. In addition, our sales and marketing teams have been working remotely and our virtual initiatives with respect to marketing and supporting the sale and administration of our products have not been as effective as our in-person sales and marketing activities. We cannot predict when we will be able to resume in-person sales and marketing activities.

Quarantines, shelter-in-place, safer-at-home and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could be re-implemented or could continue to occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products. In particular, some of our suppliers of certain materials used in the production of our drug products are located in regions that continue to be subject to COVID-19-related actions and policies that limit the conduct of normal business operations. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting commercial demand for our products in the United States or advancing development of our product candidates may become impaired. At this time, we consider our inventories on hand to be sufficient to meet our commercial requirements.

In addition, our clinical trials have been affected by COVID-19. Clinical site initiation and patient enrollment has been delayed due to prioritization of hospital resources toward COVID-19. Current or potential patients in our ongoing or planned clinical trials have chosen to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting COVID-19. Further, some patients may not be able to comply with clinical trial protocols if quarantines continue to impede patient movement or interrupt healthcare services. Some clinical sites in the United States have slowed or stopped further enrollment of new patients in clinical trials, denied access to site monitors or otherwise curtailed certain operations. For example, the clinical trial timelines for certain of our product candidates, including EA-114 (our fulvestrant product candidate), have been delayed given difficulties with patient enrollment resulting from the COVID-19 pandemic, and we expect that clinical trial timelines will continue to be delayed for the duration of the pandemic. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been and may continue to be adversely impacted. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

The spread of COVID-19 and actions taken to reduce its spread and ameliorate its impact may also materially affect us economically. As a result of the COVID-19 pandemic and actions taken to slow its spread and ameliorate its impact, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any additional debt or equity financing more difficult, more costly or more dilutive. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could continue to be a significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity and financial position or our business development activities.

The COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 continues to impact the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our access to capital and our business development activities, depends on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions, any re-opening plans, additional closures and spikes or surges in COVID-19 infection, and the impact on the economy and capital markets.

If we cannot achieve or sustain profitability, our business, prospects, operating results and financial condition would be materially harmed.

We have focused primarily on developing a broad product portfolio and currently have final regulatory approval for a limited number of products. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. We had net loss of $8.6 million for the year ended December 31, 2021, and net income of $12.0 million for the year ended December 31, 2020, $14.3 million for the year ended December 31, 2019, and $31.9 million for the year ended December 31, 2018, respectively, and we incurred significant net losses prior to 2015.

We have devoted most of our financial resources to product development and may not generate significant revenue from sales of our product candidates in the near-term, if ever.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. As a result of the foregoing, we may incur losses and negative cash flows in the future.

If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, both internally and through our external joint development agreements. Changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our product commercialization or development efforts could encounter technical or other difficulties that could increase our development costs more than we expect. In any event, we may require additional capital prior to obtaining regulatory approval for, or commercializing, any additional product candidates.

In addition, attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize additional product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our products and product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or products, or to product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

The occurrence of any of these factors could have a material adverse effect on our business, operating results and prospects.

We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or incur debt, which could adversely impact our stockholders, as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness results in increased fixed payment obligations. In addition, the incurrence of indebtedness also results in certain restrictive covenants, 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. On November 8, 2019, we entered into the Second Amended and Restated Credit Agreement, or the Revised Credit Agreement, with JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, which replaced our prior credit agreement. The terms and amounts borrowed under the Revised Credit Agreement includes a drawn term loan of $40 million and an undrawn revolving credit facility of $110 million. The schedule of principal payments for the new term loan facility has been extended until November 8, 2022.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required (causing a default under such indebtedness), which could have a material adverse effect on our business, financial condition and results of operations.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales and use or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws and regulations could be interpreted, modified or applied adversely to us. These events could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest and other costs for past amounts deemed to be due. New laws, or laws that are changed, modified or newly interpreted or applied, also could increase our compliance, operating and other costs, as well as the costs of our products. For example, the Tax Act enacted many significant changes to the U.S. tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, and may be modified in the future by the current or a future presidential administration. In addition, it is uncertain if and to what extent various states will conform to current federal law, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net operating losses, and other deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets and could increase our future tax expense.

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

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as

research tax credits, to offset its post-change income or taxes may be limited. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to Regulatory Approval

We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized.

Our business and future success are substantially dependent on our or our collaborators' ability to successfully and timely develop, obtain regulatory approval for, and commercialize our product candidates. Any delay or setback in the development of any of these product candidates could adversely affect our business. For example, on August 7, 2020, we received a CRL for our NDA for Ryanodex for the treatment of EHS. We decided that we will no longer pursue this indication in order to direct our resources to other product candidates. In addition, on January 26, 2022, Tyme announced the discontinuation of SM-88 with methoxsalen, phenytoin, and sirolimus in a trial for metastatic pancreatic cancer. Our planned development, approval and commercialization of any product candidates may fail to be completed in a timely manner or at all. The FDA or other foreign regulatory agency may refuse or delay approval of our product candidates for failure to collect sufficient clinical or animal safety data and require us or our collaborators to conduct additional clinical or animal safety studies, which may cause lengthy delays and increased costs to our programs. We cannot provide assurance that we will be able to obtain approval for any of our product candidates from the FDA or any foreign regulatory authority or that we will obtain such approval in a timely manner. If we do not obtain regulatory approval of new products or additional indications for existing products, or are significantly delayed or limited in doing so, our revenue growth will be adversely affected, we may experience surplus inventory, or our business may be materially harmed and we may need to significantly curtail operations.

If we are unable to differentiate our products or product candidates from branded reference drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, the ability to successfully commercialize our product candidates would be adversely affected.

Our strategy is to enter the market no later than the first generic to the applicable branded reference drug. We expect to compete against branded reference drugs and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our products and product candidates will be clinically differentiated from branded reference drugs and their generic counterparts, if any, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products or product candidates against other drugs, the opportunity for our products and product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

In addition to existing branded reference drugs and the related generic products, the FDA or other applicable regulatory authorities may approve generic products that compete directly with our products or product candidates, if approved. Once an NDA, including a 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 FDCA, 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 for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as our products or product candidates and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our products or product candidates. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, 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 is typically lost to the generic product. Accordingly, competition from generic equivalents of our products or product candidates would materially adversely impact our ability to successfully commercialize our product candidates or negatively impact our ability to gain market acceptance and market share for our products.

If the FDA does not conclude that our product candidates satisfy the requirements for the regulatory approval, or if the requirements for approval of any of our product candidates are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for those small molecule product candidates described in this Annual Report on Form 10-K.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us to pursue the regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue such regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue our chosen regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical testing, even when utilizing the 505(b)(2) pathway or its equivalent, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- delays in obtaining required institutional review board, or IRB, approval at each site;

- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- delays related to the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although our products or product candidates containing active ingredients that have already been approved and the side effects arising from the use of the active ingredient or class of drug in our products or product candidates are generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have obtained regulatory approval for five NDA products, but no BLA products, and we have multiple NDA product candidates in advanced stages of development and other exploratory candidates under development. However, it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs or existing biologic drugs meet the criteria for our chosen regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. There can be no assurance that the FDA will ultimately approve any submitted NDA by us in a timely fashion. For example, in March of 2016 we received a CRL from the FDA with respect to our NDA for EP-6101, and we elected not to pursue the application further or seek to exploit EP-6101 for various reasons. On August 7, 2020, we received a CRL for our NDA for Ryanodex for the treatment of EHS, and we decided that we will no longer pursue this indication in order to direct our resources to other product candidates.

The failure to receive regulatory approvals for our product candidates could have a material adverse effect on our business, financial condition and operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

Some of our product candidates will be submitted to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include certifications, known as paragraph IV certifications, that certify that any patents listed in the Patent and Exclusivity Information Addendum of the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. For example, we have been, and may in the future be, subject to litigation brought in connection with our filing of a 505(b)(2) NDA. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time-consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time-consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Companies that produce branded reference drugs routinely bring litigation against abbreviated new drug application, or ANDA, or 505(b)(2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505(b)(2) applicant. For example, we were involved in a patent case with Par related to our ANDA for vasopressin. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products.

Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505(b)(2), products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505(b)(2), products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. However, we may share truthful and not misleading information that is

otherwise consistent with our products' FDA approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the application. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

Manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the drug application. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal health care programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending application or supplements to an application submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) the laws of the FDA and similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (2) health care laws and regulations, including fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (3) laws requiring the reporting of financial information or data accurately. Specifically, the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Any relationships with health care professionals, principal investigators, consultants, customers (actual and potential) and third party payors, in addition to our general business operations, are and will continue to be subject, directly or indirectly, to federal and state health care fraud and abuse laws, marketing expenditure tracking and disclosure, or sunshine laws, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as current, proposed and future sales, marketing and education programs. In addition, we may be subject to patient data privacy and security regulation by the federal government, state governments and foreign jurisdictions in which we conduct our business, as well as transparency requirements. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit and impose penalties for, among other things, individuals or entities knowingly presenting, or causing to be presented, claims for payment or approval from the federal government including Medicare, Medicaid or certain other governmental health care programs that are false or fraudulent or knowingly making or causing to be made a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain health care providers, health plans and health care clearinghouses, known as covered entities, or business associates, as well as their respective business associates, independent contractors or agents of covered entities that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, created under Section 6002 of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services' Centers for Medicare & Medicare Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants an nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs and potentially limit our ability to offer certain marketplace discounts;
- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third party payors, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities), and drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

In addition, any sales of our products or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties,

damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in-license such product candidates, such as the license agreements we entered into with Combioxin for CAL02 and with AOP Orphan for Landiolol. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and delivery methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Commercialization of Our Products and Product Candidates

Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among physicians, nurses, pharmacists, patients and the medical community.

Even if we obtain regulatory approval for our product candidates, our products and product candidates may not gain market acceptance among physicians, nurses, pharmacists, patients, the medical community or third party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the convenience and ease of administration to patients of the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement by third party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and
- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

Guidelines and recommendations published by government agencies can reduce the use of our products and product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and health care providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

If we are unable to successfully conduct our sales and marketing capabilities or if our commercial partners do not adequately perform, the commercial opportunity for our products may be diminished.

We have a commercial organization to promote certain of our approved products in the United States. The cost of maintaining such an organization may exceed the benefits, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. In addition, we may not be successful in commercializing our products despite such commercial organization.

We and any other commercialization partner we engage in the future may not be able to attract, hire, train and retain qualified sales and sales management personnel. If we or our future partners, if any, are not successful in maintaining an effective number of qualified sales personnel, our ability to effectively market and promote our products may be impaired.

The efforts of our partners in many instances would likely be outside our control. If any future partner is unsuccessful in their efforts, or we are unable to maintain such commercial partnerships or to effectively establish alternative arrangements for our products, our business could be adversely affected.

A substantial portion of our total revenues is derived from sales of a limited number of products.

We derive a substantial portion of our revenue from royalties derived from the sales of one product: Bendeka. This product is sold by our partner Teva Pharmaceuticals. During the year ended December 31, 2021, Bendeka accounted for approximately 66% of our total revenue. The sale of our products can be significantly influenced by the efforts of our partners, which are out of our control, as well as market conditions and regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions or entry into the market for competing products, or as a result of regulatory actions related to our products or competing products, which could have a material impact on our results of operations and financial condition.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may enter into agreements with third parties to market our products outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires or public health issues or pandemics including the coronavirus.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of our competitors both in the United States and internationally, include major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. For example, Ryanodex, and products with dantrolene sodium as the API, is currently marketed in the United States by, among others, Endo International plc, Impax Laboratories, Inc., Hikma Pharmaceuticals, LLC, US WorldMeds, LLC, Mylan Institutional, LLC, and Elite Laboratories, Inc. While our formulations of this product is distinct, and we believe improvements, compared to those competitors mentioned, competition from these products on factors such as price and availability effect our commercial efforts. Additionally, we must compete with alternative drug treatments (as opposed to alternative formulations) for many of the indications that our products are approved to treat.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our products or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any application we submit.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our products and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our products or product candidates, or that reach the market sooner than our product candidates, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical.

We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or

products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates or negatively impact our ability to gain market acceptance and market share for our products. We are currently involved in various ongoing litigation matters, as discussed elsewhere in this Annual Report on Form 10-K.

Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered.

Successful sales of our products and any other approved product candidates depend on the availability of adequate coverage and reimbursement from third party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Reimbursement by a third party payor may depend upon a number of factors, including but not limited to, the third party payor’s determination that use of a product is: a covered benefit under its health plan; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; and/or neither cosmetic, experimental, nor investigational.

Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products and our product candidates will depend significantly on access to third party payors' drug formularies, or lists of medications for which third party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Third party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that could require us to provide scientific, clinical and cost effectiveness support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our commercial products, and our pre-clinical and clinical product candidates for which we may receive regulatory approval, may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain for our products.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products and our product candidates profitably, once they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the ACA was passed, which significantly changed health care financing by both governmental and private insurers. There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the Trump administration signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact ACA and our business. We cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2015 as well as certain legislative amendments, will remain in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further 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.

Additionally,there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and proposed and adopted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration’s proposals. The FDA also released a final rule and guidance in September

2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. . As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain, but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is 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. We and our CROs are required to comply with FDA regulations and other laws regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols,

regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If any of our current strategic collaborators fail to perform their obligations or terminate their agreements with us, the development and commercialization of the product candidates under such agreements could be delayed or terminated and our business could be substantially harmed.

In 2015, we entered into the Cephalon License, with Cephalon (Teva) for U.S. and Canadian rights to Bendeka for treatment of patients with CLL and patients with NHL. Pursuant to the terms of the Cephalon License, as has been amended from time to time, Teva is responsible for all U.S. commercial activities for the product including promotion and distribution, and we are responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies.

This strategic collaboration may not be scientifically or commercially successful due to a number of important factors, including the following:

- If we fail to maintain any regulatory approvals, or otherwise materially breach the agreement, we may not receive all anticipated royalty payments;
- Cephalon has significant discretion in determining the efforts and resources that it will apply to their strategic collaboration with us. The timing and amount of any cash payments, and royalties that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and the commercialization of our product by Cephalon under the Cephalon License;
- Cephalon currently markets a competitive bendamustine product, Treanda®, in the United States. In addition, it is possible that Cephalon may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us;
- Cephalon may change the focus of their commercialization efforts or pursue higher-priority programs;
- Cephalon may terminate its strategic collaboration with us on short notice, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;
- Cephalon has the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if they do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions; and
- Cephalon may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements;
- If Cephalon fails to effectively commercialize our product, we may not be able to replace them with another collaborator, and,
- If our agreement with Cephalon terminates, we are required to pay them a portion of our future profits on the product.

Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

We have entered in licensing and/or collaboration agreements with third parties, including our license agreement with AOP Orphan for Landiolol and our strategic collaboration with Tyme to advance oral SM-88 for the treatment of patients with cancer. If we are able to establish additional collaboration arrangements, any such collaborations, in addition to our current license and collaboration agreements, may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third party for development and commercialization

of a product or product candidate, we can expect to relinquish some or all of the control over the future success of that product or product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We may be subject to a number of additional risks associated with our collaborations with third parties, the occurrence of which could cause collaboration arrangements to fail. Conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;

- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and

- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

We rely on third parties to manufacture commercial supplies of our products and clinical supplies of our product candidates, and we intend to rely on third parties to manufacture commercial supplies of any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We do not own any manufacturing facilities, and we do not currently, and do not expect in the future, to independently conduct any aspects of our product manufacturing and testing, or other activities related to the clinical development and commercialization of our product candidates. We currently rely, and expect to continue to rely, on third parties with respect to these items, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product candidate development and product commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Quality problems in manufacturing are linked to a majority of shortages of sterile injectable drugs. Some of the largest manufacturers of sterile injectable drugs have had serious quality problems leading to the temporary voluntary closure or renovations of major production facilities. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with

our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities to manufacture our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates.

More generally, manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize our products or product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

The design, development, manufacture, supply, and distribution of our products and product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our products and product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products or product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our products, as well as our other product candidates, is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our contract manufacturers, must supply all necessary documentation in support of our regulatory filings for our products and product candidates on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to

implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biological product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

We rely on limited sources of supply for our products and product candidates, and any disruption in the chain of supply may impact production and sales of our products and cause delay in developing and commercializing our product candidates.

We currently have relationships with only one third party for the manufacture of each of our most advanced products and product candidates. Because of the unique equipment and process for manufacturing our products transferring manufacturing activities to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of these single-source manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the manufacture and supply of product candidates to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply.

Additionally, if the COVID-19 pandemic continues to persist for an extended period of time and impacts essential distribution systems, we could continue to experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products, which would adversely impact our ability to deliver products to clinical trial sites or to generate sales of and revenues from our approved products.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

We may not be successful in establishing development and commercialization collaborations which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. We may, however, be unable to advance the development of our products and product candidates in territories outside of the United States, which may limit the market potential for this product candidate.

In situations where we enter into a development and commercial collaboration arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. We have entered into collaboration and promotion agreements with third parties, but there is no assurance these arrangements will be successful. If we are unable to enter into any future development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

If we are unable to maintain our GPO, relationships, our revenues could decline and future profitability could be jeopardized.

Most of the end-users of injectable pharmaceutical products have relationships with GPOs whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract

with the GPO of their choice for their purchasing needs. We currently derive, and expect to continue to derive, a large percentage of our revenue from end-user customers that are members of a small number of GPOs. Maintaining strong relationships with these GPOs will require us to continue to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with companies that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to maintain our GPO relationships, sales of our products and revenue could decline.

We rely on a limited number of pharmaceutical wholesalers to distribute our products.

As is typical in the pharmaceutical industry, we rely upon pharmaceutical wholesalers in connection with the distribution of our products. A significant amount of our products are sold to end-users under GPO pricing arrangements through a limited number of pharmaceutical wholesalers. If we are unable to maintain our business relationships with these pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our sales and may prevent us from achieving profitability.

Our approved products may not achieve expected levels of market acceptance.

Even if we are able to obtain regulatory approvals for our product candidates, the success of those products is dependent upon market acceptance. Levels of market acceptance for our product candidates could be affected by several factors, including:

- the availability of alternative products from our competitors;
- the price of our products relative to those of our competitors;
- the timing of our market entry;
- the ability to market our products effectively at the retail level;
- the perception of patients and the healthcare community, including third-party payors, regarding the safety efficacy and benefits of our drug products compared to those of competing products; and
- the acceptance of our products by government and private formularies.

Some of these factors are not within our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which may call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, which include our Chief Executive Officer and President, Chief Financial Officer, Chief Medical Officer, and Chief Commercial Officer. We are currently searching for a new Chief Medical Officer, which position is currently vacant. The loss of these executives' services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2021, we had a total of 102 employees in the United States. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities.

We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among

remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to sell our products and commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials (if any), and the sale of our products and any product candidates for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products, other approved future products and our product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our products and our product candidates, if approved for commercial sale.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (commonly known as processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) and a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to the processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries, such as the United States, that do not provide an adequate level of personal data protection, and certain countries outside Europe (e.g., China) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business.

If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions in our business operations; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, and other similar threats.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our business operations. The COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively

impact our ability to grow and operate our business. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our sales of any products we may sell.

Our headquarters are located in Woodcliff Lake, New Jersey. If we encounter any disruptions to our operations at this building or if it were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

We may be constrained by our obligations under our Revised Credit Agreement to operate our business to its full potential.

Our Revised Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Under the terms of the Revised Credit Agreement, we are required to comply with (a) a maximum senior secured net leverage ratio, (b) a maximum total net leverage ratio and (c) a minimum fixed charge coverage ratio. These terms may restrict our ability to operate our business in the manner we deem most effective or desirable, and may restrict our ability to fund our operations through new public offerings of our common stock or strengthen our candidate development pipeline through acquisitions or licenses which cause us to exceed our maximum senior secured net leverage ratio.

Failure to comply with the representations and warranties or affirmative and negative covenants could constitute an event of default which, if continued beyond the cure period, would allow the administrative agent, at the request of or with the consent of the lenders holding a majority of the loans and commitments under the facility, to terminate the commitments of the lenders to make further loans and declare all the obligations of the loan parties under the Revised Credit Agreement to be immediately due and payable, either of which could harm our business.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any adverse outcome in these types of matters could result in one or more generic versions of our products being launched before the expiration of the listed patents, which could adversely affect our ability to successfully execute our business strategy to increase sales of our products and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to our products or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize our product candidates. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market our product candidates under patent protection could be reduced. If third parties have filed such patent

applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to our products and our product candidates. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third-parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in

unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products and/or our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, method of use, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. Additionally, one of our existing license agreements is a sublicense from a third party who is not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with their obligations under the

primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, which may impact our ability to continue to develop and commercialize our product candidates and companion diagnostic incorporating the relevant intellectual property. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our important technology licenses were to be terminated by the licensor, we would likely cease further development of the related program or be required to spend significant time and resources to modify the program to not use the rights under the terminated license.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

The patents and the patent applications that we have covering our products are limited to specific formulations, methods of use and processes, and our market opportunity for our products and our product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and delivery methods that may be developed by competitors.

Patent protection on the active ingredients in our currently marketed products (Ryanodex, Bendeka, Argatroban and Non-Alcohol Docetaxel Injection) has expired, and there is therefore no composition of matter patent protection available for the active ingredient in such products. This is also the case with respect to our other product candidates. We have obtained, and continue to seek to obtain patent protection of other aspects of our products and our product candidates, including specific formulations, methods of use and processes, which may not be as effective as composition of matter coverage in preventing workarounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations, methods of use and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval could be able to commercialize products with the same active ingredients as our product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as our products and our product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our products and our product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products and our product candidates that are different from ours and do not infringe our issued patents covering our products.

Ryanodex® (dantrolene sodium), Belrapzo, Bendeka, Pemfexy and vasopressin among other products have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering

our products. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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.

Ryanodex, Belrapzo, Bendeka, Pemfexy and vasopressin, among other of our products, have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. One or more third parties may also challenge the patents that we control covering our products in court or the USPTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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 non-compliance 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 or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our products and product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial condition and results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products or product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business, financial condition and results of operations.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

Our stock price may continue to fluctuate significantly.

The trading price of our common stock has fluctuated significantly in the past and is likely to continue to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully execute our commercialization strategy with respect to our approved products or any other approved product in the future;
- adverse results or delays in clinical trials, if any;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in the structure of healthcare payment systems;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to the use of our products or any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- entry into new markets by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;
- changes in the collective short interest in our common stock;
- additional repurchases of our common stock, if any, pursuant to our current share repurchase program.
- impacts of the COVID-19 pandemic, and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. For example, in May 2016, we became party to a federal securities class action lawsuit, and although it was dismissed in October 2017, we incurred substantial costs defending such lawsuit. Such lawsuit, as well as similar lawsuits instituted in the future, could result in substantial additional costs to us and could also divert the time and attention of our management.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2021, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own a significant percentage of our voting stock. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to influence all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to influence elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of February 28, 2022 we had 12,697,101 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements.

In addition, shares issued upon exercise of vested options are eligible for sale. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock..

Future issuances of our common stock or rights to purchase our common stock, including in connection with potential business development transactions we may determine to pursue and/or pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

We expect that significant additional capital will be needed in the future to continue our planned operations and/or in connection with potential business development transactions we may determine to pursue. To the extent we raise additional capital or pursue potential business development transactions by issuing equity securities, our stockholders may experience substantial dilution. We currently have on file with the SEC a shelf registration statement, which allows us to offer and sell certain registered securities, such as common stock, preferred stock, debt securities and warrants, from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. We may sell common stock, convertible securities or other equity or debt securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity or debt securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2014 Equity Incentive Plan, or the 2014 Plan, our management is authorized to grant stock options and other equity awards to our employees, directors and consultants. We have issued a significant number of stock options and other equity awards under the 2014 Plan. The shares underlying these awards are registered on a Form S-8 registration statement. As a result, upon vesting these shares can be freely exercised and sold in the public market upon issuance, subject to volume limitations applicable to affiliates. The exercise of options and the subsequent sale of the underlying common stock could cause a decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In addition, the number of shares available for future grant under the 2014 Plan will automatically increase each year by 6% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2014 Plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions (such as our Revised Credit Agreement), general business conditions, and any other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation of their stock.

There is no assurance that our Share Repurchase Program will result in repurchases of our common stock or enhance long term stockholder value.

Repurchases of our common stock pursuant to our Share Repurchase Program could affect our stock price and increase its volatility and will reduce the market liquidity for our stock. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program. Additionally, any future repurchases would diminish our cash reserves, which could impact our ability to pursue possible future strategic opportunities and acquisitions. There can be no assurance that any stock repurchases will, in fact, occur, or, if they occur, that they will enhance stockholder value.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or any action asserting a claim governed by the internal affairs doctrine. This forum selection provision does not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act or any claim for which the federal courts have exclusive jurisdiction.

This forum selection provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this forum selection provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

We are at risk of securities class action and similar litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. On May 31, 2016, a federal securities class action suit was brought against us seeking compensatory damages in connection with, among other things, the CRL we received with respect to our NDA for EP-6101. Such lawsuit was dismissed with prejudice in August 2017, however, any similar litigation in the future, could result in substantial cost and a diversion of management's attention and resources, which could harm our business.

We have incurred significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant ongoing legal, accounting and other expenses.

For example, we are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation in filing of these reports. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various other requirements on public companies and we have incurred and will continue to incur costs associated with compliance with such requirements. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel need to devote a substantial

amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2021, we had approximately 30,000 square feet of leased office space. Our corporate headquarters is located in Woodcliff Lake, New Jersey and consists of approximately 27,093 square feet of office space under a lease that will expire in June 2025.

We also lease 2,505 square feet of office space in Palm Beach Gardens, Florida under a lease that will expire in October 2024.

We also lease laboratory space located in Cambridge, Massachusetts under a lease that will expire in April 2024.

We consider our current facilities suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

The disclosures under Note 13. Legal Proceedings in the Consolidated Financial Statements included in Part IV, Item 15 of this report are incorporated into this Part I, Item 3 by reference.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock has been listed on The Nasdaq Global Market under the symbol "EGRX" since February 12, 2014. Prior to that date, there was no public trading market for our common stock.

Record Holders

As of February 28, 2022, we had 2 holders of record of our common stock. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities. The closing price per share of our common stock on February 28, 2022 was $47.39.

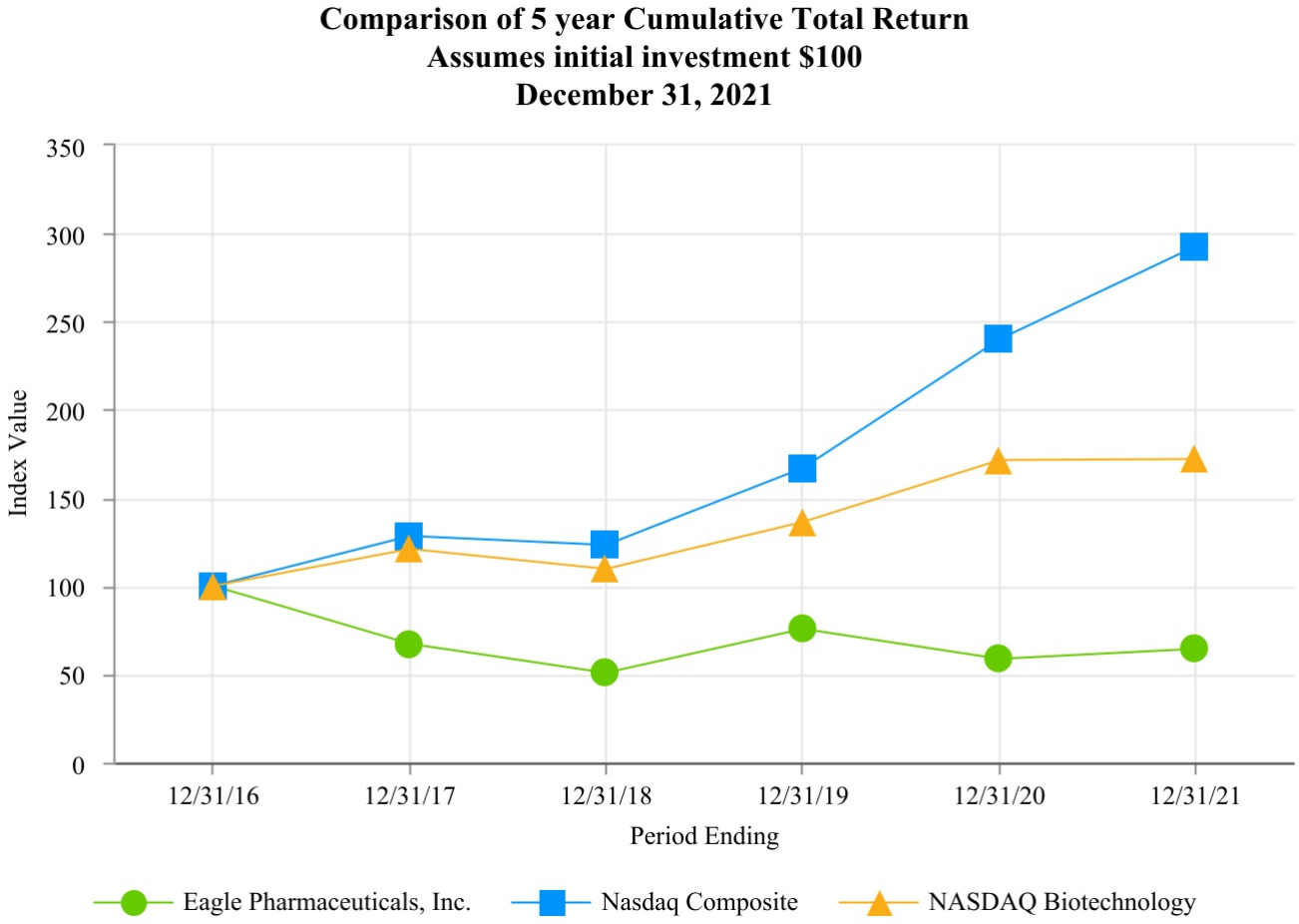
Dividends

We have never declared or paid a cash dividend on our common stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. In addition, our Revised Credit Agreement imposes contractual restrictions on us with respect to paying cash dividends. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and any other factors that our board of directors may deem relevant.

Stock Performance Graph

The following information shall not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing of Eagle Pharmaceuticals, Inc. under the Exchange Act or the Securities Act of 1933, as amended, or the Securities Act, except to the extent we specifically incorporate it by reference into such filing.

The following graph shows a five year comparison from December 31, 2016 through December 31, 2021 of the cumulative total return for our common stock, and the Nasdaq Composite Index and The Nasdaq Biotechnology Index. The graph assumes that $100 was invested at the market close on December 31, 2016 in the common stock of Eagle Pharmaceuticals, Inc, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The stock price performance of the following graph is not necessarily indicative of future stock price performance.



Company / Index	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20	12/31/21
Eagle Pharmaceuticals, Inc	$ 100	$ 67	$ 51	$ 76	$ 59	$ 64
Nasdaq Composite	$ 100	$ 128	$ 123	$ 167	$ 240	$ 293
NASDAQ Biotechnology	$ 100	$ 121	$ 110	$ 136	$ 171	$ 172

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

Share Repurchase Program

On March 17, 2020, we announced that our Board approved a share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of $160.0 million of our outstanding common stock. The Share Repurchase Program replaced our previous share repurchase program, which was announced on October 30, 2018 and was terminated in connection with the Share Repurchase Program. At termination, we had repurchased approximately $68.0 million of our outstanding common stock under our previous share repurchase program.

Under the Share Repurchase Program, we are authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws,

including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Securities Exchange Act of 1934, as amended. The repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using our cash resources.

On September 23, 2020, our board of directors approved a $25.0 million accelerated share repurchase transaction, or ASR Program, with JPMorgan Chase Bank, National Association, or JP Morgan, as part of the Share Repurchase Program. The specific number of shares to be repurchased pursuant to the ASR Program was based on the average of the daily volume weighted average share prices of our common stock, less a discount, during the term of the ASR Program. Under the terms of the ASR Program with JP Morgan, we paid $25.0 million to JP Morgan on September 24, 2020, and received 550,623 shares, representing the notional amount of the ASR, based on the average of the daily volume weighted average share prices of our common stock, less a discount, during the term of the ASR, which was $45.40. The ASR Program was completed in the fourth quarter of 2020.

The following table provides information about purchases of our equity securities during the three months ended December 31, 2021:

Period	Total Number of Shares Purchased (1)(2)(3)(4)(5)	Average Price Paid per Share	Total Number of Shares Purchased as Part Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs
				(dollars in thousands)
October 1, 2021 to October 31, 2021	31,185	$ 55.96	31,185	110,687
November 1, 2021 to November 30, 2021	—	$ —	—	110,687
December 1, 2021 to December 31, 2021	138,896	$ 49.67	138,896	103,788
Total	170,081	$ 50.83	170,081	

(1) All shares repurchased by us during the three months ended December 31, 2021 were repurchased pursuant to the Share Repurchase Program, described above.

Securities Authorized for Issuance Under Equity Compensation Plans
Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this annual report on Form 10-K.

Item 6. Reserved

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

The following discussion and analysis of financial condition and results of operations is provided to enhance the understanding of, and should be read in conjunction with, Part I, Item 1, "Business" and Item 8, "Financial Statements and Supplementary Data." For information on risks and uncertainties related to our business that may make past performance not indicative of future results, or cause actual results to differ materially from any forward-looking statements, see "Special Note Regarding Forward-Looking Statements," and Part I, Item 1A, "Risk Factors."

Overview

We are an integrated pharmaceutical company focused on finding ways to help medicines do more for patients. Along with our collaborators, we have the capabilities to take a molecule from preclinical research through regulatory approval and into the marketplace, including development, manufacturing and commercialization of our products and product candidates. Our business model applies our scientific expertise, proprietary research-based insights and marketplace proficiency to identify challenging-to-treat diseases of the central nervous system or metabolic critical care therapeutic areas as well as in oncology. By focusing on patients' unmet needs, we strive to provide healthcare professionals with urgently needed treatment solutions that are designed to improve patient care and outcomes and create near- and long-term value for our stakeholders, including patients and healthcare providers and our employees, marketing partners, collaborators and stockholders.

Our science-based business model has a proven track record with the U.S. Food and Drug Administration, or FDA, approval and commercial launches of three products: Ryanodex, Belrapzo and Bendeka. We market our products through marketing partners and/or our internal direct sales force. We market Ryanodex and Belrapzo, and Teva markets Bendeka through its subsidiary, Cephalon, Inc. RIn February 2020, we received final FDA approval for PEMFEXY™ (pemetrexed for injection) , a branded alternative to Alimta for metastatic non-squamous non-small cell lung cancer and malignant pleural mesothelioma. On February 1, 2022, we announced the commercial availability of PEMFEXY™ in the United States.

With several pipeline projects underway and the potential for product launches over the next few years, we believe we have many growth opportunities ahead. We believe that each of our pipeline projects currently has the potential to enter the market as a first-in-class, first-to-file or best-in-class product. In particular, we are applying our expertise to conduct novel research regarding the potential for Ryanodex to address conditions including nerve agent, acute radiation syndrome, traumatic brain injury/concussion and Alzheimer's disease as well as investigations of compounds such as EA-114 (our fulvestrant product candidate) for patients with HR-positive advanced breast cancer. Our clinical development program also includes a license agreement with Combioxin, SA under which the Company was granted exclusive, worldwide development commercialization rights to CAL02, a novel first-in-class antitoxin agent for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs and a license agreement with AOP Orphan, for the commercial rights to its product, landiolol in the United States. Landiolol is a leading hospital emergency use product, which is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias.

Recent Developments

PEMFEXY

On February 1, 2022, we announced the commercial availability of our novel product PEMFEXY™ (pemetrexed for injection). A branded alternative to ALIMTA®, Eagle's PEMFEXY is a ready-to-use liquid with a unique J-code approved to treat nonsquamous non-small cell lung cancer and mesothelioma.

In February 2020, Eagle received final approval from the U.S. Food and Drug Administration of its New Drug Application for PEMFEXY, following the settlement agreement of patent litigation with Eli Lilly and Company (NYSE: LLY) in December 2019. The agreement provided for a release of all claims by the parties and allows for an initial entry of PEMFEXY into the market (equivalent to approximately a three-week supply of current ALIMTA utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022.

Landiolol

On January 31, 2022, we announced that AOP Orphan Pharmaceuticals GmbH, Member of the AOP Health Group, ("AOP Health"), with whom we entered into a licensing agreement in August 2021, has engaged with the U.S. Food and Drug Administration ("FDA") to obtain alignment on the content and format of the pre-clinical and clinical data required to support a new drug application ("NDA") seeking approval of Landiolol, a novel therapeutic, for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.

In August 2021, Eagle entered into a licensing agreement with AOP Health, a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to Landiolol in the United States.

Vasopressin

On January 18, 2022, we announced the commercial availability of our recently approved product, vasopressin, an A-rated generic alternative to Vasostrict®, with 180 days of marketing exclusivity.

On December 15, 2021, the FDA approved Eagle's abbreviated new drug application ("ANDA") for vasopressin, a product that is indicated for use to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

TREAKISYM

As of January 5, 2022, Eagle's bendamustine franchise continues to grow, including the launch of the TREAKISYM ready-todilute ("RTD") formulation in Japan in the first quarter of 2021. Together with a potential approval of the rapid infusion ("RI") (50ml) liquid formulation.

Fulvestrant

As of January 5, 2022, based on discussions with the FDA, we reformulated and plan to commence human pilot studies of our fulvestrant product candidate for the treatment of HR+/HER- advanced breast cancer shortly.

CAL02

As of January 5, 2022, we were preparing to begin clinical trials for CAL02, a novel approach to the treatment of severe bacterial pneumonia, later in 2022.

Executive Officer Transitions

On September 27, 2021, our board of directors appointed Scott Tarriff as our President and Michael Moran as our Executive Vice President, Chief Commercial Officer. In addition, David Pernock, our former President and Chief Operating Officer since January 2017, was appointed as Executive Vice President, Operations.

On December 27, 2021, Judith Ng-Cashin, M.D., ceased to serve as our Executive Vice President, Chief Medical Officer. We are currently in search for a replacement.

On December 31, 2021, David Pernock, ceased to serve as our Executive Vice President, Operations.

COVID-19 Business Update

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on its business, such as remote working policies, facilitating management’s daily communication to address employee and business concerns and providing frequent updates to the Board. We anticipate that the COVID-19 pandemic may have an impact on the clinical development timeline for EA-114. We anticipate that the COVID-19 pandemic will continue to delay our supply chain and marketing and sales efforts for certain of its products, including Bendeka, although it is not currently expected that any disruption would be material. The COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically lead to a continuing reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. In addition, the COVID-19 pandemic has delayed the timing of ongoing litigation, including the litigation with Par Pharmaceutical, Inc. and its affiliated entities with respect to Vasopressin, and we anticipate that such delays will continue for the duration of the pandemic. While we have experienced variable financial impacts to date, the ongoing COVID-19 pandemic, including the global economic slowdown, government measures taken in response thereto, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic, could materially adversely affect our business, financial condition, results of operations and growth prospects. We continue to closely monitor the COVID-19 pandemic as we evaluate and evolve our business plans and response strategy. The impact of the COVID-19 pandemic on our business and financial condition is more fully described below in *Trends and Uncertainties*.

Financial Operations Overview

Revenue

Our revenue consists of product sales, royalty revenue and license and other revenue.

Product Sales. As of December 31, 2021, we have recognized revenues from product sales of Bendeka, Treakisym, Ryanodex and Belrapzo. Sales of Bendeka and Treakisym were made to our commercial partners, Teva and SymBio, respectively. Sales to our commercial partners are typically made at little or no profit for resale. Ryanodex and Belrapzo were sold directly to wholesalers, hospitals and surgery centers through a third-party logistics partner.

We typically enter into agreements with group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals’ purchases of our direct commercial products. Based on these agreements, most of our hospital

customers have contracted prices for products and volume-based rebates on product purchases. These amounts are estimated and recorded at the time of sale. In the case of discounted pricing, we typically pay a chargeback, representing the difference between the price invoiced to the wholesaler and the customer contract price.

Royalty Revenue. We recognize revenue from royalties based on a percentage of Teva's net sales of Bendeka and SymBio's net sales of Treakisym. Royalty revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

License and Other Revenue. Our revenues may either be in the form of the recognition of deferred revenues upon milestone achievement for which cash has already been received or recognition of revenue upon milestone achievement for which the payment is reasonably assured to be received in the future.

The primary factors that determine our revenues derived from Bendeka are:

- the level of orders submitted by our commercial partner, Teva;
- the rate at which Teva can convert the current market to Bendeka;
- the level of institutional demand for Bendeka;
- unit sales prices charged by Teva, net of any sales reserves; and
- the level of orders submitted by wholesalers, hospitals and surgery centers.

The primary factors that may determine our revenues derived from TREAKISYM are:

- the level of orders submitted by our commercial partner, Symbioi;
- the level of institutional demand for TREAKISYM; and
- unit sales prices charged by Symbio, net of any sales reserves.

The primary factors that may determine our revenues derived from Ryanodex, Belrapzo and our future products are:

- the effectiveness of our sales force;
- the level of orders submitted by wholesalers, hospitals and surgery centers;
- the level of institutional demand for our products; and
- unit sales prices, net of any sales reserves.

Cost of Revenues

Cost of revenue consists of the costs associated with producing our products for our commercial partners. In particular, our cost of revenue includes production costs of our products paid to a contract manufacturing organization coupled with shipping and customs charges, cost of royalty and the amortization of intangible assets. Cost of revenue may also include the effects of product recalls, if applicable.

Research and Development

Costs for research and development are charged to expenses as incurred and include: employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel; expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies; costs associated with preclinical activities and development activities; costs associated with regulatory operations; and depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate. Recoveries of previously recognized research and development expenses from third parties are recorded as a reduction to research and development expense in the period it becomes realizable.

Selling, General and Administrative

Selling, general and administrative costs consist of employee-related costs including salaries, benefits and other related costs, stock-based compensation for executive, finance, sales and operations personnel. Selling, general and administrative expenses also include facility and related costs, professional fees for legal, consulting, tax and accounting services, insurance, selling, marketing, market research, advisory board and key opinion leaders, depreciation and general corporate expenses.

Income Taxes

We account for income taxes using the liability method in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 740, "Income Taxes," or ASC 740. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income (loss) in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that it has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense. The benefit (provision) for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the years ended December 31, 2021, 2020 and 2019 reflect items such as the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Tyme, certain non-deductible executive compensation, changes in state filing positions partially offset by credits for research and development activity.

Results of Operations

Comparison of Years Ended December 31, 2021 and December 31, 2020

Revenues

	Year Ended December 31,		
	2021	2020	(Decrease)
	(in thousands)		
Product sales, net	$ 65,023	$ 72,323	$ (7,300)
Royalty revenue	106,523	110,479	(3,956)
License and other revenue	—	5,000	(5,000)
Total revenue	$ 171,546	$ 187,802	$ (16,256)

Product sales decreased $7.3 million in the year ended December 31, 2021, primarily driven by decreases in product sales of Bendeka of $4.3 million, Belrapzo of $3.8 million, due to price decreases and Ryanodex of $3.0 million, due to volume decreases. In addition, the COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically have led to a reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. These decreases were partially offset by $3.9 million in product sales of Treakisym, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021.

Royalty revenue decreased $4.0 million in the year ended December 31, 2021 primarily as a result of lower royalties on Teva's sales of Bendeka of $7.7 million, which were partially offset by new royalties on Symbio's sales of Treakisym of $4.2 million.

License and other revenue reflects a $5.0 million milestone payment that we earned during 2020 when SymBio received regulatory approval for Treakisym RTD bendamustine formulation from the Pharmaceuticals and Medical Devices Agency in Japan.

Cost of Revenue

	Year Ended December 31,		
	2021	2020	(Decrease)
	(in thousands)		
Cost of product sales	$ 31,528	$ 33,647	$ (2,119)
Cost of royalty revenue	10,652	11,818	(1,166)
Total cost of revenue	$ 42,180	$ 45,465	$ (3,285)

Cost of product sales decreased $2.1 million in the year ended December 31, 2021, primarily as a result of decreased product sales of Bendeka, Ryanodex, and Belrapzo, each related to lower unit sales, partially offset by increased product sales of

Treakisym resulting from product unit sales, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021.

Cost of royalty revenue decreased $1.2 million in the year ended December 31, 2021 primarily as a result of a decrease in royalty revenue on Teva's sales of Bendeka, coupled with lower cost of royalty associated with Belrapzo and the ending of royalties related to Argatroban.

Research and Development

The table below details our research and development expenses by significant project for the periods presented.

	Year Ended December 31,		Increase / (Decrease)
	2021	2020	
	(in thousands)		
Fulvestrant	$ 7,016	$ 6,802	$ 214
Vasopressin	6,976	4,727	2,249
Ryanodex related projects	1,692	2,865	(1,173)
CAL02 / Combioxin	10,334	—	10,334
Landilol / AOP	5,005	—	5,005
Pemfexy	2,211	608	1,603
All other projects	3,014	3,085	(71)
Salary and other personnel related	15,027	12,698	2,329
Research and development	$ 51,275	$ 30,785	$ 20,490

The increase primarily resulted from a $10.0 million upfront payment related to our license agreement with Combioxin, a $5.0 million upfront payment related our licensing agreement with AOP Orphan, a $2.3 million increase in development cost for vasopressin, a $1.6 million increase related to Pemfexy, coupled with a $2.0 million total increase in salaries, bonuses, and severance, included with Salary and other personnel related costs.

Selling, General and Administrative

	Year Ended December 31,		(Decrease)
	2021	2020	
	(in thousands)		
Selling, general and administrative	$ 75,322	$ 78,598	$ (3,276)

The decrease is primarily related to lower stock compensation expense of $5.2 million, the non-recurrence of $2.5 million of costs related to the collaboration with Tyme in 2020, partially offset by increased expense related to salaries and bonuses of $2.3 million and ongoing litigation matters of $1.9 million.

Other (Expense) Income, net

	Year Ended December 31,		(Decrease) / Increase
	2021	2020	
	(in thousands)		
Interest income	$ 560	$ 562	$ (2)
Interest expense	(1,635)	(2,577)	942
Other (expense) income	(6,242)	(8,262)	2,020
Total other (expense) income, net	$ (7,317)	$ (10,277)	$ 2,960

Interest income decreased primarily due to lower interest rates associated with money market funds as compared to the year ended December 31, 2020.

Interest expense decreased primarily due to lower total long-term debt outstanding due to recurring principal payments required by the Revised Credit Agreement. This decrease is primarily due to lower borrowings from our revolving credit facility during 2021 as compared to the year ended December 31, 2020.

Our other (expense) income, net decreased $2.0 million for the year ended December 31, 2021 as compared to the year ended December 31, 2020. The $6.2 million expense amount for the year ended December 31, 2021 primarily resulted from fair value adjustments on equity investment in Tyme. The $8.3 million expense amount for the year ended December 31, 2020 related to fair value adjustments on equity investment in Tyme in the amount of $5.3 million and the related fair value adjustments related to the final settlement of the $25.0 million ASR transaction with JPMorgan. We determined the ASR contained a forward contract and therefore we recorded fair value adjustments on unsettled accelerated share repurchase agreement in the amount of $3.0 million in the year ended December 31, 2020.

Provision for income taxes

	Year Ended December 31,	
	2021	**2020**
	(in thousands)	
Provision for income taxes	$ (4,079)	$ (10,688)
Effective tax rate	(90)%	47 %

Our provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the year ended December 31, 2021, reflects certain non-deductible executive compensation, tax effect on stock options exercises, net of forfeitures and valuation allowance established on the deferred tax asset for an unrealized capital loss in our investment in Tyme partially offset by credits for research and development activities. The effective tax rate for the year ended December 31, 2020, reflects the impact of a valuation allowance established on the deferred tax asset for an unrealized capital loss in our investment in Tyme, certain non-deductible executive compensation, non-deductible nature of the fair value adjustment of our ASR agreement and changes in state filing positions partially offset by credits for research and development activities.

Net (Loss) Income

Net loss for the year ended December 31, 2021 was $8.6 million as compared to a net income of $12.0 million for the year ended December 31, 2020, as a result of the factors discussed above.

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

Revenues

	Year Ended December 31,		
	2020	**2019**	**(Decrease)**
	(in thousands)		
Product sales, net	$ 72,323	$ 73,989	$ (1,666)
Royalty revenue	110,479	112,903	(2,424)
License and other revenue	5,000	9,000	(4,000)
Total revenue	$ 187,802	$ 195,892	$ (8,090)

Product sales decreased $1.7 million in the year ended December 31, 2020, primarily driven by decreases in product sales of Bendeka of $15.7 million coupled with decreases in Belrapzo's product sales of $2.1 million primarily due to volume decreases. In addition, the COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically have led to a reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. The decreased sales were partially offset by increases in product sales of Ryanodex of $15.2 million due to higher volume coupled with product sales of $0.9 million from the 2020 product launch of Treakisym.

Royalty revenue decreased $2.4 million in the year ended December 31, 2020 as a result of decreases in royalties on Teva's sales of Bendeka of $1.1 million and royalties on sales of Argatroban of $1.3 million.

Our license and other revenue decreased $4.0 million in the year ended December 31, 2020 as compared to the year ended December 31, 2019. In 2019, we received an upfront cash payment of $9.0 million upon execution of an amendment to the Bendeka License Agreement, dated March 29, 2019 to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S. In 2020, we received a $5.0 million milestone payment earned in the three months ended

September 30, 2020 from SymBio upon regulatory approval of Treakisym ready-to-dilute (250 ml) liquid bendamustine formulation from the Pharmaceuticals and Medical Devices Agency in Japan.

Cost of Revenue

	Year Ended December 31,		
	2020	2019	(Decrease)
	(in thousands)		
Cost of product sales	$ 33,647	$ 47,891	$ (14,244)
Cost of royalty revenue	11,818	13,006	(1,188)
Total cost of revenue	$ 45,465	$ 60,897	$ (15,432)

Cost of product sales decreased $14.2 million in the year ended December 31, 2020, primarily as a result of decreased product sales of Belrapzo and Bendeka, partially offset by increased product sales of Ryanodex and the 2020 product launch of Treakisym.

Cost of royalty revenue decreased $1.2 million in the year ended December 31, 2020 primarily as a result of a decrease in royalty revenue on Teva's sales of Bendeka.

Research and Development

The table below details our research and development expenses by significant project for the periods presented.

	Year Ended December 31,		Increase /
	2020	2019	(Decrease)
	(in thousands)		
Fulvestrant	$ 6,802	$ 5,053	$ 1,749
Vasopressin	4,727	7,779	(3,052)
Ryanodex related projects	1,972	$ 5,192	(3,220)
All other projects	4,586	$ 3,980	606
Salary and other personnel related	$ 12,698	$ 14,806	(2,108)
Research and development	$ 30,785	$ 36,810	$ (6,025)

The decrease primarily resulted from a decrease in clinical study project spending for vasopressin and Ryanodex for EHS indication, and employee-related costs, primarily stock compensation expense. This decrease was partially offset by increased spend related to Fulvestrant.

Selling, General and Administrative

	Year Ended December 31,		
	2020	2019	Increase
	(in thousands)		
Selling, general and administrative	$ 78,598	$ 76,370	$ 2,228

The increase is primarily related to $2.5 million of costs related to the collaboration with Tyme, coupled with $4.5 million increase in stock compensation. These increases were partially offset by travel and entertainment expense which decreased by $2.0 million primarily due to Covid-19 restrictions on travel coupled with a decrease in external legal fees related to ongoing litigation matters of $3.2 million.

Other (Expense) Income, net

	Year Ended December 31,		(Decrease) / Increase
	2020	2019	
	(in thousands)		
Interest income	$ 562	$ 2,169	$ (1,607)
Interest expense	(2,577)	(2,686)	109
Other (expense) income	(8,262)	700	(8,962)
Total other (expense) income, net	$ (10,277)	$ 183	$ (10,460)

Interest income decreased primarily due to lower interest rates associated with money market funds as compared to the year ended December 31, 2019.

Interest expense decreased primarily due to lower total long-term debt outstanding due to recurring principal payments required by the Revised Credit Agreement.

Our other (expense) income, net increased $9.0 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. This increase is related to fair value adjustments on equity investment in Tyme in the amount of $5.3 million and the related fair value adjustments related to the final settlement of the $25.0 million ASR transaction with JPMorgan as part of the Company's Share Repurchase Program. The Company determined the ASR contained a forward contract and therefore the Company recorded fair value adjustments on the accelerated share repurchase agreement in the amount of $3.0 million in the year ended December 31, 2020. The increase in other expense is also related to our settlement agreement in December 2019 with Lilly for $0.7 million.

Provision for income taxes

	Year Ended December 31,	
	2020	2019
	(in thousands)	
Provision for income taxes	$ 10,688	$ 7,685
Effective tax rate	47 %	35 %

Our provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the year ended December 31, 2020 reflects the impact of a valuation allowance established on the deferred tax asset for an unrealized capital loss in our investment in Tyme, certain non-deductible executive compensation, non-deductible nature of the fair value adjustment of our ASR agreement and changes in state filing positions partially offset by credits for research and development activity. The effective tax rate for the year ended December 31, 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity.

Net Income

Net income for the year ended December 31, 2020 was $12.0 million as compared to a net income of $14.3 million for the year ended December 31, 2019, as a result of the factors discussed above.

Liquidity and Capital Resources

Our principal sources of liquidity are our cash and cash equivalents, cash flows from operations and availability of borrowing under our revolving credit facility. Our primary uses of cash are to fund working capital requirements, including repayment of debt, product development costs, operating expenses as well as repurchases of our common stock. Cash and cash equivalents were $97.7 million, and $103.2 million as of December 31, 2021 and December 31, 2020, respectively.

For the year ended December 31, 2021, we recorded net loss of $8.6 million. As of December 31, 2021, we had a working capital surplus of $98.2 million. For the year ended December 31, 2020, we recorded net income of $12.0 million.

We believe that our cash and cash equivalents and future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for at least the next twelve months. We believe we will be able to meet our expected future cash and working capital requirements through a combination of cash flows from operations, cash and cash equivalents, availability of borrowings under our revolving credit facility and additional funding in the capital markets, if needed.

The COVID-19 pandemic has disrupted and continues to disrupt the U.S. healthcare system, global economies and global capital markets. There are significant uncertainties surrounding the full extent and duration of the impact of the COVID-19 pandemic on our business and operations. We have experienced variable financial impacts to date, as a result of the COVID-19 pandemic and the ongoing pandemic could have a material adverse impact on our financial condition and results of operations in the future, including our ability to obtain financing when and if needed. The impact of COVID-19 on our business and financial condition is more fully described below in *Trends and Uncertainties.*

Operating Activities:

Net cash provided by operating activities for the year ended December 31, 2021 was $28.2 million. Net loss for the same period was $8.6 million more than offset by the net of non-cash adjustments of approximately $27.3 million from deferred income taxes, depreciation expense, noncash operating lease expense related to right-of-use assets, amortization expense of intangible assets, convertible promissory note related credit losses, stock-based compensation expense, fair value adjustments on equity investment, amortization of debt issuance costs, fair value adjustments related to derivative instrument, and accretion of discount on convertible promissory note. Net changes in working capital increased cash from operating activities by approximately $9.5 million, due to changes in working capital accounts. The total amount of accounts receivable as of December 31, 2021 was approximately $41.1 million, which included $15.0 million related to product sales and $26.1 million related to royalty revenue. Receivables from our product sales have payment terms ranging from 30 to 70 days with select extended terms to wholesalers on initial purchases of product launch quantities. Our receivables from royalty revenue are due 45 days from the end of the quarter or year end.

Net cash provided by operating activities for the year ended December 31, 2020 was $49.5 million. Net income for the same period was $12.0 million before non-cash adjustments of approximately $36.7 million from deferred income taxes, depreciation expense, noncash operating lease expense related to right-of-use assets, amortization expense of intangible assets, stock-based compensation expense, fair value adjustments on equity investment, amortization of debt issuance costs and fair value adjustments on settled accelerated share repurchase agreement. Net changes in working capital decreased cash provided from operating activities by approximately $0.8 million, due to an increase in accounts receivable of $3.1 million, an increase in inventory of $1.5 million, a decrease in accrued expenses and other liabilities of $4.4 million, coupled with a decrease in prepaid expenses and other current assets of $11.4 million, and an increase in accounts payable of $0.8 million. The total amount of accounts receivable as of December 31, 2020 was approximately $51.1 million. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities. Our receivables from royalty revenue are due 45-days from the end of the quarter.

Net cash provided by operating activities for the year ended December 31, 2019 was $56.0 million. Net income for the same period was $14.3 million before non-cash adjustments of approximately $27.3 million from deferred income taxes, depreciation expense, noncash operating lease expense related to right-of-use assets, amortization expense of intangible assets, stock-based compensation expense, and amortization of debt issuance costs. Net changes in working capital increased cash provided from operating activities by $14.4 million, due to a decrease in accounts receivable of $18.5 million primarily due to Belrapzo launch in 2018, a decrease in inventory of $1.7 million, an increase in accrued expenses and other liabilities of $4.1 million, partially offset by an increase in other assets of $0.6 million, a decrease in prepaid expenses and other current assets of $4.8 million, and a decrease in accounts payable of $4.5 million. The total amount of accounts receivable at December 31, 2019 was approximately $48.0 million.

Investing Activities:

During the years ended December 31, 2021, 2020 and 2019, we invested $0.3 million, $0.7 million, and $0.8 million, respectively, for the purchase of property and equipment.

Net cash used in investing activities for the year December 31, 2021 primarily was as a result of $5.0 million of investment to purchase a convertible promissory note of a privately held clinical-stage biotechnology company.

Net cash used in investing activities for the year December 31, 2020 primarily was $17.5 million related to our purchase of 10 million restricted shares of Tyme’s common stock.

Financing Activities:

Net cash used by financing activities for the year ended December 31, 2021 was $28.4 million, as a result of $8.0 million of principal payments for outstanding debt under our Revised Credit Agreement with JPMorgan Chase Bank, N.A., as administrative agent and the lenders party thereto, or the Credit Agreement, $21.2 million in payments related to the repurchases of our common stock, $1.6 million of payments associated with employee withholding tax upon vesting of stock-based awards, partially offset by $2.4 million of proceeds from common stock exercises of employee stock options.

Net cash used in financing activities for the year ended December 31, 2020 was $37.9 million, as a result of $5.0 million of principal payments for debt required by the Company's Second Amended and Restated Credit Agreement with JPMorgan Chase Bank, N.A., as administrative agent and the lenders party thereto, or the Revised Credit Agreement, $35.0 million in payments related to the repurchases of our common stock, $1.5 million of payments associated with employee withholding tax upon vesting of stock-based awards, partially offset by $3.7 million of proceeds from common stock exercises of employee stock options.

Net cash used in financing activities for the year ended December 31, 2019 was $24.2 million, primarily resulting from principal payments for debt required by the Revised Credit Agreement of $6.0 million and payments related to the repurchases of our common stock of $18.0 million.

Trends and Uncertainties

Impact of the COVID-19 Pandemic

The COVID-19 pandemic has resulted in authorities implementing aggressive actions. Government authorities in the United States have recommended or imposed various social distancing, quarantine, and isolation measures on large portions of the population, and similar measures have also been taken in many other countries around the world. While many of these governmental restrictions have begun to be lifted, the timing and extent to which such orders and restrictions will be removed remains uncertain. Both the COVID-19 pandemic and the containment and mitigation efforts related to the pandemic have had a serious adverse impact on the U.S. economy and the economies of other countries around the world, the severity and duration of which are uncertain. There is no guarantee that prior or new restrictions will not be reinstated in response to the continued spread of COVID-19.

During the year ended December 31, 2021, we have experienced a variable impact on our business and financial condition due to the COVID-19 pandemic, which impacts include a decrease in revenue from sales of Belrapzo resulting, in part, from a decrease in inventory stocking and utilization rates, as well as a decrease in research and development expenses partially resulting from preclinical program delays. We also incurred an insignificant amount of incremental administrative costs related to the COVID-19 pandemic. The COVID-19 pandemic, including containment and mitigation measures, has impacted, and is expected to continue to impact, our business and operations in a number of ways, including:

- *Day-to-Day Operations*: Since mid-March 2020, certain of our employees, including customer-facing employees, had been primarily working remotely. The duration and extent of these restrictions are anticipated to be eased in the short term. During the second quarter of 2021, we developed and implemented plans to resume in-person work practices while adhering to relevant health authority guidance. We may incur additional expenses in 2022 related to the impact of the COVID-19 pandemic on our operations, including updates to our facilities to align with safety protocols.
- *Manufacturing and Supply Chain:* We are working closely with our commercial partners and third-party manufacturers to mitigate potential disruptions as a result of the COVID-19 pandemic by continuing to monitor the supply and availability of Bendeka, Ryanodex and Belrapzo for the patients who rely on these products. We anticipate that the COVID-19 pandemic will continue to delay our supply chain and marketing and sales efforts for certain of our products, including Bendeka, although it is not currently expected that any disruption would be material. If the COVID-19 pandemic continues to persist for an extended period of time and impacts essential distribution systems such as FedEx and postal delivery, we could experience future disruptions to our supply chain and operations, and associated delays in the manufacturing and our clinical supply, which would adversely impact our development activities.
- *Marketing and Sale of Products*: In addition to the impact on our product revenues resulting in a decrease in sales from Belrapzo, driven, in part, by the COVID-19 pandemic, we have also observed a reduction in the number of Bendeka patients visiting infusion centers, hospitals and clinics for intravenous administration of Bendeka due to interruptions in healthcare services, and the patients' inability to visit administration sites as well as desire to avoid contact with infected individuals. In addition, our sales and marketing teams have been working remotely and our virtual initiatives with respect to marketing and supporting the sale and administration of our products have not been as effective as our in-person sales and marketing activities.

- *Liquidity and Capital Resources*: We believe that our cash and cash equivalents and availability of borrowings under our Credit Agreement will be sufficient to fund our currently anticipated working capital requirements for at least the next twelve months. While the COVID-19 pandemic has not had, and we do not expect it to have, a material adverse effect on our liquidity, the situation continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists or deepens, we could experience an inability to access additional capital when and if needed. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate distribution of our commercialized products, product portfolio expansion or some or all of our research and development programs, which would adversely affect our business prospects. We expect to be able to obtain future funding under the terms of the Credit Agreement, for general corporate purposes and any strategic acquisitions.
- *Regulatory Activities*: We may experience further delays in the timing of NDA review and/or our interactions with FDA due to, for example, absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of FDA's efforts and attention to approval of other therapeutics or other activities related to the COVID-19 pandemic, which could further delay approval decisions with respect to regulatory submissions or obtain new product approvals.
- *Clinical Development Timelines:* The clinical trial timelines for certain of our product candidates have been delayed given difficulties with limited patient enrollment resulting from the impact of the COVID-19 pandemic, and we expect that our clinical trial timelines will continue to be impacted for the duration of the pandemic.

There are significant uncertainties surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations. We continue to evaluate the impact of the COVID-19 pandemic on our operating results and financial condition. The COVID-19 pandemic has had a variable impact on our results of operations during the year ended December 31, 2021 and, it could have a material adverse impact on our financial condition and results of operations in the future.

Contractual Obligations

Our future material contractual obligations include the following (in thousands):

Obligation	Total	2022	2023	2024	2025
Operating leases (1)	$ 4,329	$ 1,423	$ 1,455	$ 1,038	$ 413
Credit facility	26,000	26,000	—	—	—
Purchase obligations (2)	69,549	69,549	—	—	—
Total obligations	$ 99,878	$ 96,972	$ 1,455	$ 1,038	$ 413

(1) We lease our corporate office location. On August 8, 2019, we amended the lease for our corporate office location in order to rent additional office space and extend the term of our existing lease to June 30, 2025. The Company also leases its lab space under a lease agreement that expires on April 30, 2024. We also lease office space located in Palm Beach Gardens, FL. The new lease agreement commenced on November 1, 2021 and will expire 36 months from the lease commencement date, which is October 31, 2024. Rental expense was $1,407, $1,323, and $1,146, for the year ended December 31, 2021, 2020, and 2019, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $4,329 as of December 31, 2021, payable monthly.

(2) As of December 31, 2021, the Company has purchase obligations in the amount of $69,549 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In March 2020, the FASB issued Update 2020-04 Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting to provide temporary optional guidance to ease the potential burden in accounting for reference rate reform. The amendments in Update 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR, formerly known as the London Interbank Offered Rate,
or another reference rate expected to be discontinued due to reference rate reform. The new guidance provides optional expedients, including; (1) Simplify accounting analyses under current GAAP for contract modifications, such as modifications of contracts within the scope of Topic 470, Debt, that will be accounted for by prospectively adjusting the effective interest rate, as if any modification was not substantial. That is, the original contract and the new contract shall be accounted for as if they were not substantially different from one another; (2) Simplify the assessment of hedge effectiveness and allow hedging relationships affected by reference rate reform to continue; (3) Allow a one-time election to sell or transfer debt securities

classified as held to maturity before January 1, 2020 that reference a rate affected by reference rate reform. The amendments are effective for all entities from the beginning of an interim period that includes the issuance date of the ASU. An entity may elect to apply the amendments prospectively through December 31, 2022. The adoption of ASU 2020-4 is not expected to have a material impact on the Company's financial position or results of operations.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and other financial information. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The amount of assets and liabilities reported in our consolidated balance sheets and the amounts reported in our consolidated statements of operations are affected by estimates and assumptions, which are used for, but not limited to, the accounting for revenue recognition. The accounting estimates discussed below involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations. Actual results could differ materially from our estimates. For additional accounting policies, see Note 2 to our Consolidated Financial Statements—*Summary of Significant Accounting Policies*.

Revenue Recognition

Revenue 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. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product revenue - The Company recognizes net revenue on sales to its commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of the Company’s product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract.

Revenue on sales to commercial partners relates to Bendeka and Treakisym. Sales to our commercial partners are presented gross because the Company is primarily responsible for fulfilling the promise to provide the product, is responsible to ensure that the product is produced in accordance with the related supply agreement and bears risk of loss while the inventory is in-transit to the commercial partner.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method to which the Company expects to be entitled. As such, revenue on sales to end users for Belrapzo and Ryanodex are recorded net of certain deductions. Our products are contracted with a limited number of oncology distributors and hospital buying groups with narrow differences in ultimate realized contract prices used to estimate our chargeback and rebate reserves. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

Components of Gross-to-Net (GTN) Estimates

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, including group purchasing organizations, or GPOs, public health service institutions and federal government entities purchasing via the Federal Supply Schedule, purchase from the Company's distributors. The Company's distributors purchase product from us at invoice price, then resell the product to certain contracted customers on the basis of prices negotiated between us and the providers. The difference between the distributors' purchase price and the typically lower certain contracted customers' purchase price is refunded to the distributors through a chargeback credit. We record estimates for these chargebacks at the time of sale as deductions from gross revenues, with corresponding adjustments to our accounts receivable allowances.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. We are exposed to market risk related to changes in interest rates. As of December 31, 2021, we had cash and cash equivalents of $97.7 million held primarily in money market mutual funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, however, due to the short-term duration of our money market mutual funds and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio.

Our exposure to interest rate risk also relates to our variable-rate indebtedness associated with our Revised Credit Agreement. As of December 31, 2021 and 2020, the aggregate principal amount of such variable-rate indebtedness was $26.0 million and $34.0 million, respectively. Borrowings under the Revised Credit Agreement may from time to time bear interest at variable rates, which rates are further described in Note 6. Debt in the Consolidated Financial Statements included in Part IV, Item 15 of this report. As of December 31, 2021 and 2020, a hypothetical 1% increase in the applicable rate would not have a material effect on the incremental annual interest expense related to our variable-rate debt borrowings.

Item 8. Financial Statements and Supplementary Data

Our Financial Statements and Supplementary Data are set forth in Item 15 of Part IV of this Annual Report on Form 10-K.

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

Not Applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2021, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act). Based on this evaluation, such officers have concluded that our disclosure controls and procedures were effective as of December 31, 2021. Management has concluded that our consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented therein.

Management's Annual Report on Internal Control Over Financial Reporting

The management of Eagle Pharmaceuticals, Inc. ("Eagle") has prepared, and is responsible for, Eagle's financial statements and related footnotes. These financial statements have been prepared in conformity with U.S. generally accepted accounting principles. Eagle's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of the Company's principal executive and principal financial officers and effected by the Company's board of directors, management, and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of Eagle's assets;
- 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 Eagle are being made only in accordance with authorizations of management and directors of Eagle;
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of Eagle's assets that could have a material effect on the financial statements; and
- Eagle's management must also disclose any material weaknesses identified.

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. Eagle's management conducted an assessment of the Company's internal control over financial reporting as of December 31, 2021 based upon the criteria established in "Internal Control - Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on this assessment, our management has concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

Ernst & Young, LLP, the independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting as of December 31, 2021. This attestation report appears below.

/s/ Scott Tarriff
President, Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Brian Cahill

Chief Financial Officer
(Principal Accounting and Financial Officer)

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Eagle Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control— Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Eagle Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, and the related consolidated statements of operations, comprehensive (loss) income, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021 and the related notes and our report dated March 7, 2022 expressed an unqualified opinion thereon.

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

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

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young, LLP

Stamford, Connecticut

March 7, 2022

Item 9B. Other information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

We will file a definitive proxy statement for our 2022 Annual Meeting of Stockholders, or the 2022 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2022 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our 2022 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our 2022 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this item is incorporated by reference to our 2022 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated by reference to our 2022 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to our 2022 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

The following documents are filed as part of this report:

1. Consolidated Financial Statements

2. Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

3. Exhibits

The exhibits listed in the below index to exhibits are filed as part of, or incorporated by reference into, this report.

Exhibit Number		Description
3.1		Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
3.2		Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
4.1		Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
4.2		Description of securities Description of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934. pursuant to Section 12 of the Securities Exchange Act of 1934. (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 2, 2020).
10.1	†	Form of Indemnification Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.2	†	Eagle Pharmaceuticals, Inc. 2007 Incentive Compensation Plan and Form of Stock Option Agreement thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), as amended December 15, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.3	†	Eagle Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended and restated, and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015), as amended with an additional form of Stock Option Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.4	†	Eagle Pharmaceuticals, Inc. 2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 22, 2014)

10.5	†	Eagle Pharmaceuticals, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 22, 2014)
10.6	†	Employment Agreement by and between the Registrant and Scott Tarriff dated March 8, 2007, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A, SEC File No. 333-192984, filed January 28, 2014)
10.7		Lease Agreement between the Registrant and Mack-Cali Chestnut Ridge L.L.C. dated May 28, 2013, as amended on July 1, 2013 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on March 16, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K , SEC File No. 001-36306, filed March 20, 2015)
10.8	*	Development and License Agreement, by and between the Registrant and SciDose, LLC, dated September 24, 2007, as amended March 18, 2008, May 22, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.11(a) to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.9	*	Development and License Agreement, by and between the Registrant and SciDose, LLC, dated June 12, 2007, as amended March 18, 2008, March 25, 2008, December 3, 2008, May 22, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.11(b) to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on August 5, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.10	*	License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated October 16, 2008 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.11	*	License and Development Agreement, by and between the Registrant and The Medicines Company, effective as of September 24, 2009, as amended January 2010 and September 1, 2012 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.12	*	Supply Agreement, by and between the Registrant and The Medicines Company, dated September 24, 2009 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.13	*	Agreement for the Supply of Argatroban and Topotecan, by and between the Registrant and Cipla Limited, dated December 14, 2012, as amended August 30, 2013 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.14	*	Supply and Distribution Agreement, by and between the Registrant and Sandoz AG, dated January 28, 2013 (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.15	*	Development and License Agreement, by and between the Registrant and Robert One, LLC (bendamustine), dated March 18, 2008, as amended November 11, 2009 and July 16, 2013 (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013)
10.16	*	Development and License Agreement, by and between the Registrant and Robert One, LLC (pemetrexed), dated February 13, 2009, as amended May 22, 2009, December 23, 2010 and July 16, 2013 (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013), and as amended on August 5, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015)
10.17	*	Exclusive License Agreement, by and between the Registrant and Cephalon, Inc., dated February 13, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q/A, SEC File No. 001-36306, filed February 12, 2016)
10.18	*	Settlement and License Agreement, by and between the Registrant and Cephalon, Inc., dated February 13, 2015 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed May 15, 2015)
10.19	†	Eagle Pharmaceuticals, Inc. Officer Severance Benefit Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 10, 2015), as amended and restated by the Eagle Pharmaceuticals, Inc. Amended and Restated Severance Benefit Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 16, 2019).
10.20	†	Form of Letter Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 21, 2015)
10.21	*	License Agreement, by and between the Registrant and Teikoku Pharma USA, Inc., dated October 13, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 29, 2016)
10.22	*	Co-Promotion Agreement, by and between the Registrant and Spectrum Pharmaceuticals, Inc., dated November 4, 2015 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 29, 2016)

10.23		Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated January 26, 2017 (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017) as amended and restated by the Amended and Restated Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated August 8, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed August 9, 2017), and as amended and restated by the Second Amended and Restated Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated November 8, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 12, 2019).
10.24		Amendment to License and Sublicense Agreement, by and between the Registrant and Lyotropic Therapeutics, Inc., dated August 3, 2016 (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017)
10.25	*	Product Collaboration and License Agreement, by and between the Registrant and SymBio Pharmaceuticals Limited, effective as of September 19, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 8, 2017)
10.26	†	Form of Restricted Stock Unit Grant Package (2014 Equity Incentive Plan) (incoporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed February 26, 2018)
10.27	†	Form of Performance Stock Unit Grant Package (2014 Equity Incentive Plan) (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 5, 2021).
10.28	† +	Form of Performance Stock Unit Grant Package (2014 Equity Incentive Plan) (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 5, 2021).
10.29		Stock Purchase Agreement, dated as of November 10, 2016, by and among Eagle Pharmaceuticals, Inc., Arsia Therapeutics, LLC, Arsia Therapeutics, Inc., Amy Schulman, as the Seller Representative, and each person that executed a joinder to the Purchase Agreement (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Commission on November 14, 2016)), as amended by Amendment No. 1 to Stock Purchase Agreement, dated as of February 8, 2018 (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, SEC File No. 001-36306, filed with the Commission on February 14, 2018)
10.30		Fifth Amendment to Lease Agreement between the Registrant and CAPSTONE TICE BLVD LLC. dated as of August 8, 2019 (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 2, 2020).
10.31		Fourth Amendment to Exclusive License Agreement, by and between the Registrant and Teva Pharmaceuticals International GmbH, dated April 12, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 7, 2019).
10.32	+	Settlement Agreement, by and between the Registrant and Eli Lilly and Company, dated December 13, 2019 (incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 2, 2020).
10.33	+	Co-Promotion Agreement with Tyme Technologies, Inc., dated January 7, 2020 (incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 2, 2020).
10.34		Securities Purchase Agreement, between the Registrant and Tyme Technologies, Inc., dated January 7, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 8, 2020).
10.35		License Agreement between the Registrant and Combioxin SA, dated August 19, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 9, 2021)
10.36		License Agreement between the Registrant and AOP Orphan Pharmaceuticals GmbH, dated August 6, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-36306, filed November 9, 2021).
21.1	(1)	List of subsidiaries of Eagle Pharmaceuticals, Inc.
23.1	(1)	Consent of Ernst & Young, LLP, an Independent Registered Public Accounting Firm
23.2	(1)	Consent of BDO USA, LLP, an Independent Registered Public Accounting Firm
24.1		Power of Attorney (incorporated by reference to this signature page of this Annual Report on Form 10-K)
31.1	(1)	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	(1)	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	(2)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS	iXBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	iXBRL Taxonomy Extension Schema
101.CAL	iXBRL Taxonomy Extension Calculation Linkbase
101.DEF	iXBRL Taxonomy Extension Definition Linkbase
101.LAB	iXBRL Taxonomy Extension Labels Linkbase
101.PRE	iXBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File, formatted as Inline XBRL, contained in Exhibit 101 attachments

†Management contract or compensatory plan or arrangement.

*Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

+Certain portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K..

(1) Filed herewith.

(2) Furnished (and not filed) herewith pursuant to Item 601 (b)(32)(ii) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 7, 2022.

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
President and Chief Executive Officer
(Principal Executive Officer)

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Tarriff and Brian Cahill, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/S/ SCOTT TARRIFF Scott Tarriff	President, Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2022
/S/ BRIAN CAHILL Brian Cahill	Chief Financial Officer (Principal Accounting and Financial Officer)	March 7, 2022
/S/ MICHAEL GRAVES Michael Graves	Chairman of the Board of Directors	March 7, 2022
/S/ STEVEN RATOFF Steven Ratoff	Member of the Board of Directors	March 7, 2022
/S/ JENNIFER K. SIMPSON Jennifer K. Simpson	Member of the Board of Directors	March 7, 2022
/S/ ROBERT L. GLENNING Robert L. Glenning	Member of the Board of Directors	March 7, 2022
/S/ RICHARD A. EDLIN Richard A. Edlin	Member of the Board of Directors	March 7, 2022
/S/ LUCIANA BORIO Luciana Borio	Member of the Board of Directors	March 7, 2022

INDEX TO FINANCIAL STATEMENTS OF
EAGLE PHARMACEUTICALS, INC.

APPENDIX A

Report of Independent Registered Public Accounting Firm – Ernst & Young, LLP

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Eagle Pharmaceuticals, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive (loss) income, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 7, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

	Revenue Recognition - Chargebacks
Description of the Matter	At December 31, 2021, the Company recorded an allowance for chargebacks totaling $3.8 million. As described in Note 2 of the consolidated financial statements, the Company recognizes revenues from product sales net of allowances for chargebacks. These allowances are recorded in the period when the related sales occur and are based on the estimated amounts to be claimed which are not known at the point of sale. Chargebacks are estimated based on assumptions about the third-party payors and contracted prices to be paid by those payors. Given the estimation uncertainty involved, auditing the allowance for chargebacks was complex. A higher degree of auditor judgment was required to evaluate the mix of third-party payors and applicable contract prices assumed by management to determine the amount of the allowance.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of internal controls over the Company's process for estimating its allowance for chargebacks, including controls over management’s review of significant assumptions used to calculate the estimates such as the mix of third-party payors and applicable contract prices. To test the Company's estimated allowance for chargebacks, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the Company’s analyses and evaluating the assumptions described above. We compared the assumed payor mix used to calculate the estimate to actual historical data and compared the assumed contract prices to executed agreements with the applicable payors. We also analyzed the effect of reasonable changes in assumptions on the amounts recorded. We assessed the historical accuracy of management’s estimate. We tested credit memos issued subsequent to year-end for recording in the proper period.

/s/ Ernst & Young, LLP

We have served as the Company's auditor since 2020.

Stamford, Connecticut
March 7, 2022

Report of Independent Registered Public Accounting Firm – BDO USA, LLP

Board of Directors and Stockholders
Eagle Pharmaceuticals, Inc.
Woodcliff Lake, New Jersey

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Eagle Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2019, the related consolidated statements of operations, comprehensive (loss) income, changes in stockholders' equity and cash flows for the year ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We served as the Company's auditor from 2007 to 2020.

Woodbridge, New Jersey
March 2, 2020

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 97,659	$ 103,155
Accounts receivable, net	41,149	51,117
Inventories	21,908	8,075
Prepaid expenses and other current assets	11,890	3,718
Total current assets	172,606	166,065
Property and equipment, net	1,636	2,077
Intangible assets, net	10,671	12,917
Goodwill	39,743	39,743
Deferred tax asset, net	18,798	15,180
Other assets	10,278	17,208
Total assets	$ 253,732	$ 253,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 16,431	$ 6,268
Accrued expenses and other liabilities	32,338	23,817
Short-term debt	25,607	8,000
Total current liabilities	74,376	38,085
Other long-term liabilities	2,903	3,959
Long-term debt	—	25,135
Total liabilities	77,279	67,179
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of December 31, 2021 and 2020	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 16,903,034 and 16,739,203 shares issued as of December 31, 2021 and 2020, respectively	17	17
Additional paid in capital	325,779	305,403
Accumulated other comprehensive loss	(94)	—
Retained earnings	75,862	84,489
Treasury stock, at cost, 4,111,622 and 3,682,176 shares as of December 31, 2021 and 2020, respectively	(225,111)	(203,898)
Total stockholders' equity	176,453	186,011
Total liabilities and stockholders' equity	$ 253,732	$ 253,190

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenue:			
Product sales, net	$ 65,023	$ 72,323	$ 73,989
Royalty revenue	106,523	110,479	112,903
License and other revenue	—	5,000	9,000
Total revenue	171,546	187,802	195,892
Operating expenses:			
Cost of product sales	31,528	33,647	47,891
Cost of royalty revenue	10,652	11,818	13,006
Research and development	51,275	30,785	36,810
Selling, general and administrative	75,322	78,598	76,370
Total operating expenses	168,777	154,848	174,077
Income from operations	2,769	32,954	21,815
Interest income	560	562	2,169
Interest expense	(1,635)	(2,577)	(2,686)
Other (expense) income	(6,242)	(8,262)	700
Total other (expense) income, net	(7,317)	(10,277)	183
(Loss) income before income tax provision	(4,548)	22,677	21,998
Income tax provision	(4,079)	(10,688)	(7,685)
Net (loss) income	$ (8,627)	$ 11,989	$ 14,313
(Loss) Earnings per common share:			
Basic	$ (0.66)	$ 0.89	$ 1.04
Diluted	$ (0.66)	$ 0.87	$ 1.01
Weighted average number of common shares outstanding:			
Basic	13,051,095	13,481,525	13,754,516
Diluted	13,051,095	13,771,393	14,138,733

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(In thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Net (loss) income	$ (8,627)	$ 11,989	$ 14,313
Other comprehensive loss, net of tax:			
Unrealized loss for convertible promissory note	(94)	—	—
Total other comprehensive loss	(94)	—	—
Comprehensive (loss) income	$ (8,721)	$ 11,989	$ 14,313

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock						
	Number of Shares	Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2018	**16,504**	**$ 17**	**$ 256,458**	**$(153,900)**	$ —	**$ 58,187**	**$ 160,762**
Stock-based compensation expense	—	—	21,998	—	—	—	21,998
Issuance of common stock upon exercise of stock option grants	34	—	260	—	—	—	260
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(198)	—	—	—	(198)
Common stock repurchases	—	—	—	(17,961)	—	—	(17,961)
Net income	—	—	—	—	—	14,313	14,313
Balance at December 31, 2019	**16,538**	**$ 17**	**$ 278,518**	**$(171,861)**	$ —	**$ 72,500**	**$ 179,174**
Stock-based compensation expense	—	—	24,756	—	—	—	24,756
Issuance of common stock upon exercise of stock option grants	149	—	3,654	—	—	—	3,654
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(1,525)	—	—	—	(1,525)
Issuance of common stock related to vesting of restricted stock	52	—	—	—	—	—	—
Common stock repurchases	—	—	—	(32,037)	—	—	(32,037)
Net income	—	—	—	—	—	11,989	11,989
Balance at December 31, 2020	**16,739**	**$ 17**	**$ 305,403**	**$(203,898)**	$ —	**$ 84,489**	**$ 186,011**
Stock-based compensation expense	—	—	19,555	—	—	—	19,555
Issuance of common stock upon exercise of stock option grants	101	—	2,398	—	—	—	2,398
Issuance of common stock related to vesting of restricted stock	63	—	(1,577)	—	—	—	(1,577)
Common stock repurchases	—	—	—	(21,213)	—	—	(21,213)
Other comprehensive loss	—	—	—	—	(94)	—	(94)
Net loss	—	—	—	—	—	(8,627)	(8,627)
Balance at December 31, 2021	**16,903**	**$ 17**	**$ 325,779**	**$(225,111)**	**$ (94)**	**$ 75,862**	**$ 176,453**

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net (loss) income	$ (8,627)	$ 11,989	$ 14,313
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Deferred income taxes	(3,618)	(1,511)	152
Depreciation expense	764	872	972
Noncash operating lease expense related to right-of-use assets	1,046	1,228	1,159
Amortization expense of intangible assets	2,996	2,666	2,520
Convertible promissory note related credit losses	758	—	—
Stock-based compensation expense	19,555	24,756	21,998
Fair value adjustments on equity investment	6,170	5,300	—
Amortization of debt issuance costs	472	419	480
Fair value adjustments on settled accelerated share repurchase agreement	—	2,962	—
Fair value adjustments related to derivative instrument	(686)	—	—
Accretion of discount on convertible promissory note	(148)	—	—
Changes in operating assets and liabilities which provided (used) cash:			
Accounts receivable	9,529	(3,113)	18,481
Inventories	(13,833)	(1,509)	1,739
Prepaid expenses and other current assets	(2,770)	11,386	(4,841)
Other assets	(1,321)	(2,325)	(599)
Accounts payable	10,162	806	(4,455)
Accrued expenses and other liabilities	7,770	(4,429)	4,067
Net cash provided by operating activities	28,219	49,497	55,986
Cash flows from investing activities:			
Purchase of equity investment security	—	(17,500)	—
Purchase of property and equipment	(323)	(747)	(777)
Purchase of convertible promissory note	(5,000)	—	—
Net cash used in investing activities	(5,323)	(18,247)	(777)
Cash flows from financing activities:			
Repurchases of common stock	(21,213)	(34,999)	(17,961)
Proceeds from existing revolving credit facility	—	110,000	—
Repayment of existing revolving credit facility	—	(110,000)	—
Payment of debt	(8,000)	(5,000)	(6,000)
Payment of debt financing costs	—	—	(326)
Payment of employee withholding tax upon vesting of stock-based awards	(1,577)	(1,525)	(198)
Proceeds from common stock option exercises	2,398	3,654	260
Net cash used in financing activities	(28,392)	(37,870)	(24,225)

See accompanying notes to consolidated financial statements

EAGLE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Net (decrease) increase in cash and cash equivalents	(5,496)	(6,620)	30,984
Cash and cash equivalents at beginning of period	103,155	109,775	78,791
Cash and cash equivalents at end of period	$ 97,659	$ 103,155	$ 109,775
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Income taxes, net	$ 10,005	$ 6,428	$ 6,673
Interest	1,197	2,224	2,478
Right-of-use asset obtained in exchange for lease obligation, inclusive of a lease amendment	270	855	3,716

See accompanying notes to consolidated financial statements

1. Organization and Business

Eagle Pharmaceuticals, Inc. (the "Company", "Eagle", or "we") is an integrated pharmaceutical company focused on finding ways to help medicines do more for patients. We and our collaborators have the capabilities to take a molecule from preclinical research through regulatory approval and into the marketplace, including development, manufacturing and commercialization. Our business model applies our scientific expertise, proprietary research-based insights and marketplace proficiency to identify challenging-to-treat diseases of the central nervous system or metabolic critical care therapeutic areas as well as in oncology. By focusing on patients' unmet needs, we strive to provide healthcare professionals with urgently needed treatment solutions that are designed to improve patient care and outcomes and create near- and long-term value for our stakeholders, including patients and healthcare providers and our employees, marketing partners, collaborators and investors. Our science-based business model has a proven track record with the U.S. Food and Drug Administration ("FDA") approval and commercial launches of three products: Ryanodex® (dantrolene sodium) ("Ryanodex"), bendamustine ready-to-dilute ("RTD") 500ml solution ("Belrapzo"), and rapidly infused bendamustine RTD ("Bendeka"). We market our products through marketing partners and/or our internal direct sales force. We market Ryanodex and Belrapzo, and Teva Pharmaceutical Industries Ltd. ("Teva") markets Bendeka through its subsidiary Cephalon, Inc. SymBio Pharmaceuticals Limited, or SymBio, markets Treakisym, a RTD product, in Japan. Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for Pemfexy, a branded alternative to Alimta for metastatic non-squamous non-small cell lung cancer and malignant pleural mesothelioma.

In December 2021, the FDA approved our first-to-file Abbreviated New Drug Application, or, ANDA for vasopressin, that references Endo International plc’s Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids. Par Pharmaceutical, Inc. (“Par”), subsidiary of Endo International plc then unilaterally withdrew its request that the U.S. District Court for the District of Delaware issue a temporary restraining order and preliminary injunction preventing the launch of our approved vasopressin product. The FDA then determined that we have maintained our 180 days of marketing exclusivity for our approved ANDA for vasopressin. We launched vasopressin in 2022.

Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for Pemfexy® (“Pemfexy”) and in July 2020, we announced that the Centers for Medicare & Medicaid Services (“CMS”) had established a unique, product-specific billing code for Pemfexy, effective on October 1, 2020. Pemfexy, our novel pemetrexed product, is a branded alternative to Alimta® for metastatic non-squamous non-small cell lung cancer and malignant pleural mesothelioma. The conversion from tentative to a final approval follows the Company’s settlement agreement reached with Eli Lilly and Company (“Lilly”) on December 13, 2019. This agreement provides for a release of all claims by the parties and allows for an initial entry of Pemfexy into the market (equivalent to approximately a three-week supply of current Alimta utilization) on February 1, 2022, and a subsequent uncapped entry on April 1, 2022.

Segment Information

The Company operates in one reportable business segment because we have a single management team that reports to the Chief Executive Officer, the chief operating decision maker, who comprehensively manages the entire business. The Company does not operate separate lines of business with respect to its products or product candidates. Accordingly, the Company has one reportable segment.

Share Repurchase Program

As of December 31, 2021, the Company had repurchased an aggregate of 4,111,622 shares of common stock for an aggregate of $228.1 million pursuant to the Company’s share repurchase programs in effect since August 2016. Refer to Note 7. "Common Stock and Stock-Based Compensation" for further details.

Long-term Debt

On November 8, 2019, the Company entered into the Second Amended and Restated Credit Agreement (the “Revised Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which replaced the Company’s existing credit agreement, dated as of August 8, 2017 (the "Amended Credit Agreement"). Refer to Note 6. "Debt" for further details.

Significant License and Collaboration Agreements - Refer to Note 9. "License and Collaboration Agreements" for further details.

SymBio License Agreement

On September 20, 2017, the Company entered into a Product Collaboration and License Agreement, effective as of September 19, 2017, (the "SymBio License Agreement") with SymBio Pharmaceuticals Limited ("SymBio") for the rights to develop and commercialize the Company's bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product (collectively, the "Products") in Japan. SymBio currently markets in Japan TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma ("MCL"), and as a first line treatment of low-grade NHL and MCL. Under the SymBio License Agreement, SymBio may continue to market TREAKISYM® in Japan and SymBio will be permitted to develop and market certain other bendamustine hydrochloride products in Japan for limited indications.

Combioxin License Agreement

In August 2021, the Company entered into a license agreement with Combioxin, SA ("Combioxin") under which the Company was granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs. The Company will be solely responsible for the development, regulatory, manufacturing and commercialization activities of CAL02. Combioxin will assist the Company in transitioning the manufacturing and supply of CAL02 to the Company.

AOP Orphan License Agreement

In August 2021, the Company entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH ("AOP Orphan"), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, Landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. The Company will support the submission of a new drug application by AOP Orphan to the FDA seeking approval for Landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.

Products and Product Candidates Overview

Bendeka

In March 2018, the FDA approved a second manufacturing site for Bendeka.

On May 15, 2018, the FDA granted final approval for Eagle's ready-to-dilute bendamustine hydrochloride solution in a 500ml admixture for the treatment of patients with chronic lymphocytic leukemia ("CLL") and patients with indolent B-cell non-Hodgkin lymphoma ("NHL") that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

On March 24, 2016 the FDA denied the Company's request for seven years of orphan drug exclusivity in the U.S., for Bendeka. In April 2016, the Company filed a lawsuit against the FDA arguing that Bendeka is entitled to orphan drug exclusivity as a matter of law (see Note 13. Legal Proceedings). On July 2, 2014, the FDA granted the Company orphan drug designations for Bendeka for the treatment of CLL and indolent B-cell NHL. The designations were based on a plausible hypothesis that Bendeka is "clinically superior" to a drug previously approved for the same indications. Generally, an orphan-designated drug is eligible for seven years of marketing exclusivity for the orphan-designated indications upon approval of the drug for those indications. On June 8, 2018, the U.S. District Court for the District of Columbia (the "Court") issued a decision requiring the FDA to grant seven years of orphan drug exclusivity ("ODE") in the U.S., for Bendeka, and on July 8, 2018 the FDA granted such ODE through December 2022. In addition, on July 8, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested the Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA's motion was denied by the Court on August 1, 2018 on the grounds that FDA was seeking an inappropriate advisory opinion. On February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. Pursuant to the decision, no bendamustine product (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka. The Company expects to vigorously pursue the scope of its exclusivity grant.

As of March 29, 2019, the Company and Teva Pharmaceutical Industries Ltd. ("Teva") executed an amendment to the Cephalon License Agreement to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S., which included an upfront cash payment of $9 million that was recorded as License and other revenue on the consolidated statements of operations.

On April 13, 2019, the Company and Teva entered into an Amendment to the Cephalon License Agreement ("Cephalon License", amending the terms of the License Agreement to increase the U.S. royalty paid to the Company and re-allocated certain litigation expenses. Pursuant to the Amendment, beginning on October 1, 2019, the Company's royalty payment has increased from 25% to 30% of Bendeka net U.S. sales. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter. The Amendment also extends the U.S. royalty term for Bendeka until it is no longer sold in the United States. The previous U.S. royalty term was set to expire in 2025. The extended term coincides with the bendamustine patents with expiries through 2033. Pursuant to the amendment, Eagle will continue to be responsible for the manufacture of Bendeka for the U.S. market for so long as it is sold in the United States.

Ryanodex

On October 3, 2018, the Company announced that it entered into an agreement with the United States Army Medical Research Institute of Chemical Defense, the nation’s leading science and technology laboratory in the area of medical chemical countermeasures research and development, to conduct a study to evaluate the neuroprotective effects of Ryanodex® (dantrolene sodium).

On May 7, 2019, the Company announced positive results of its study to evaluate the neuroprotective effects of Ryanodex secondary to nerve agent exposure, conducted with the United States Army Medical Research Institute of Chemical Defense.

On December 16, 2019, we announced that the FDA has granted orphan drug designation (ODD) for Ryanodex®(dantrolene sodium) for the treatment of organophosphate exposure. Organophosphates are a class of chemicals that include potent pesticides and chemical weapons, known as nerve agents. Acute intoxication with organophospates may result in severe consequences, including brain damage and death. About 2,700 people in the United States are treated for accidental exposure to organophosphate pesticides every year. Eagle is currently evaluating Ryanodex for the treatment of brain damage secondary to nerve agent exposure. If approved, Ryanodex would represent the first product available for this indication.

On January 6, 2020, we issued a press release announcing a new research agreement with NorthShore University HealthSystem in Evanston, Illinois, focused on studying Ryanodex for traumatic brain injury (TBI) in animal models. TBI can acutely cause brain lesions that result in direct tissue damage that may prompt apoptotic cell mechanisms for several weeks post-injury, which may lead to worsened long-term outcomes. Disruption of certain intracellular mechanisms may affect cell functioning and survival.

Fulvestrant

On October 30, 2018, the Company announced that the Company’s fulvestrant formulation has not met the primary pharmacokinetic endpoint evaluating the bioequivalence of the Company’s formulation compared to Faslodex in its open label, randomized, pharmacokinetic and safety study conducted in 600 healthy female volunteers across multiple U.S. sites. On May 7, 2019, the Company announced positive results of its study to evaluate the neuroprotective effects of Ryanodex secondary to nerve agent exposure, conducted with the United States Army Medical Research Institute of Chemical Defense.

PEMFEXY

On February 1, 2022, the Company announced the commercial availability of its novel product PEMFEXY™ (pemetrexed for injection) in the United States. A branded alternative to ALIMTA®, PEMFEXY is a ready-to-use liquid with a unique J-code, approved to treat nonsquamous non-small cell lung cancer and mesothelioma.

Previously, in February 2020, the Company received final approval from the FDA of its NDA for PEMFEXY, following the settlement agreement of patent litigation with Eli Lilly and Company (NYSE: LLY) in December 2019. The agreement provided for a release of all claims by the parties and allowed for an initial entry of PEMFEXY into the market (equivalent to approximately a three-week supply of ALIMTA utilization) on February 1, 2022 and a subsequent uncapped entry on April 1,

2022. Under the settlement agreement, we will pay a royalty equal to one percent of the net sales of PEMFEXY during the royalty term, which will end no later than May 24, 2022.

Tyme

On January 7, 2020, Tyme Technologies, Inc. and the Company announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. SM-88 was an investigational agent in two Phase 2 studies for pancreatic cancer and in a Phase 2 study for prostate cancer.

On January 26, 2022, Tyme announced the discontinuation of SM-88 with methoxsalen, phenytoin, and sirolimus in a trial for metastatic pancreatic cancer. On February 11, 2022, Tyme stated SM-88 is being evaluated in a Phase II study evaluating SM-88 in breast cancer (HR+/HER2-), as well as continuing enrollment of a Phase II study in high-risk metastatic sarcomas.

2. Summary of Significant Accounting Policies

Significant Risks and Uncertainties

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on our business, such as remote working policies, facilitating management's periodic communication to address employee and business concerns and providing frequent updates to our Board of Directors ("Board"). During the second quarter of 2021, we implemented a plan to reopen our office to allow employees to return to the office, with a focus on employee safety and optimal work environment. Our management continues to monitor and evaluate such plans as the pandemic continues to evolve. We anticipate that the COVID-19 pandemic may also have an impact on the clinical development timelines for certain of our clinical programs. We also anticipate that the COVID-19 pandemic may have an impact on our supply chain. The COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically lead to a continuing reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. In addition, the COVID-19 pandemic has delayed the timing of certain litigation and we anticipate that such delays will continue for the duration of the pandemic. The extent to which the COVID-19 pandemic will continue to impact our business, clinical development and regulatory efforts, supply chain and sales efforts, corporate development objectives and the value of, and market for, our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic have impacted our operations and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we are subject to other challenges and risks specific to our business and our ability to execute on our business plan and strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with research and development operations, including, without limitation, risks and uncertainties associated with: delays or problems in obtaining clinical supply; obtaining regulatory approval of product candidates; loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or product candidates; product development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing intellectual property rights; and the challenges of complying with applicable regulatory requirements. In addition, as the ongoing COVID-19 pandemic affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

Use of Estimates

These financial statements are presented in U.S. dollars and are prepared in accordance with U.S. GAAP. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements including disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period and accompanying notes. Our critical accounting policies are those that are both most important to our financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We anticipate that the COVID-19 pandemic will continue to disrupt our supply chain and marketing and sales efforts for certain of our products, including Bendeka, although it is not currently expected that any disruption would be significant. As of the date of issuance of these financial statements, we are not aware of any specific event or circumstance that would require us to update our estimates, assumptions and judgments or revise the carrying value of our assets or liabilities. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the financial statements, actual results may materially vary from these estimates, and any such differences may be material to our financial statements.

Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which generally is at the time we ship the product to the customer. Provisions for chargebacks, rebates, discounts, and returns are established in the same period the related sales are recognized. Significant judgments must be made in determining the transaction price for our sales of products related to anticipated rebates, discounts and returns. Refer below for further details.

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation, including for amounts related to accounts receivable, net and prepaid expenses and other current assets. None of the amounts pertaining to the reclassifications were significant.

Cash and Cash Equivalents

The Company considers cash and cash equivalents to be highly liquid investments with an original maturity of three months or less from the date of purchase. All cash and cash equivalents are held in United States financial institutions. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

We, at times, maintain balances with financial institutions in excess of the Federal Deposit Insurance Corporation limit.

Fair Value Measurements

U.S. GAAP establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes the following 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:

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

The fair value of interest-bearing cash, cash equivalents, accounts receivable and accounts payable approximate fair value due to their life being short term in nature, and are classified as Level 1 for all periods presented.

(In thousands, except as indicated and share and per share amounts)

The following tables present the Company's hierarchy for its assets measured at fair value as of December 31, 2021 and 2020:

	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 57,357	$ 57,357	$ —	$ —
Convertible promissory note	4,021	—	—	4,021
Embedded derivative asset in convertible promissory note	962	—	—	962
Investment in Tyme	6,030	6,030	—	—
Total financial assets	$ 68,370	$ 63,387	$ —	$ 4,983

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 79,682	$ 79,682	$ —	$ —
Investment in Tyme	12,200	12,200		
Total financial assets	$ 91,882	$ 91,882	$ —	$ —

The Company recognizes transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no transfers in or out of Level 1, Level 2 or Level 3 during the years ended December 31, 2021 and 2020, respectively.

Our investment in the convertible promissory note and the embedded derivative are classified as Level 3. We analyzed and assessed the embedded derivative feature contained in the convertible promissory note agreement. We used a probability factor to value the embedded derivative asset based on management's best estimate, including the principal and estimated accrued interest among other contractual terms. The convertible promissory note is accounted for as available for sale. The convertible promissory note is reported at fair value with unrealized gains and losses included in Accumulated other comprehensive income (loss). Refer to Note 14, Convertible Promissory Note for further details.

Our investment in restricted shares of common stock of Tyme Technologies, Inc. (“Tyme”) are classified as Level 1. Refer to Note 9, "License and Collaboration Agreements" for further details.

The fair value of debt is classified as Level 2 for the periods presented and approximates its fair value due to the variable interest rate.

Intangible Assets

Finite-lived intangible assets are measured at their respective fair values on the date they were recorded at the date of subsequent adjustments of fair value and stated net of accumulated amortization. The fair values assigned to the Company's intangible assets are based on reasonable estimates and assumptions given available facts and circumstances. The Company amortizes its definite-lived intangible assets using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows.

The Company reviews the recoverability of its finite-lived intangible assets and long-lived assets for indicators of impairments. Events or circumstances that may require an impairment assessment significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to

(In thousands, except as indicated and share and per share amounts)

expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. If such indicators are present, the Company assesses the recoverability of affected assets by determining if the carrying value of such assets is less than the sum of the undiscounted future cash flows of the assets. If such assets are found to not be recoverable, the Company measures the amount of the impairment by comparing the carrying value of the assets to the fair value of the assets. The Company determined that no indicators of impairment of finite-lived intangible assets or long-lived assets existed as of December 31, 2021.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition. Goodwill is not amortized, but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if events or changes in circumstances indicate that the fair value of the reporting unit's goodwill is less than it's carrying amount. The Company performed a qualitative annual test for goodwill as of October 1, 2021. During the year ended December 31, 2021, the Company concluded that no impairment exists.

Concentration of Major Customers and Vendors

The Company is dependent on its commercial partner to market and sell Bendeka; therefore, the Company's future revenues are highly dependent on the collaboration and distribution arrangement with Teva.

Teva markets Bendeka through a license agreement with the Company. Pursuant to that license agreement, Teva pays the Company a royalty based on net sales of the product and also purchases the product from the Company. A disruption in this arrangement, caused by, among other things, a supply disruption, loss of exclusivity or the launch of a superior product would have a material adverse effect of the Company's financial position, results of operations and cash flows.

The total revenues and accounts receivables broken down by major customers as a percentage of the total are as follows:

	Year Ended December 31,		
	2021	2020	2019
Net revenues			
Cephalon, Inc. (Teva) - See Revenue Recognition	66 %	67 %	77 %
Other	34 %	33 %	23 %
	100 %	100 %	100 %

	December 31,	
	2021	2020
Accounts receivable		
Cephalon, Inc. (Teva) - See Revenue Recognition	63 %	58 %
Other	37 %	42 %
	100 %	100 %

Inventories

Inventories are recorded at the lower of cost and net realizable value, with cost determined on a first-in first-out basis. The Company periodically reviews the composition of its inventories in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventories, the Company will record a write-down to net realizable value in the period that the decline in value is first recognized.

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded over the estimated useful lives of the assets utilizing the straight-line method. Leasehold improvements are being amortized over the shorter of their useful lives or the lease term.

Research and Development Expense

Costs for research and development are charged to expense as incurred and include; employee-related expenses including salaries, benefits, travel and stock-based compensation expense for research and development personnel; expenses incurred under agreements with contract research organizations, contract manufacturing organizations and service providers that assist in conducting clinical and preclinical studies; costs associated with preclinical activities and development activities, costs associated with regulatory operations; and depreciation expense for assets used in research and development activities.

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the consolidated financial statements as prepaid expenses or accrued expenses as deemed appropriate.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were $2.6 million, $2.7 million, and $2.4 million for the year ended December 31, 2021, 2020, and 2019, respectively.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 740 - Income Taxes (“ASC 740”). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is “more likely than not” that all or a portion of deferred tax assets will not be realized. ASC 740 also prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Revenue Recognition

Revenue 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. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product revenue - The Company recognizes net revenue on sales to its commercial partners and to end users. In each instance, revenue is generally recognized when the customer obtains control of the Company’s product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price generally utilizing the expected value method to which

the Company expects to be entitled. As such, revenue on sales to end users for Belrapzo and Ryanodex are recorded net of chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions. Our products are contracted with a limited number of oncology distributors and hospital buying groups with narrow differences in ultimate realized contract prices used to estimate our allowance for chargebacks and rebate reserves. The Company has a product returns policy on some of its products that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product's expiration date. The Company's estimate of the provision for returns is analyzed quarterly and is based upon many factors, including historical experience of actual returns and analysis of the level of inventory in the distribution channel, if any. The Company has terms on sales of Ryanodex by which the Company does not accept returns. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration are made generally using the expected value method and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

Components of Gross-to-Net (GTN) Estimates

Chargebacks: Chargebacks are discounts that occur when certain contracted customers, including group purchasing organizations ("GPOs"), public health service institutions and federal government entities purchasing via the Federal Supply Schedule, purchase from the Company's distributors. The Company's distributors purchase product from us at invoice price, then resell the product to certain contracted customers on the basis of prices negotiated between us and the providers. The difference between the distributors' purchase price and the typically lower certain contracted customers' purchase price is refunded to the distributors through a chargeback credit. We record estimates for these chargebacks at the time of sale as deductions from gross revenues, with corresponding adjustments to our accounts receivable reserves and allowances.

The provision for chargebacks is the most significant provision in the context of the Company's gross-to-net adjustments in the determination of net revenue. Chargebacks are estimated based on payer mix and contracted price, adjusted for current period assumptions.

Commercial and Medicaid Rebates: The Company contracts with government agencies or collectively, third-party payors, so that Belrapzo and Ryanodex will be eligible for purchase by, or partial or full reimbursement from, such third-party payors. The Company estimates the rebates it will provide to third-party payors and deducts these estimated amounts from total gross product revenues at the time the revenues are recognized. These reserves are recorded in the same period in which the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. The current liability is included in accrued expenses and other current liabilities on the consolidated balance sheets. The Company estimates the rebates that it will provide to third-party payors based upon (i) the Company's contracts with these third-party payors, (ii) the government mandated discounts applicable to government-funded programs, (iii) a range of possible outcomes that are probability-weighted for the estimated payer mix, and (iv) information obtained from the Company's distributors.

The information that the Company also considers when establishing its rebate reserves are purchases by customers, projected annual sales for customers, actual rebates payments made, processing time lags, and for indirect rebates, the level of inventory in the distribution channel that will be subject to indirect rebates. We do not provide incentives designed to increase shipments to our customers that we believe would result in out-of-the-ordinary course of business inventory for them. The Company regularly reviews and monitors estimated or actual customer inventory information at its largest distributors for its key products to ascertain whether customer inventories are in excess of ordinary course of business levels.

Product Returns: The Company's provision for product returns based on the factors noted above generally encompass a time range from 12 to 48 months after revenue is recognized. The Company's distributors have the right to return unopened unprescribed Belrapzo during certain time periods around the period beginning prior to the labeled expiration date and ending after the labeled expiration date. The Company estimates future product returns on sales of Belrapzo based on: (i) data provided to the Company by its distributors (including weekly reporting of distributors' sales and inventory held by distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iii) historical industry information regarding return rates for similar pharmaceutical products, (iv) the estimated remaining shelf life of Belrapzo previously shipped and currently being shipped to distributors and

(v) contractual agreements intended to limit the amount of inventory maintained by the Company's distributors. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets.

Wholesaler fees and other incentives: The Company generally provides invoice discounts on Belrapzo and Ryanodex sales to its distributors for prompt payment and fees for distribution services, such as fees for certain data that distributors provide to the Company. The payment terms for sales to distributors generally include a 2% discount for prompt payment which is generally defined in invoice terms as a range from 15 to 45 days, while the fees for distribution services are based on contractual rates agreed with the respective distributors. Based on historical data, the Company expects its distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

The Company recorded product sales, net as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Bendeka	$ 11,167	$ 15,439	$ 31,182
Belrapzo	23,728	27,527	29,665
Ryanodex	25,271	28,268	13,039
Other	4,857	1,089	103
Product sales, net	$ 65,023	$ 72,323	$ 73,989

The following table provides a summary roll-forward of the Company's net product revenue allowances and related reserves for the years ended December 31, 2021 and 2020, on the consolidated balance sheets (in thousands):

	Chargebacks	Commercial Rebates	Medicaid Rebates	Product Returns	Wholesaler Fees and Other Incentives	Total
Balance at December 31, 2019	$ 2,988	$ 1,131	$ 567	$ 2,403	$ 2,011	$ 9,100
Provisions / Adjustments	20,368	1,243	484	(391)	8,526	30,230
Charges processed / Payments	(21,067)	(602)	(367)	(346)	(5,146)	(27,528)
Balance at December 31, 2020	$ 2,289	$ 1,772	$ 684	$ 1,666	$ 5,391	$ 11,802
Provisions / Adjustments	27,402	3,042	268	2,531	9,650	42,893
Charges processed / Payments	(25,852)	(2,838)	(332)	(2,674)	(13,070)	(44,766)
Balance at December 31, 2021	$ 3,839	$ 1,976	$ 620	$ 1,523	$ 1,971	$ 9,929

Such net product revenue allowances and reserves are included within accounts receivable, net and accrued expenses and other current liabilities within the consolidated balance sheets.

Royalty Revenue — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 25 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter and subsequently determines a true-up when it receives royalty reports from its commercial partners. Historically, these true-up adjustments have been immaterial. Our receivables from royalty revenue are due 45-days from the end of the quarter.

License and other revenue — The Company analyzes each element of its licensing agreements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determined that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, the Company will not recognize revenue from the milestone until there is not a high probability of a reversal of revenue, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2021.

Stock-Based Compensation

The Company utilize stock-based compensation in the form of stock options, restricted stock units ("RSUs") and performance-based stock units ("PSUs"), each of which may be granted separately or in tandem with other awards.

Compensation expense is recognized in the Consolidated Statements of operations based on the estimated fair value of the awards at grant date ratably over the requisite service period, which generally equals the vesting period of the award.

The grant-date fair value of stock awards is based upon the underlying price of the stock on the date of grant. The grant-date fair value of stock option awards must be determined using an option pricing model. The Company uses the Black-Scholes option pricing formula for determining the grant-date fair value of such awards. Option pricing models require the use of estimates and assumptions as to (a) the expected term of the option, (b) the expected volatility of the price of the underlying stock and (c) the risk-free interest rate for the expected term of the option.

The Company may also grant performance-based stock awards to employees from time-to-time in form of market condition or performance condition. The grant-date fair value of awards that vest based on achievement of certain market condition are determined using a Monte Carlo simulation technique. The grant-date fair value of awards that vest based on achievement of certain performance condition are determined using the accelerated attribution method once it is probable that the performance condition will be achieved.

Earnings Per Share

Basic earnings per common share is computed using the weighted average number of shares outstanding during the period. Diluted earnings per share is computed in a manner similar to the basic earnings per share, except that the weighted-average number of shares outstanding is increased to include all common shares, including those with the potential to be issued by virtue of options. Diluted earnings per share contemplate a complete conversion to common shares of all convertible instruments only if they are dilutive in nature with regards to earnings per share, as calculated under the treasury method.

(In thousands, except as indicated and share and per share amounts)

The anti-dilutive common shares equivalents outstanding at December 31, 2021, 2020, and 2019 were as follows:

	Year Ended December 31,		
	2021	2020	2019
Options	2,336,586	2,767,501	2,454,077
Restricted stock units	98,416	207,177	—
Total	2,435,002	2,974,678	2,454,077

The following table sets forth the computation for basic and diluted net (loss) income per share for December 31, 2021, 2020, and 2019:

	Year Ended December 31,		
	2021	2020	2019
Numerator			
Numerator for basic and diluted earnings per share-net (loss) income	$ (8,627)	11,989	$ 14,313
Denominator			
Basic weighted average common shares outstanding	13,051,095	13,481,525	13,754,516
Dilutive effect of stock options	—	289,868	384,217
Diluted weighted average common shares outstanding	13,051,095	13,771,393	14,138,733
Basic net (loss) income per share			
Basic net (loss) income per share	$ (0.66)	$ 0.89	$ 1.04
Diluted net (loss) income per share			
Diluted net (loss) income per share	$ (0.66)	$ 0.87	$ 1.01

All potentially dilutive items were excluded from the diluted share calculation for the year ended December 31, 2021 because their effect would have been anti-dilutive, as the Company was in a loss position.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In March 2020, the FASB issued Update 2020-04 Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting to provide temporary optional guidance to ease the potential burden in accounting for reference rate reform. The amendments in Update 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR, formerly known as the London Interbank Offered Rate,
or another reference rate expected to be discontinued due to reference rate reform. The new guidance provides optional expedients, including; (1) Simplify accounting analyses under current GAAP for contract modifications, such as modifications of contracts within the scope of Topic 470, Debt, that will be accounted for by prospectively adjusting the effective interest rate, as if any modification was not substantial. That is, the original contract and the new contract shall be accounted for as if they were not substantially different from one another; (2) Simplify the assessment of hedge effectiveness and allow hedging relationships affected by reference rate reform to continue; (3) Allow a one-time election to sell or transfer debt securities classified as held to maturity before January 1, 2020 that reference a rate affected by reference rate reform. The amendments are effective for all entities from the beginning of an interim period that includes the issuance date of the ASU. An entity may elect to apply the amendments prospectively through December 31, 2022. The adoption of ASU 2020-4 is not expected to have a material impact on the Company's financial position or results of operations.

CARES Act

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was signed into U.S. federal law, which is aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the

COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, includes provisions related to refundable payroll tax credits, deferment of the employer portion of social security payments, net operating loss carryback periods, modifications to the net interest deduction limitations, and technical corrections to tax depreciation methods for qualified improvement property. Reimbursement was not sought by the Company. The CARES Act has not had, and the Company does not currently expect it to have, a material impact on the Company's financial statements at this time.

(In thousands, except as indicated and share and per share amounts)

3. Inventories

The Company's inventory balance consists of the following:

	December 31,	
	2021	2020
Raw materials	$ 7,317	$ 3,515
Work-in-process	9,666	2,589
Finished goods	4,925	1,971
	$ 21,908	$ 8,075

(In thousands, except as indicated and share and per share amounts)

4. Property and Equipment, net

Property and equipment consists of the following:

	December 31,		Estimated Useful Life (years)
	2021	2020	
Furniture and fixtures	$ 1,525	$ 1,476	7
Office equipment	1,077	1,152	3
Equipment	3,834	3,485	7
Leasehold improvements	1,155	1,155	2
	7,591	7,268	
Less accumulated depreciation	(5,955)	(5,191)	
Property and equipment, net	$ 1,636	$ 2,077	

Depreciation expense was $764 and $872 for the years ended December 31, 2021 and 2020, respectively.

(In thousands, except as indicated and share and per share amounts)

5. Balance Sheet Accounts

Prepaid expenses and Other Current Assets

Prepaid and other current assets consist of the following:

	December 31,	
	2021	2020
Advances to commercial manufacturers	$ 942	$ 660
Prepaid FDA user fee and advances to CROs	1,108	1,262
Prepaid insurance	196	191
Prepaid income taxes	1,173	—
Convertible promissory note, net	5,312	—
All other	3,159	1,605
Total Prepaid expenses and other current assets	$ 11,890	$ 3,718

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

	December 31,	
	2021	2020
Royalties payable to commercial partners	$ 5,085	$ 5,996
Accrued research & development	4,100	2,724
Accrued professional fees	2,013	2,370
Accrued salary and other compensation	8,466	4,686
Accrued product sales reserves	4,390	4,966
Current portion of lease liability	1,309	1,123
All other	6,975	1,952
Total Accrued expenses and other liabilities	$ 32,338	$ 23,817

Leases

We lease office space in Woodcliff Lake, New Jersey for our principal office under an amended lease agreement through June 2025. We also lease a lab space in Cambridge, Massachusetts under a lease agreement through April 2024, and a new office space located in Palm Beach Gardens, FL. The new lease agreement commenced on November 1, 2021 and will expire 36 months from the lease commencement date, which is October 31, 2024. All of our leases are classified as operating leases and have remaining lease terms of approximately 3.1 years. The principal office and the lab space leases include renewal options to extend the lease for up to 5 years. Furthermore, we have not elected the practical expedient to separate lease and non-lease components for all classes of underlying assets.

The table below summarizes the Company's total lease costs included in the consolidated financial statements, as well as other required quantitative disclosures (in thousands):

	As of December 31,	
	July 13, 1905	July 12, 1905
Operating lease cost	$ 1,407	$ 1,323
Total lease cost	$ 1,407	$ 1,323
Other information:		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	$ 1,407	$ 1,323
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 270	$ 855
Weighted-average remaining lease term - operating leases	3.1 years	4.1 years
Weighted-average discount rate - operating leases	6.0 %	6.0 %

Year Ending December 31,	Operating Leases
2022	1,423
2023	1,455
2024	1,038
2025	413
Thereafter	—
Total	4,329
Less: present value discount	(116)
Present value of lease liabilities	$ 4,213
Balance Sheet Classification as of December 31, 2021	
Current lease liabilities (included with Accrued expenses and other liabilities)	$ 1,309
Long-term lease liabilities (included with Other long-term liabilities)	2,904
Total lease liabilities	$ 4,213

6. Debt

On November 8, 2019, the Company entered into the Second Amended and Restated Credit Agreement (the “Revised Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which replaced the Company’s existing credit agreement, dated as of August 8, 2017 (the "Amended Credit Agreement"). The terms and amounts borrowed under the Revised Credit Agreement includes a drawn term loan of $40 million and a undrawn revolving credit facility of $110 million. The schedule of principal payments for the new term loan facility has been extended until November 8, 2022. The Company classified the current portion of long-term debt of $26 million on the consolidated balance sheet as of December 31, 2021. Per the terms of the Revised Credit Agreement, the Company is limited in its ability to pay dividends. As of December 31, 2021, the Company was in compliance with each of the senior secured net leverage ratio; total net leverage ratio; and fixed charge coverage ratio covenants.

The new term loan facility shall bear interest at the Adjusted LIBOR (equal to (a) the LIBOR for such Interest Period multiplied by (b) the Statutory Reserve Rate as established by Board of Governors of the Federal Reserve System of the United States of

(In thousands, except as indicated and share and per share amounts)

America) for the Interest Period in effect for such Borrowing plus the Applicable Rate as described below. The Agent and the Company may amend the Revised Credit Agreement to replace the LIBOR with a Benchmark Replacement, described below.

Loans under the Revised Credit Agreement bear interest at a rate equal to either (a) the LIBOR rate, plus an applicable margin ranging from 2.25% to 3.0% per annum, based upon the total net leverage ratio (as defined in the Revised Credit Agreement), or (b) the Benchmark Replacement which is defined as the greatest of the prime lending rate, or the NYFRB Rate (the rate for a federal funds transaction) in effect on such day plus ½ of 1% or the Adjusted LIBO Rate for a one month Interest Period on such day plus 1% plus an applicable margin ranging from 1.25% to 2.0% per annum, based upon the total net leverage ratio. The Company is required to pay a commitment fee on the unused portion of the new revolving credit facility in the Revised Credit Agreement at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio.

As of December 31, 2021, the Company had $0.4 million of unamortized deferred debt issuance costs in its consolidated balance sheets.

Debt Maturities	As of December 31, 2021
2022	$ 26,000
Total	$ 26,000

7. Common Stock and Stock-Based Compensation

Common Stock

On March 17, 2020, the Company, announced that its Board approved a new share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of $160.0 million of the Company’s outstanding common stock. The Share Repurchase Program replaced the Company’s then existing share repurchase program, or the Previous Share Repurchase Program, which was announced on October 30, 2018 and was terminated in connection with the Board’s approval of the Share Repurchase Program. At termination, the Company had repurchased approximately $68.0 million of the Company’s outstanding common stock under the Previous Share Repurchase Program.

Under the Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Exchange Act. The repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company’s cash resources.

On September 23, 2020, the Company's Board of Directors approved a $25.0 million accelerated share repurchase (“ASR”) transaction with JPMorgan Chase Bank, National Association (“JP Morgan”) as part of the Company’s existing $160.0 million share repurchase program. The specific number of shares to be repurchased pursuant to the ASR is based on the average of the daily volume weighted average share prices of the Company’s common stock, less a discount, during the term of the ASR program. Under the terms of the Company's agreement with JP Morgan, the Company paid $25.0 million to JP Morgan on September 24, 2020, and received 550,623 shares, representing the notional amount of the ASR, based on the average of the daily volume weighted average share prices of the Company’s common stock, less a discount, during the term of the ASR, which was $45.40. The ASR was completed in the fourth quarter of 2020. The Company determined the ASR contained a forward contract and therefore the Company recorded fair value adjustments on the accelerated share repurchase agreement in the amount of $3.0 million which was a loss recorded in Other expense on our consolidated statements of operations in the year ended December 31, 2020.

As of December 31, 2021, the Company had repurchased an aggregate of 4,111,622 shares of common stock for an aggregate of $228.1 million pursuant to the Company’s share repurchase programs in effect since August 2016.

(In thousands, except as indicated and share and per share amounts)

We repurchased the following shares of common stock with cash resources:

	Year Ended December 31,		
	2021	2020	2019
Shares of common stock repurchased	429,446	774,489	317,429
Cash paid for repurchases of common stock	$ 21,213	$ 34,999	$ 17,961

Stock-Based Compensation

In December 2007, the Company's board of directors approved the 2007 Incentive Compensation Plan (the "2007 Plan") enabling the Company to grant multiple stock-based awards to employees, directors and consultants, the most common being stock options and restricted stock awards. In November 2013, the Company's board of directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2007 Plan was terminated upon the effectiveness of the 2014 Plan and all shares available for issuance under the 2007 Plan were made available under the 2014 Plan. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based awards. Awards generally vest equally over a period of four years from grant date. Vesting is accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited. At the Company's annual meeting of stockholders held on August 4, 2015, the stockholders approved an amendment to the 2014 Plan to, among other things, increase the number of shares of common stock authorized for issuance thereunder by 500,000 shares. After accounting for such increase, and as of such amendment, the Company has reserved and made available 1,934,193 shares of common stock for issuance under the 2014 Plan.

During the year ended December 31, 2018, the Company introduced a new long-term incentive program with the objective to better align the share-based awards granted to management with the Company's focus on improving total shareholder return over the long-term. The share-based awards granted under this long-term incentive program consist of time-based stock options, time-based restricted stock units ("RSUs") and performance-based stock units ("PSUs"). PSUs are comprised of awards that vest upon achievement of certain share price appreciation conditions. These share-based awards expired in January 2021.

Stock Options

The fair value of stock options granted to employees, directors, and consultants is estimated using the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Risk-free interest rate	0.51% - 1.26%	0.37% - 1.65%	1.42% - 2.61%
Volatility	52.87% - 60.02%	54.89% - 55.51%	40.83%
Expected term (in years)	5.50 - 6.08 years	5.50 - 6.08 years	1.51 - 9.41 years
Expected dividend yield	0.0%	0.0%	0.0%

The following table summarizes information about stock option activity related to the 2014 Plan:

	Number of Stock Option Shares	Weighted Average Exercise Price (Per Share)	Non-Exercisable	Exercisable
Outstanding at December 31, 2019	**3,096,161**	**$ 59.29**	**1,070,054**	**2,026,107**
Granted	762,200	$ 55.76		
Exercised	(149,473)	$ 24.43		
Forfeited or expired	(376,998)	$ 66.71		
Outstanding at December 31, 2020	**3,331,890**	**$ 59.20**	**1,028,142**	**2,303,748**
Granted	114,000	$ 46.74		
Exercised	(122,847)	$ 27.64		
Forfeited or expired	(508,165)	$ 62.00		
Outstanding at December 31, 2021	**2,814,878**	**$ 58.51**	**472,916**	**2,341,962**

The weighted-average grant-date fair value of options granted during the year ended December 31, 2021, 2020, and 2019 was $23.62, $28.98, and $22.18, respectively. As of December 31, 2021, there was $8,853 unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.0 years. The total intrinsic value of options exercised during the year ended December 31, 2021 was $2,434.

The weighted average contractual terms of options outstanding as of December 31, 2021, 2020, and 2019 was 5.2, 6.1, and 6.8 years, respectively.

The aggregate pre-tax intrinsic value of options outstanding as of December 31, 2021, 2020, and 2019 was $13.8 million, $11.6 million, and $31.9 million, respectively.

RSUs

Each vested time-based RSU represents the right of a holder to receive one of the Company's common shares. The fair value of each RSU granted was estimated based on the trading price of the Company's common shares on the date of grant.

The following table summarizes information about RSU activity related to the 2014 Plan:

	Number of Restricted Stock Units		Weighted Average Grant Date Fair Value (Per Share)
Non-vested at December 31, 2019	**251,215**	**$**	**44.84**
Granted	236,450	$	59.48
Vested	(79,420)	$	46.78
Forfeited	(79,849)	$	52.76
Non-vested at December 31, 2020	**328,396**	**$**	**53.09**
Granted	106,600	$	48.55
Vested	(95,523)	$	52.26
Forfeited	(76,167)	$	52.29
Non-vested at December 31, 2021	**263,306**	**$**	**51.77**

As of December 31, 2021, there was $7,562 of unrecognized stock-based compensation expense related to non-vested RSUs

(In thousands, except as indicated and share and per share amounts)

that is expected to be recognized over a weighted average period of 2.3 years.

PSUs

During the first quarter of 2018, we introduced a new long-term incentive program with the objective to better align the stock-based awards granted to management with our focus on improving total shareholder return over the long-term. The stock-based awards granted under this long-term incentive program consist of time-based stock options, time-based RSUs and PSUs. PSUs are comprised of awards: i) that would have vested upon achievement of certain share price appreciation conditions or ii) that would have vested upon achievement of certain milestone events. These PSUs expired in the first quarter of 2021.

During the first quarter of 2021, 97,750 market condition PSUs expired. We also granted 99,500 market condition PSUs based on our total shareholder return ("TSR") relative to the TSR of each member of the S&P Biotechnology Select Industry Index (the defined peer group) with a weighted-average grant date fair value of $71.09 per respective PSU. The fair value of PSUs granted to employees was estimated using a Monte Carlo simulation model. Inputs used in the calculation include a risk-free interest rate of 0.18%, an expected volatility of 44%, contractual term of 3 years, and no expected dividend yield.

During the first quarter of 2021, we also granted 59,500 performance based (milestones) PSUs with grant date fair value of $49.32 using our closing stock price on the date of the grant. These PSUs will vest (if earned) from 0% to 200% of target number granted based on the achievement of one or more of three milestones related to i) regulatory approval of Fulvestrant ("EA-114"), ii) sales of Pemfexy and; iii) sales of Vasopressin, respectively. The contractual term of these awards is 3 years. We estimated 0% probability of achievement for the year ended December 31, 2021.

The following table summarizes information about PSU activity related to the 2014 Plan:

	Number of Performance Stock Units		Weighted Average Grant Date Fair Value (Per Share)
Non-vested at December 31, 2019	**116,181**	**$**	**90.19**
Granted	**—**	**$**	**—**
Vested	**—**	**$**	**—**
Forfeited	(18,431)	$	90.19
Non-vested at December 31, 2020	**97,750**	**$**	**90.19**
Granted	159,000	$	62.94
Vested	**—**	**$**	**—**
Forfeited	(119,450)	$	84.90
Non-vested at December 31, 2021	**137,300**	**$**	**63.24**

(In thousands, except as indicated and share and per share amounts)

The Company recognized stock-based compensation in its consolidated statements of operations for the year ended December 31, 2021, 2020, and 2019 as follows:

	Year Ended December 31,		
	2021	2020	2019
Stock options	$ 11,521	$ 17,694	$ 16,394
PSUs	2,729	1,635	3,062
RSUs	5,305	5,427	2,542
Stock-based compensation expense	$ 19,555	$ 24,756	$ 21,998
Selling, general and administrative	$ 16,873	$ 22,074	$ 17,556
Research and development	2,682	2,682	4,442
Stock-based compensation expense	$ 19,555	$ 24,756	$ 21,998

(In thousands, except as indicated and share and per share amounts)

8. Income Taxes

The components of our provision from income taxes is as follows:

	Year Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ 6,912	$ 10,140	$ 6,689
State	785	2,059	844
	$ 7,697	$ 12,199	$ 7,533
Deferred:			
Federal	(3,030)	(1,227)	392
State	(588)	(284)	(240)
	$ (3,618)	$ (1,511)	$ 152
Provision for income taxes	$ 4,079	$ 10,688	$ 7,685

The reconciliation of the statutory U.S. Federal income tax rate to the Company's effective income tax rate is as follows;

	Year Ended December 31,		
	2021	2020	2019
U.S. Federal statutory tax rate	21 %	21 %	21 %
State income taxes, net of federal benefit	(1)%	6 %	2 %
Tax effect on stock option exercises, net of forfeitures	(44)%	4 %	1 %
R&D tax credits and Orphan Drug credits	31 %	(2)%	(2)%
Limitation on executive compensation	(60)%	9 %	10 %
Change in valuation allowance	(40)%	9 %	4 %
Foreign rate differential	4 %	(1)%	(2)%
Other	(1)%	1 %	1 %
Effective tax rate	(90)%	47 %	35 %

The effective tax rate for the year ended December 31, 2021, reflects certain non-deductible executive compensation, tax effect on stock option exercises, net of forfeitures and valuation allowance established on the deferred tax asset for an unrealized capital loss in our investment in Tyme partially offset by credits for research and development activities.

(In thousands, except as indicated and share and per share amounts)

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets were as follows:

	December 31,	
	2021	2020
Deferred tax assets		
Net operating loss carryforward	$ 1,563	$ 841
Stock based compensation	10,405	12,015
Other asset - equity investment with readily determined fair value	3,190	1,771
Inventories	2,123	2,338
Employee-related expenses	1,240	51
Intangible assets	4,207	708
Right-of-use liability	962	1,154
R&D tax credit carryforwards	329	86
Other	1,489	1,216
Total deferred tax assets	25,508	20,180
Deferred tax liabilities		
Installment sale - Malta	485	483
Prepaid expenses	45	43
Fixed assets	300	315
Lease liability	921	1,092
Total deferred tax liabilities	1,751	1,933
Valuation allowance	(4,959)	(3,067)
Net deferred tax assets	$ 18,798	$ 15,180

In July 2006, the Financial Accounting Standards Board (“FASB”) issued ASC 740-10, Uncertainty in Income Taxes, which defines the threshold for recognizing the benefits of tax-return positions in the financial statements as “more-likely-than-not” to be sustained by the taxing authorities. This statement also requires explicit disclosure requirements about a Company’s uncertainties related to their income tax position, including a detailed roll forward of tax benefits taken that do not qualify for financial statement recognition.

The Company files income tax returns in the U.S. federal jurisdiction and several states. The Company is under audit by the Internal Revenue Service and three states tax jurisdiction as of December 31, 2021. The Company has no amount recorded for any unrecognized tax benefits as of December 31, 2021. The Company regularly evaluates its tax positions for additional unrecognized tax benefits and associated interest and penalties, if applicable. There are many factors that are considered when evaluating these tax positions including: interpretation of tax laws, recent tax litigation on a position, past audit or examination history, and subjective estimates and assumptions.

As of December 31, 2021, the Company has a net operating loss ("NOL") carryforward in Malta of $4.5 million which has no expiration date and can be carried forward indefinitely until utilized.

9. License and Collaboration Agreements

License Agreements

License agreement with Combioxin

In August 2021, we entered into a license agreement with Combioxin, SA under which the Company was granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class antitoxin agent ready for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs. The Company will be solely responsible for the development, regulatory, manufacturing and commercialization activities of CAL02. Combioxin will assist the Company in transitioning the manufacturing and supply of CAL02 to the Company.

Under the terms of the agreement, we paid $10 million as upfront license consideration that was expensed immediately as research and development and is reflected within the operating activities of the condensed consolidated statements of cash flows. The Company may pay to Combioxin up to $105 million upon achievement of certain development, regulatory and sales based milestone payments plus royalty payments at royalty rates ranging in low double digit percentages on the net sales of all products sold, subject to certain adjustments as provided in the agreement. The Company is also obligated to make certain payments based upon amounts received by sublicensees under the agreement.

License agreement with AOP Orphan

In August 2021, we entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH (“AOP Orphan”), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We will support the submission of a new drug application (“NDA”) by AOP Orphan to the FDA seeking approval for landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia (“SVT”), including atrial fibrillation and atrial flutter.

Under the terms of the agreement, we paid $5 million as upfront license consideration that was expensed immediately as research and development and is reflected within the operating activities of the condensed consolidated statements of cash flows. The Company may pay to AOP Orphan up to $25 million upon achievement of certain regulatory milestone payments plus profit share payments, subject to certain adjustments as provided in the agreement. We also entered into a supply agreement at the same time as the licensing agreement.

Collaboration with Tyme

On January 7, 2020, Tyme and we announced a strategic collaboration to advance SM-88, an oral product candidate for the treatment of patients with cancer. SM-88 was an investigational agent in two Phase II studies, one for pancreatic cancer and another for prostate cancer.

On January 26, 2022, Tyme announced the discontinuation of SM-88 with methoxsalen, phenytoin, and sirolimus in a trial for metastatic pancreatic cancer. On February 11, 2022, Tyme stated SM-88 is being evaluated in a Phase II study evaluating SM-88 in breast cancer (HR+/HER2-), as well as continuing enrollment of a Phase II study in high-risk metastatic sarcomas

Under the terms of a related co-promotion agreement, we would be responsible for 25% of the promotional sales effort of SM-88 and would receive 15% royalty on the net revenues of SM-88 in the United States. Tyme is responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. Tyme retains the remaining 85% of net U.S. revenues and reserves the right to repurchase our U.S. co-promotion right for $200.0 million.

Our equity investment in Tyme is included in Other assets on our consolidated balance sheet. For the years ended December 31, 2021 and 2020, the fair value adjustments for the equity investment was a loss of $6.2 million and a loss of $5.3 million, respectively. These adjustments were recorded in Other (expense) income on our consolidated statements of operations.

(In thousands, except as indicated and share and per share amounts)

10. Commitments

Our future material contractual obligations include the following:

Obligation	Total	2022	2023	2024	2025
Operating leases (1)	$ 4,329	$ 1,423	$ 1,455	$ 1,038	$ 413
Credit facility	26,000	26,000	—	—	—
Purchase obligations (2)	69,549	69,549	—	—	—
Total obligations	$ 99,878	$ 96,972	$ 1,455	$ 1,038	$ 413

(1) We lease our corporate office location. On August 8, 2019, we amended the lease for our corporate office location in order to rent additional office space and extend the term of our existing lease to June 30, 2025. The Company also leases its lab space under a lease agreement that expires on April 30, 2024. We also lease office space located in Palm Beach Gardens, FL. The new lease agreement commenced on November 1, 2021 and will expire 36 months from the lease commencement date, which is October 31, 2024. Rental expense was $1,407, $1,323, and $1,146, for the years ended December 31, 2021, 2020, and 2019, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $4,329 as of December 31, 2021, payable monthly.

	December 31, 2021
Total operating lease payments	$ 4,329
Less: imputed interest	(116)
Total lease liabilities	$ 4,213

(2) As of December 31, 2021, the Company has purchase obligations in the amount of $69,549 which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligation under the supply agreement is primarily for finished product, inventory, and research and development.

11. Related Party Transaction

On May 10, 2019, Hudson Executive Capital LP ("Hudson Capital") sold 100,000 shares of the Company's common stock and the Company purchased those 100,000 shares in a block trade at a price of $56.14 per share. Douglas Braunstein is the Managing Partner of Hudson Capital and was a member of Eagle’s Board of Directors at the time of the transaction.

(In thousands, except as indicated and share and per share amounts)

12. Intangible Assets, Net

The gross carrying amounts and net book value of our intangible assets are as follows:

		December 31, 2021			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment Charges	Net Book Value
Ryanodex intangible	18.5	$ 15,000	$ (5,079)	$ —	$ 9,921
Developed technology	5	8,100	(8,100)	—	—
Vasopressin Milestone	1	750	—	—	750
Total		$ 23,850	$ (13,179)	$ —	$ 10,671

		December 31, 2020			
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment Charge	Net Book Value
Ryanodex intangible	20	15,000	(3,500)	—	11,500
Developed technology	5	8,100	(6,683)	—	1,417
Total		$ 23,100	$ (10,183)	$ —	$ 12,917

Amortization expense amounted to $3.0 million, $2.7 million, and $2.5 million, for the year ended December 31, 2021, 2020, and 2019, respectively.

Estimated Useful Lives

The Company reviews the estimated useful lives of its intangible assets on a periodic basis. The review indicated that the actual life of the Ryanodex intangible asset was shorter than the estimated useful life used for amortization purposes in the Company’s financial statements. As a result, the estimated useful life of the Ryanodex related intangible assets was shortened from 2036 to 2025. The change in the estimated useful life is considered a change in accounting estimate and will result in changes to the Company's amortization expense prospectively. As of December 31, 2021, the net carrying value of the Ryanodex related intangible assets was $9.9 million. The effect of this change in estimate increased the 2021 amortization expense by $0.4 million.

Impairment Assessment

The Company reviews the recoverability of its finite-lived intangible assets and long-lived assets for indicators of impairments. Events or circumstances that may require an impairment assessment include negative clinical trial results, a significant decrease in the market price of the asset, or a significant adverse change in legal factors or the manner in which the asset is used. If such indicators are present, the Company assess the recoverability of affected assets by determining if the carrying value of such assets is less than the sum of the undiscounted future cash flows of the assets. If such assets are found to not be recoverable, the Company measures the amount of the impairment by comparing to the carrying value of the assets to the fair value of the assets. The Company determined that no indicators of impairment of finite-lived intangible assets or long-lived assets existed at December 31, 2021 and 2020.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of December 31, 2021, and assuming that the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses are estimated as follows:

(In thousands, except as indicated and share and per share amounts)

	Estimated Amortization Expense
Year Ending December 31,	
2022	3,073
2023	2,785
2024	2,511
2025	2,302
All other	—
Total estimated amortization expense	$ 10,671

13. Legal Proceedings

In addition to the below legal proceedings, from time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters, or matters discussed below, will not have a material adverse effect on our business nor have we recorded any loss in connection with these matters because we believe that loss is neither probable nor estimable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

Cipla v. Eagle

On April 16, 2020, Cipla Limited ("Cipla") filed a request for arbitration against Eagle with the London Court of International Arbitration. The request alleges that Eagle's refusal to take delivery of several batches of Argatroban finished drug product constitutes a breach of the parties' December 14, 2012 supply agreement. Eagle believes that the allegations against it are without merit and is vigorously defending itself in the Arbitration, which is scheduled for April 2022.

Patent Litigation

Eagle Pharmaceuticals, Inc., et al. v. Slayback Pharma Limited Liability Company; Eagle Pharmaceuticals, Inc., et al. v. Apotex Inc. and Apotex Corp.; Eagle Pharmaceuticals, Inc., et al. v. Fresenius Kabi USA, LLC; Eagle Pharmaceuticals, Inc., et al. v. Mylan Laboratories Limited; Eagle Pharmaceuticals, Inc. et al. v. Hospira, Inc; Eagle Pharmaceuticals, Inc. et al. v. Lupin, Ltd. and Lupin Pharmaceuticals, Inc.; Teva Pharmaceuticals Int'l GmbH et al v. Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd.; Teva Pharmaceuticals Int'l GmbH et al v. Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd.; Teva Pharmaceuticals Int'l GmbH et al v. Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. - (BENDEKA®)

Bendeka, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Slayback Pharma Limited Liability Company ("Slayback"), Apotex Inc. and Apotex Corp. ("Apotex"), Fresenius Kabi USA, LLC ("Fresenius"), Mylan Laboratories Limited ("Mylan"), Lupin, Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin"), and Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd ("Aurobindo") have filed Abbreviated New Drug Applications ("ANDA's") referencing Bendeka® that include challenges to one or more of the Bendeka® Orange Book-listed patents. Hospira, Inc. ("Hospira") filed a 505(b)(2) NDA.

We, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the "Patentees"), filed separate suits against Slayback, Apotex, Fresenius, Mylan, Hospira, Lupin, and Aurobindo in the United States District Court for the District of Delaware on August 16, 2017 (Slayback ("Slayback I")), August 18, 2017 (Apotex), August 24, 2017 (Fresenius), December 12, 2017 (Mylan), January 19, 2018 (Slayback ("Slayback II")), July 19, 2018 (Hospira), and July 2, 2019 (Lupin) and May 11, 2020 (Aurobindo). In these Complaints, the Patentees allege infringement of the challenged patents, namely U.S. Patent Nos.

8,791,270 and 9,572,887 against Slayback (Slayback I and Slayback II), and of U.S. Patent Nos. 8,609,707, 8,791,270, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399 against Fresenius, Apotex, and Mylan, and of U.S. Patent Nos. 9,572,887, 10,010,533, 9,034,908, 9,144,568, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384 against Hospira, and of U.S. Patent Nos. 8,609,707, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399, 10,010,533, and 10,052,385 against Lupin and of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385 against Aurobindo. The parties stipulated to dismiss without prejudice U.S. Patent No. 8,791,270 as to Apotex, Fresenius and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018, respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively. On October 15, 2018, the Patentees filed a suit against Fresenius and Mylan in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 10,010,533 and 10,052,385. The Slayback I, Slayback II, Apotex, Fresenius and Mylan cases have been consolidated for all purposes (the “Consolidated Bendeka Litigation”), and a bench trial in these cases was held September 9-19, 2019. On April 27, 2020, the district court held that the asserted patents are valid and infringed by Slayback, Apotex, Fresenius and Mylan. On July 6, 2020, the district court entered a final judgment reflecting this decision, stating that pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA shall not approve Apotex’s, Fresenius’s, Mylan’s, or Slayback’s ANDA products on a date which is earlier than January 28, 2031, and enjoining Apotex, Fresenius, Mylan, and Slayback from commercially manufacturing, using, offering to sell, or selling within the US or importing into the US, their ANDA products before that date. On August 4, 2020, Apotex, Fresenius, and Mylan appealed this final judgment, and filed their opening briefs on November 4, 2020. Plaintiffs’ responsive appeal brief was filed on February 12, 2021. Defendants’ reply briefs were filed April 5, 2021. On August 2, 2021, Fresenius’s appeal was dismissed pursuant to a settlement agreement reached with Patentees. Oral argument for the remaining defendants occurred on August 3, 2021. On August 13, 2021, the appeals court affirmed the trial court’s decision. The mandate was issued on October 22, 2021. Apotex filed a petition for certiorari on December 14, 2021, which the Supreme Court denied on February 22, 2022.

Hospira filed a motion to dismiss, which was fully briefed on November 16, 2018. On December 16, 2019, the United States District Court for the District of Delaware denied Hospira’s motion to dismiss with respect to U.S. Patent No. 9,572,887 and granted that motion with respect to the remaining patents. On December 15, 2020, the Court held a claim construction hearing, ruling in our favor on all claim terms. Fact discovery closed on April 1, 2021. Expert discovery is ongoing. Trial has been rescheduled for April 25, 2022. The case remains pending.

Patentees filed suit against Hospira, Inc. on November 16, 2021. Patentees have asserted U.S. Patent No. 11,103,483. Hospira filed its Answer on December 8, 2021. Scheduling for the case is ongoing. The parties submitted disputed scheduling proposals on February 15, 2022, a decision on which is currently pending before the Court.

On March 10, 2020, the parties filed a stipulation and order of dismissal without prejudice as to Lupin, which the Court entered March 11, 2020.

Aurobindo answered the Complaint on July 20, 2020. The parties exchanged initial disclosures on December 11, 2020. Plaintiffs provided their infringement contentions on March 12, 2021. On October 20, 2021, the Court entered a stipulation of dismissal based on a settlement between the parties

Patentees filed suit against Dr. Reddy’s Laboratories on May 13, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. Dr. Reddy’s answer was filed August 16, 2021. On December 27, 2021, Dr. Reddy’s moved for judgment on the pleadings, seeking a dismissal of all patents except the ‘887 patent. On January 27, 2022, the Court entered an agreed stipulation by the parties dismissing all patents except the ‘887. On February 8, 2022, consistent with that stipulation, Patentees filed an Amended Complaint removing the dismissed patents and adding U.S. Patent No 11,103,483. Dr. Reddy’s filed its Answer and Counterclaims to that Amended Complaint on February 22, 2022. Patentees’ Counterclaim Answer is due March 15, 2022.Fact discovery is ongoing, and the case is set for trial on May 1, 2023.

Patentees filed suit against Accord Healthcare on June 29, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384,

10,010,533, and 10,052,385. On January 13, 2022, Accord filed a Motion to Dismiss for failure to state a claim. On January 26, 2022, Patentees filed a First Amended Complaint, removing all patents except the '887 patent and additionally asserting U.S. Patent No. 11,103,483. Accord filed its Answer and Counterclaims to that Amended Complaint on February 10, 2022. On February 28, 2022, Patentees filed their Answer to Accord's Counterclaims. Scheduling for the case is ongoing and a proposed schedule is due to the Court on March 16, 2022

*Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company - (*Belrapzo®)

Slayback filed an ANDA referencing Eagle's Belrapzo NDA. Slayback's ANDA includes challenges to one or more of the Belrapzo Orange Book-listed patents. On September 20, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797 and 10,010,533. On October 10, 2018, Slayback answered the Complaint and filed various counterclaims. On October 31, 2018, the Company answered Slayback's counterclaims. Pursuant to a stipulation between the parties, Slayback is bound by any final judgment entered in the Consolidated Bendeka Litigation. This case is currently stayed.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company, Apotex, Inc. and Apotex Corp., Celerity Pharmaceuticals, LLC - (BELRAPZO®)

Slayback, Apotex, and Celerity Pharmaceuticals, LLC ("Celerity") filed NDAs referencing Eagle's Belrapzo NDA. The Company filed suits against Slayback, Apotex, and Celerity in the United States District Court for the District of Delaware on August 31, 2021 (Slayback and Apotex) and on January 11, 2022 (Celerity) alleging infringement of U.S. Patent No. 11,103,483. On September 22, 2021, both Slayback and Apotex filed their Answers. The suit against Slayback and Apotex is set for trial on October 26, 2022, and fact discovery is ongoing. On February 2, 2022, Celerity moved to dismiss the pending complaint. In response, the Company filed an Amended Complaint on March 1, 2022. Celerity's response is due March 15, 2022.

Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc. (Vasopressin)

On May 31, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (together, "Par") filed suit against the Company in the United States District Court for the District of Delaware. Par alleged patent infringement based on the filing of the Company's ANDA seeking approval to manufacture and sell the Company's vasopressin product. The Company's vasopressin product, if approved by FDA, will be an alternative to Vasostrict, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The Company answered the complaint on August 6, 2018, and filed an amended answer and counterclaims on October 30, 2019. The court issued a Markman ruling on July 1, 2019. On December 20, 2019, Par dismissed with prejudice claims of three of the patents asserted against Eagle, and the Court entered an Order reflecting that dismissal on December 27, 2019. Mediation took place on March 3, 2020. On April 17, 2020, we submitted a letter requesting leave to file a motion for summary judgment of non-infringement. Par's responsive letter was submitted on May 8, 2020. On May 18, 2020, the court said it would hear non-infringement arguments at trial and not through summary judgment. Fact discovery ended in October 2019, and expert discovery ended in February 2020. Due to the COVID-19 pandemic, the trial, which was scheduled to begin May 18, 2020, was rescheduled to and occurred on July 7-9, 2021. Post-trial briefing was submitted on July 28, 2021. The Court issued an opinion on August 31, 2021 and entered a final judgment of non-infringement in favor of Eagle on September 16, 2021. Par filed a Notice of Appeal of the final judgment on September 22, 2021, and the appeal was docketed with the United States Court of Appeals for the Federal Circuit on September 23, 2021. Par filed its principal appeal brief on December 6, 2021, Eagle filed its responsive appeal brief on February 1, 2022, and Par filed its reply appeal brief on February 22, 2022. The 30-month stay of FDA approval expired on October 17, 2020. The FDA approved Eagle's ANDA on December 15, 2021. On December 16, 2021, Par filed an emergency motion for temporary restraining order and preliminary injunction in the district court to enjoin Eagle from launching its product, but Par voluntarily withdrew the motion on December 20, 2021.
Eagle commercially launched its ANDA product in January 2022. This suit is pending.

On December 7, 2020, Par filed a separate suit against us in the United States District Court for the District of New Jersey, asserting patent infringement of U.S. Patent No. 10,844,435, based on the filing of our ANDA seeking approval to manufacture and sell our vasopressin product. Eagle moved to dismiss Par's complaint on March 2, 2021. On March 22, 2021, Par amended its complaint to additionally assert U.S. Patent No. 10,920,278, and on April 5, 2021, Eagle moved to dismiss Par's amended complaint. This suit is pending.

(In thousands, except as indicated and share and per share amounts)

14. Convertible Promissory Note

During the first quarter of 2021, we invested $5 million in a convertible promissory note ("the note") of a privately held clinical-stage biotechnology company (the "issuer"). The note bears an 8% annual interest rate and has an 18-month term. The issuer is not required to make any principal or interest payments until the end of the term. The note, along with any accrued interest, may automatically convert into equity securities of the issuer under either a financing event or a change in control event as defined in the convertible promissory note agreement. The issuer's product development efforts could encounter technical or other difficulties that could increase their development costs more than expected. The issuer will likely require additional capital prior to obtaining certain regulatory approval or to be able to repay the convertible promissory note with accrued interest at the end of the term.

The following table summarizes the amounts recorded and activity during the year ended December 31, 2021;

	Initial	Fair Value Adjustments to the note	Accretion of Discount	Estimated Credit Loss	Interest Income	Fair Value Adjustment to Embedded Derivative	December 31, 2021
Fair value of the note	$ 5,000	$ (94)	$ —	$ —	$ —	$ —	$ 4,906
Discount on the note	(276)	—	149	—	—	—	(127)
Estimated Credit Loss	—	—	—	(758)	—	—	(758)
Convertible Promissory Note, net	$ 4,724	$ (94)	$ 149	$ (758)	$ —	$ —	$ 4,021
Embedded Derivative	$ 276	$ —	$ —	$ —	$ —	$ 686	$ 962
Interest Receivable	$ —	$ —	$ —	$ —	$ 329	$ —	$ 329
Total in Other Current Assets	$ 5,000	$ (94)	$ 149	$ (758)	$ 329	$ 686	$ 5,312