# 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, 2020**

**or**

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

**For the transition period from _____ to _____ .**

**Commission File Number 001-36306**

# 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. ☐

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 $514,326,120 computed by reference to the last reported sale price of $55.68 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, 2020. 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 25, 2021 was 13,217,284 shares.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the definitive proxy statement for our 2021 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2020, 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 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; delays in regulatory review; manufacturing and supply chain interruptions; and the adverse effects on healthcare systems and disruption of the global economy overall;
- the potential benefits and commercial potential of rapidly infused bendamustine RTD, or Bendeka, Ryanodex® (dantrolene sodium), or Ryanodex, and bendamustine ready-to-dilute, or RTD, 500ml solution, or Belrapzo 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 program;
- 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 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 interruption of 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 and others in connection with the ongoing COVID-19 pandemic;
- 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 Paragraph IV patent litigation;
- our expectations regarding anticipated future costs, operating expenses and capital requirements;
- our expectations regarding our abbreviated new drug application, or ANDA, and the related complete response letter for for vasopressin; and
- our expectations regarding our fulvestrant (EA-114) product candidate; next step is to submit formal protocol for clinical study.

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.

## 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. 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.
b. We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
c. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
d. 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.
e. 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.
f. If we cannot sustain profitability, our business, prospects, operating results and financial condition would be materially harmed.
g. If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs.
h. 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.
i. We cannot give any assurance that we will receive regulatory approval for our product candidates, which is necessary before they can be commercialized.
j. 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.
k. 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.
l. 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.
m. 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.
n. 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.
o. A substantial portion of our total revenues is derived from sales of a limited number of products.
p. 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.
q. 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.
r. Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
s. We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.
t. 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.
u. 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.
v. Our stock price may continue to fluctuate significantly.
w. There is no assurance that our share repurchase program will result in repurchases of our common stock or enhance long term stockholder value.

**EAGLE PHARMACEUTICALS, INC.**

**ANNUAL REPORT ON FORM 10-K**

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

## 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.

*Business*

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, with approval and commercial launches of three products: Ryanodex (dantrolene sodium), or Ryanodex, bendamustine ready-to-dilute, or RTD, 500ml solution, or Belrapzo, and rapidly infused bendamustine RTD, or 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., or Teva, markets Bendeka through its subsidiary, Cephalon, Inc., or Cephalon. 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. We expect to launch Pemfexy in early 2022.

With several pipeline projects underway and the potential for up to five product launches over the next several 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, first-to-market 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 Alzheimer's disease, traumatic brain injury/concussion, nerve agent exposure and acute radiation syndrome. In addition, our clinical development program includes a strategic partnership with Tyme Technologies, Inc., or Tyme, for Tyme's product candidate for the treatment of patients with pancreatic or other advanced cancers, SM-88, as well as investigations of compounds such as EA-114 (our fulvestrant product candidate) for patients with HR-positive advanced breast cancer. Other products in development include Vasopressin, our first-to-file Abbreviated New Drug Application, or ANDA, that references Endo International plc's Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; and EA-111, a new chemical entity and next-generation ryanodine receptor antagonist, in an intramuscular formulation that that would allow for easier and more rapid administration in emergency situations (military and civilian).

### Recent Developments

Vasopressin - FDA

On February 2, 2021, we announced that the U.S. Food and Drug Administration, or FDA, issued a complete response letter, or CRL, for our ANDA for vasopressin. Eagle has now had two conversations with FDA regarding the CRL and expects to have an additional meeting with FDA in the near-term. Importantly, Eagle has completed an extensive amount of developmental work and continues to do so for its first-to-file polypeptide, where brand sales of the product are over $700 million annually. In its communication with the Company, FDA restated that it has prioritized Eagle's ANDA, and that the ANDA has also been flagged as a COVID-19 priority by FDA. Eagle believes it can fully respond to the questions raised. There is one additional short duration study that will need to be completed and analyzed. The study will be run either in mid-February or mid-March. Based on similar studies previously run on the Company's vasopressin product, Eagle expects the results will be satisfactory. In addition, the Company expects it will have 180 days of exclusivity for vasopressin.

Vasopressin - Patent litigation

On February 2, 2021, we also announced that our ongoing patent suit with Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC, or together, Par, is now scheduled to begin on July 7, 2021. Eagle remains confident about this litigation given that Par's asserted patents claim a formulation with a pH of 3.7-3.9 and Eagle's proposed ANDA product specifies a pH outside of that range. The Company is confident that its ANDA will be approved in a reasonable timeframe.

***Executive Officer Transitions***

*Chief Medical Officer*

Effective July 31, 2020, Adrian J. Hepner, M.D., Ph.D. resigned as our Executive Vice President and Chief Medical Officer. On July 31, 2020, we entered into a consulting agreement with Dr. Hepner, or the Consulting Agreement. Pursuant to the Consulting Agreement, Dr. Hepner will provide consulting services to us until July 31, 2021, unless earlier terminated, or the Consulting Period. In consideration of Dr. Hepner's provision of consulting services, we have agreed to pay Dr. Hepner (i) a weekly retainer of $8,000 for 20 hours of services each week for the first six months of the Consulting Period and (ii) a weekly retainer of $4,000 for 10 hours of services each week for the remaining six months of the Consulting Period. We will also continue to pay the employer portion of Dr. Hepner's COBRA medical continuation benefits until January 31, 2022.

On October 29, 2020, Judith Ng-Cashin, M.D. was appointed as our Chief Medical Officer.

*Chief Financial Officer*

As of October 29, 2020, Pete Meyers ceased to serve as our Chief Financial Officer. In connection with his departure, Mr. Meyers received the severance compensation provided for under our previously disclosed Amended and Restated Severance Benefit Plan and Mr. Meyers' participation agreement thereunder, for a non-change in control covered termination.

On October 29, 2020, Brian Cahill was appointed as our Chief Financial Officer. Mr. Cahill has served as our Vice President of Finance since January 2018 and previously served as our Corporate Controller from October 2016 to December 2017. On December 18, 2020, in connection with his new role, the compensation committee of our board of directors approved an annual base salary for Mr. Cahill of $380,000 effective as of October 29, 2020 and a target annual bonus for fiscal year 2021 set at 60% of his base salary, with the amount of his bonus to be determined by the compensation committee based on our achievement of our annual corporate objectives established by the compensation committee. The compensation committee also approved equity grants to Mr. Cahill of 5,000 restricted stock units and 10,000 stock options.

***Change in Independent Registered Public Accounting Firm***

On September 25, 2020, the Audit Committee of the Board of Directors approved the engagement of Ernst & Young, LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2020, and dismissed BDO USA, LLP, as our current independent registered public accounting firm.

***Complete Response Letter for NDA for Ryanodex***

On August 7, 2020, we received a Complete Response Letter for its NDA for Ryanodex for the treatment of exertional heat stroke, or EHS; we decided that we will no longer pursue this indication in order to direct our resources to other product candidates.

***Other 2020 Events***

On February 10, 2020, we received final approval from the FDA for our novel product PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

On January 13, 2020, we issued a press release announcing that the Company and the University of Pennsylvania had agreed on terms of a new exclusive worldwide license agreement for the development of dantrolene sodium for the potential treatment of people living with Alzheimer's disease, including an agreement to fund additional research and provisions regarding commercialization of products developed under the license.

On January 7, 2020, Tyme Technologies, Inc. and Eagle Pharmaceuticals announced a strategic collaboration to advance oral SM-88 for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase 2 studies for pancreatic cancer and in a Phase 2 study for prostate cancer. Data is expected in 2021.

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.

***Pemfexy Billing Code***

On July 9, 2020, we announced that the Centers for Medicare & Medicaid Services, or CMS, had established a unique, product-specific billing code for Pemfexy. The new Healthcare Common Procedure Coding System, or J-code, became effective on October 1, 2020.

We expect that the new HCPCS code will provide coding clarity to outpatient facilities and physicians who administer Pemfexy, facilitating access for patients and reimbursement from Medicare, Medicaid and commercial insurance.

***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 replaces our 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, we had repurchased approximately $68.0 million of our outstanding common stock under the 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 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 our 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 was 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.

As of December 31, 2020, we have repurchased an aggregate of 3,682,176 shares of common stock for an aggregate of $206.9 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 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 Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations - *Trends and Uncertainties*.

We have built an internal commercial team consisting of 46 direct sales representatives, support staff and management who are a part of our independent commercial organization.

**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., Symbio and Tyme); our Pemetrexed project, with an expected launch in 2022; our Ryanodex related development projects; our vasopressin ANDA that is currently being litigated; 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. 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 will opportunistically in-license or acquire product candidates that fit our therapeutic areas of focus and meet our rigorous evaluation process.

*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 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 and Bendeka (Licensed to Teva and SymBio) for Chronic Lymphocytic Leukemia ("CLL") and Non-Hodgkin's Lymphoma ("NHL")***

*Overview*

Bendamustine is an alkylating agent approved for use in CLL, and indolent B-cell 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 (“RTD”), multi-dose liquid with extended drug stability for use with a 500mL intravenous, or IV, infusion bag.

*Teva License- Bendeka*

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.*

***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 ("MH"). There are only 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, (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 ("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 will be 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 (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 will 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 has granted orphan drug designation (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 with arm using an intermuscular formulation of EA-111. We expect the preliminary results from these studies will allow us to update our SPA with the FDA. If approved, Ryanodex would represent the first product available for this indication.

***EP-5101 (PEMFEXY™) for Lung Cancer***

EP-5101 is an IV-administered cancer agent indicated for locally advanced or metastatic non-small cell lung cancer and mesothelioma. We have developed EP-5101 as a ready-to-use/dilute liquid form of pemetrexed that will be available in a 25mg/mL per vial. Because our product will be available in liquid form, product reconstitution will not be 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 ("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 power 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: EP-5101 (PEMFEXY™)*

EP-5101 is an RTD liquid formulation of pemetrexed. As an RTD liquid formulation, EP-5101 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.

*EP-5101 (PEMFEXY™) Development and Regulatory Status*

We submitted an NDA for EP-5101 on December 30, 2016 for use in non-small cell lung cancer and mesothelioma. On October 27, 2017, we were granted tentative approval for EP-5101 by the FDA. On December 13, 2019, we reached a settlement agreement with Lilly related to Pemfexy. The agreement provides for a release of all claims by the parties and allows 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. We expect to launch Pemfexy in early 2022

***EGL-5385-C-1701 (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: EGL-5385-C-1701*

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 is

to determine if the unique properties of our fulvestrant formulation will 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.

***Additional Products in our Portfolio***

*Vasopressin*

Vasopressin injection is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines. We filed an ANDA in April 2018 for a generic version of VASOSTRICT® (vasopressin IV solution (infusion), which variously covers either vasopressin-containing pharmaceutical compositions or methods of using a vasopressin-containing dosage form to increase blood pressure in humans. On February 2, 2021, we announced that the FDA had issued a CRL for our ANDA for vasopressin. We have had conversations with FDA regarding the CRL, pursuant to which FDA restated that it has prioritized our ANDA, and that the ANDA has is also been flagged as a COVID-19 priority by FDA. We believe we can fully respond to the questions raised. There is one additional short duration study that will need to be completed and analyzed. The study will be run either in mid-February or mid-March. Based on similar studies previously run on our vasopressin product, we expect the results will be satisfactory. In addition, we expects we will have 180 days of exclusivity.

In May 2018, the NDA owner filed a lawsuit against us within the 45-day deadline to invoke a 30-month stay of FDA approval pursuant to the Hatch-Waxman legislative scheme. In August 2018, we filed an answer and a counterclaim for non-infringement and invalidity of asserted patents, 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 us, and the Court entered an Order reflecting that dismissal on December 27, 2019. The trial is scheduled to begin on July 7, 2021.

*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.

In addition to our internal efforts, in January 2016 we entered into an agreement with the United States Army Medical Research Institute of Chemical Defense, or AMRI, to jointly develop and manufacture several select and complex parenteral drug products for registration and subsequent commercialization in the United States.

Under the terms of the agreement, AMRI will develop and initially provide cGMP manufacturing and analytical support for the registration of the new product candidates. We will be responsible for advancing the product candidates through clinical trials and regulatory submissions.

**Sales and Marketing**

Other than products subject to existing commercialization arrangements, we commercialize our product portfolio in the United States with our commercial organization. Ryanodex and Belrapzo are marketed by our internal commercial team consisting of 46 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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| **Net revenues** | | | |
| Cephalon, Inc. (Teva) - See Revenue Recognition | 67 % | 77 % | 75 % |
| Other | 33 % | 23 % | 25 % |
| | 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.

Eagle also has a patent portfolio of issued and/or pending U.S. patent applications and corresponding foreign patent application in a range of countries that cover its 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., ("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 ("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 (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, orTPIG, all of Cephalon's rights and obligations under the Cephalon License. Accordingly, all references to "Cephalon" or to the "Cephalon License" and the related supply agreements for Bendeka should be read and construed as references to TPIG and to the license agreement and supply agreements for Bendeka to which we and TPIG are now parties. Pursuant to the terms of the Cephalon License, Cephalon 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, hawse have entered into a supply agreement with Cephalon, pursuant to which we are responsible for supplying product to Cephalon.

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 will bear 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 ("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, Eagle 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 Eagle 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. SymBio expects to launch the Treakisym RTD product in the first quarter of 2021, after obtaining marketing authorization.

**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 ("FDCA"), and in the case of biologics, the Public Health Service Act ("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 ("cGLP") regulations;
- submission to the FDA of an Investigational New Drug ("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 ("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 ("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 Prescription Drug Marketing Act ("PDMA") which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. 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 (“HHS”) and its various enforcement divisions, such as the Centers for Medicare & Medicaid Services

(“CMS”), the Office of Inspector General ("OIG"), the Office for Human Research Protections ("OHRP"), and the Office of Research Integrity ("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 (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 ("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 ("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, 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. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

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 December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation, 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, including the BBA, will remain in effect through 2030, except for a temporary suspension from
May 1, 2020 through March 31, 2021 due to COVID-19, unless additional Congressional action is taken. 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, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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 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, effective November 30, 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 pending review by the Biden administration until March 22, 2021. 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

**Human Capital Management**

As of December 31, 2020, we had a total of 106 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.

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 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.***

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. The COVID-19 pandemic has resulted in authorities implementing aggressive actions, and they may from time to time take additional actions, to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions). 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. We expect to work from home in the near future and will closely follow the guidance from federal and state authorities, including the Centers for Disease Control and Prevention and the New Jersey Department of Health, in deciding when to transition back to working in our offices. 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.

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

Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (“Tax Act”) as modified by the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), 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 the Tax Act, or the CARES Act. 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.

***If we cannot 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. Although we had 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, 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. As of December 31, 2020, we commercialize the following main products, Ryanodex, Belrapzo and Bendeka.

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. We believe that our existing cash and cash equivalents, together with interest thereon and expected operating cash flows, are sufficient to fund our future operations and debt costs for a minimum of twelve months.

***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, such as with AMRI. 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 our business, cash flow, financial condition or results of operations 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. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, 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 under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U.S. tax expense.

**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 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 February 2, 2021, we announced that the FDA had issued a CRL for our ANDA for vasopressin. Although we believe that this submission addresses the Complete Response Letter received in July 2017. Although we believe that we can fully respond to the questions raised, we may receive another CRL, rather than approval, for this ANDA. 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 Federal Food, Drug and Cosmetic Act ("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. In addition, on February 2, 2021, we announced that the FDA had issued a CRL for our ANDA for vasopressin.

Although we believe that we can fully respond to the questions raised in the CRL, we may receive another CRL, rather than approval, for this ANDA.

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 are currently involved in an ongoing patent case with Par related to our ANDA for vasopressin, which is scheduled for trial on July 7, 2021. 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. For example, the Food and Drug Administration Safety and Innovation Act, or FDASIA, requires the FDA to issue new guidance on permissible forms of Internet and social media promotion of regulated medical products, and the FDA may soon specify new restrictions on this type of promotion. 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, 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) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- 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. 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, 2020, Bendeka accounted for approximately 61% 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 December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 unclear how the Supreme Court ruling, other such litigation, 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 other legislative amendments, including the BBA, will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. 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 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, effective November 30, 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 pending review by the Biden administration until March 22, 2021. 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. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

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**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 contract research organizations (each a "CRO") 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 (" 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 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 begins to impact essential distribution systems such as FedEx and postal delivery, we could 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, such as the agreement with AMRI, 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.

***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.***

On January 7, 2020, we and Tyme announced a strategic collaboration 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 the collaboration with Tyme, 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, including Tyme, 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.

***If we are unable to maintain our group purchasing organization, ("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, Chief Financial Officer, Chief Medical Officer, and President and Chief Operating Officer. 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, 2020, we had a total of 106 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 rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.***

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The loss, theft or sabotage of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

***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 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.

Although we have not currently drawn on the Revised Credit Agreement, 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. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

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, and Bendeka ® 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, and Bendeka, 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;
- 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; and
- additional repurchases of our common stock, if any, pursuant to our current share repurchase program.

The stock market in general, and The Nasdaq Stock Market, or Nasdaq, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

In addition, the market price of our shares of common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- 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;
- share price and volume fluctuations attributable to short interest positions and/or inconsistent trading volume levels of our shares;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- 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, 2020, 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.

***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.

***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 25, 2021 we had 13,217,284 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 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.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity 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 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, ("the 2014 Plan"), our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. 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 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 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 Credit Facility), 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 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.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

As of December 31, 2020 we conducted all of our commercial operations for Eagle Pharmaceuticals, Inc. at our 27,093 square foot leased office space located at 50 Tice Boulevard, Suite 315, Woodcliff Lake, NJ 07677. The lease will expire in June 2025.

As of December 31, 2020, we conducted all of our non-outsourced operations at a leased space located at 47 Moulton St. Cambridge, MA 02138. The lease 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 25, 2021, we had 4 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 25, 2021 was $45.78.

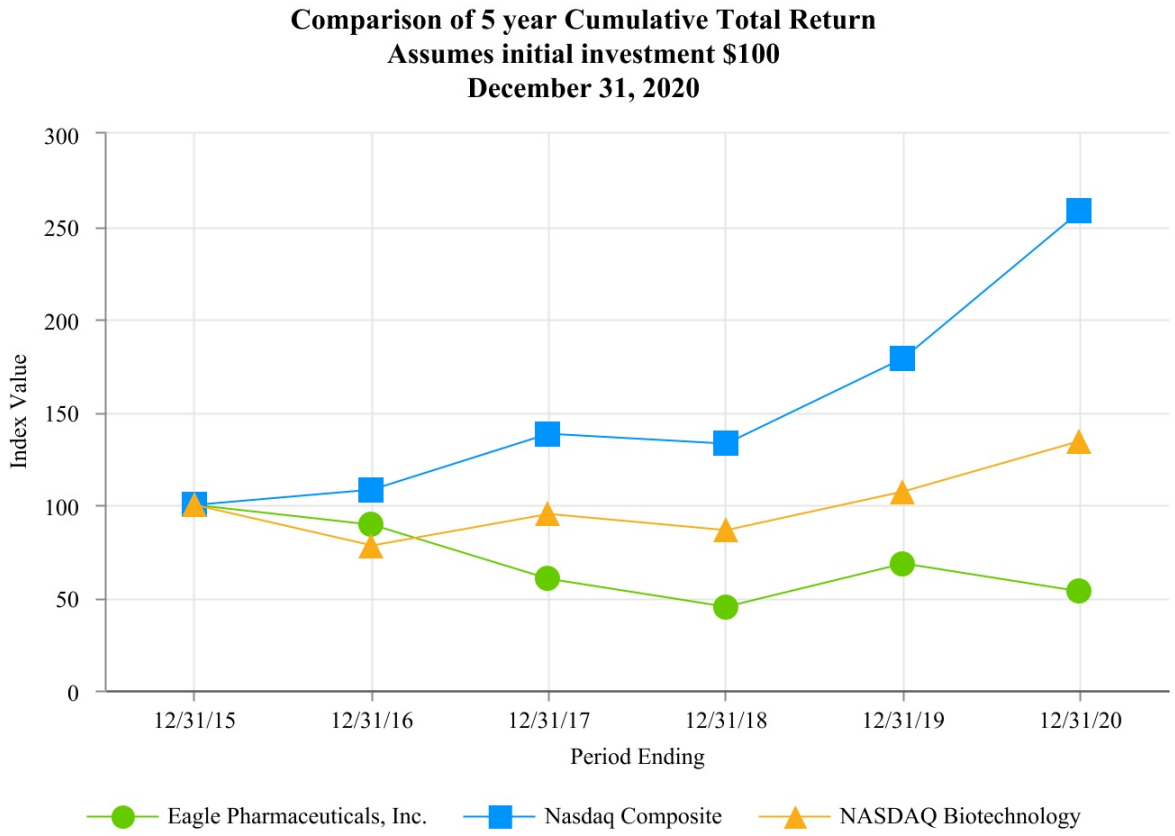
*Dividends*

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 Credit Facility 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, ("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, ("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, 2015 through December 31, 2020 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, 2015 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 | 12/31/15 | 12/31/16 | 12/31/17 | 12/31/18 | 12/31/19 | 12/31/20 |
|---|---|---|---|---|---|---|
| Eagle Pharmaceuticals, Inc | $ 100 | $ 89 | $ 60 | $ 45 | $ 68 | $ 53 |
| Nasdaq Composite | $ 100 | $ 108 | $ 138 | $ 133 | $ 179 | $ 258 |
| NASDAQ Biotechnology | $ 100 | $ 78 | $ 95 | $ 86 | $ 107 | $ 134 |

*Recent Sales of Unregistered Securities*

Pursuant to a Warrant to Purchase Common Stock, dated September 2018, the Company issued a warrant to FoxKiser LLP to purchase 7,467 shares of the Company's common stock at an exercise price of $66.96 per share in connection with certain services rendered to the Company. This warrant was issued in reliance on an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

*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 the Company’s outstanding common stock. The Share Repurchase Program replaces 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, we had repurchased approximately $68.0 million of our outstanding common stock under the 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, 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 following table provides information about purchases of our equity securities during the three months ended December 31, 2020:

| 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, 2020 to October 31, 2020 | — | $ — | — | 131,998 |
| November 1, 2020 to November 30, 2020 | 44,806 | $ 45.40 | 44,806 | 126,998 |
| December 1, 2020 to December 31, 2020 | 42,819 | $ 46.71 | 42,819 | 124,997 |
| **Total** | 87,625 | $ 46.04 | 87,625 | |

(1) All shares repurchased by us during the three months ended December 31, 2020 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. Selected Financial Data**

The following table sets forth our selected financial data for the periods and as of the dates indicated. The following selected financial data should be read in conjunction with our audited financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report on Form 10-K.

The statement of operations data for the years ended December 31, 2020, 2019, 2018, 2017, and 2016 and the balance sheet data as of December 31, 2020, 2019, 2018, 2017 and 2016, are derived from our audited consolidated financial statements. Our audited consolidated financial statements have been prepared in U.S. dollars in accordance with U.S. GAAP.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

| Statement of Operations Data: | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2020 | 2019 | 2018 | 2017 | 2016 |
| | (in thousands except share and per share amounts) | | | | |
| Total revenue | $ 187,802 | $ 195,892 | $ 213,312 | $ 236,707 | $ 189,482 |
| Cost of product sales | 33,647 | 47,891 | 42,374 | 33,714 | 35,785 |
| Cost of royalty revenue | 11,818 | 13,006 | 19,542 | 23,472 | 19,521 |
| Research and development | 30,785 | 36,810 | 44,419 | 32,607 | 28,289 |
| Selling, general and administrative | 78,598 | 76,370 | 60,509 | 71,416 | 53,329 |
| Income from operations | 32,954 | 21,815 | 36,616 | 73,990 | 53,351 |
| Income tax provision (benefit) | 10,688 | 7,685 | 2,135 | 21,002 | (28,026) |
| Net income attributable to common stockholders | 11,989 | 14,313 | 31,903 | 51,943 | 81,453 |
| Earnings per share- basic | $ 0.89 | $ 1.04 | $ 2.16 | $ 3.44 | $ 5.24 |
| Earnings per share- diluted | $ 0.87 | $ 1.01 | $ 2.09 | $ 3.27 | $ 4.96 |
| Weighted average common shares outstanding- basic | 13,481,525 | 13,754,516 | 14,768,625 | 15,102,890 | 15,533,681 |
| Weighted average common shares outstanding- diluted | 13,771,393 | 14,138,733 | 15,278,651 | 15,908,211 | 16,434,104 |

| Balance Sheet Data: | December 31, | | | | |
|---|---|---|---|---|---|
| | 2020 | 2019 | 2018 | 2017 | 2016 |
| | (in thousands) | | | | |
| Cash and cash equivalents | $ 103,155 | $ 109,775 | $ 78,791 | $ 114,657 | $ 52,820 |
| Accounts receivable | 51,117 | 48,004 | 66,486 | 53,821 | 42,194 |
| Total assets | 253,190 | 254,554 | 238,603 | 270,060 | 214,320 |
| Total current liabilities | 38,085 | 38,823 | 39,686 | 47,302 | 40,965 |
| Long-term debt, less current portion | 25,135 | 33,557 | 38,155 | 42,905 | — |
| Retained earnings (Accumulated deficit) | 84,489 | 72,500 | 58,187 | 26,284 | (25,659) |
| Total stockholders' equity | $ 186,011 | $ 179,174 | $ 160,762 | $ 179,144 | $ 151,226 |

**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. 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. We expect to launch Pemfexy in early 2022.

With several pipeline projects underway and the potential for up to five or more product launches over the next several 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 Alzheimer's disease, traumatic brain injury/concussion, nerve agent exposure and acute radiation syndrome. In addition, our clinical development program includes a strategic partnership with Tyme for SM-88, a product candidate for the treatment of patients with pancreatic or other advanced cancers, as well as investigations of compounds such as EA-114 and our Fulvestrant product candidate for patients with HR-positive advanced breast cancer. Other products in development include Vasopressin, our first-to-file Abbreviated New Drug Application, or ANDA, that references Endo International plc's Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; and EA-111, a new chemical entity and next-generation ryanodine receptor antagonist, in an intramuscular formulation that that would allow for easier and more rapid administration in emergency situations (military and civilian).

**Recent Developments**

***Vasopressin - FDA***

On February 2, 2021, we announced that the U.S. Food and Drug Administration, or FDA, issued a complete response letter, or CRL, for our ANDA for vasopressin. Eagle has now had two conversations with FDA regarding the CRL and expects to have an additional meeting with FDA in the near-term. Importantly, Eagle has completed an extensive amount of developmental work and continues to do so for its first-to-file polypeptide, where brand sales of the product are over $700 million annually. In its communication with the Company, FDA restated that it has prioritized Eagle's ANDA, and that the ANDA has also been flagged as a COVID-19 priority by FDA. Eagle believes it can fully respond to the questions raised. There is one additional short duration study that will need to be completed and analyzed. The study will be run in mid-March. Based on similar studies previously run on our vasopressin product, we expect the results will be satisfactory. In addition, we expect we will have a 180 day period of exclusivity for Vasopressin.

***Vasopressin - Patent litigation***

On February 2, 2021, we also announced that our ongoing patent suit with Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC, or together, Par, is now scheduled to begin on July 7, 2021. Eagle remains confident about this litigation given that Par's asserted patents claim a formulation with a pH of 3.7-3.9 and Eagle's proposed ANDA product specifies a pH outside of that range. The Company is confident that its ANDA will be approved in a reasonable timeframe.

***Complete Response Letter for NDA for Ryanodex***

On August 7, 2020, we received a Complete Response Letter for our NDA for Ryanodex for the treatment of exertional heat stroke, or EHS; we decided that we will no longer pursue this indication in order to direct our resources to other product candidates.

***Executive Officer Transitions***

*Chief Medical Officer*

Effective July 31, 2020, Adrian J. Hepner, M.D., Ph.D. resigned as our Executive Vice President and Chief Medical Officer. On July 31, 2020, we entered into a consulting agreement with Dr. Hepner, or the Consulting Agreement. Pursuant to the

Consulting Agreement, Dr. Hepner will provide consulting services to us until July 31, 2021, unless earlier terminated, or the Consulting Period. In consideration of Dr. Hepner's provision of consulting services, we have agreed to pay Dr. Hepner (i) a weekly retainer of $8,000 for 20 hours of services each week for the first six months of the Consulting Period and (ii) a weekly retainer of $4,000 for 10 hours of services each week for the remaining six months of the Consulting Period. We will also continue to pay the employer portion of Dr. Hepner's COBRA medical continuation benefits until January 31, 2022.

On October 29, 2020, Judith Ng-Cashin, M.D. was appointed as our Chief Medical Officer.

*Chief Financial Officer*
As of October 29, 2020, Pete Meyers ceased to serve as our Chief Financial Officer. In connection with his departure, Mr. Meyers received the severance compensation provided for under our previously disclosed Amended and Restated Severance Benefit Plan and Mr. Meyers' participation agreement thereunder, for a non-change in control covered termination.

On October 29, 2020, Brian Cahill was appointed as our Chief Financial Officer. Mr. Cahill has served as our Vice President of Finance since January 2018 and previously served as our Corporate Controller from October 2016 to December 2017. O
n December 18, 2020, in connection with his new role, the compensation committee of our board of directors approved an annual base salary for Mr. Cahill of $380,000 effective as of October 29, 2020 and a target annual bonus for fiscal year 2021 set at 60% of his base salary, with the amount of his bonus to be determined by the compensation committee based on our achievement of our annual corporate objectives established by the compensation committee. The compensation committee also approved equity grants to Mr. Cahill of 5,000 restricted stock units and 10,000 stock options.

***Change in Independent Registered Public Accounting Firm***
On September 25, 2020, the Audit Committee of the Board of Directors approved the engagement of Ernst & Young, LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2020, and dismissed BDO USA, LLP, as our current independent registered public accounting firm.

***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*. Through December 31, 2020, we have recognized revenues from product sales of Bendeka, Argatroban, Ryanodex and Belrapzo. Sales of Bendeka were made to our commercial partner, Teva, while Argatroban was sold directly to our commercial partners, Chiesi USA, Inc. ("Chiesi") and Sandoz AG, or Sandoz. 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 Sandoz's and Chiesi's gross profits of Argatroban, both net of discounts, returns and allowances incurred by our commercial partners. 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 Argatroban are:

- the level of orders submitted by our commercial partners, Sandoz and Chiesi;
- the level of institutional demand for Argatroban; and
- unit sales prices charged by Sandoz and Chiesi, 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 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. 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 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, 2020, 2019 and 2018 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, 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 / (Decrease) |
|---|---|---|---|
| | 2020 | 2019 | |
| | (in thousands) | | |
| Fulvestrant "EGL-5385-C-1701" | $ 6,802 | $ 5,053 | $ 1,749 |
| Vasopressin | 4,727 | 7,779 | (3,052) |
| Ryanodex EHS "EP-4104" | 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 our EGL-5385-C-1701 (our fulvestrant formulation) initiative.

***Selling, General and Administrative***

| | Year Ended December 31, | | Increase |
|---|---|---|---|
| | 2020 | 2019 | |
| | (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.

***Comparison of Years Ended December 31, 2019 and December 31, 2018***

| | Year Ended December 31, | | Increase / (Decrease) |
|---|---|---|---|
| | 2019 | 2018 | |
| | (in thousands) | | |
| Product sales, net | $ 73,989 | $ 70,385 | $ 3,604 |
| Royalty revenue | 112,903 | 142,927 | (30,024) |
| License and other revenue | 9,000 | — | 9,000 |
| Total revenue | $ 195,892 | $ 213,312 | $ (17,420) |

Product sales increased $3.6 million in the year ended December 31, 2019, primarily driven by increases in product sales of Belrapzo of $6.8 million, which was due to volume increases and Bendeka of $6.4 million, which was also due to volume increases. The increased sales were partially offset by decreases in product sales of Ryanodex of $7.2 million due to lower volume on a low reorder cycle period and the discontinuation of Non-Alcohol Docetaxel Injection in September 2018 that resulted in a negative impact to revenues of $2.6 million.

Royalty revenue decreased $30.0 million in the year ended December 31, 2019 as a result of decreases in royalties on Teva's sales of Bendeka of $23.2 million and royalties on sales of Argatroban of $6.8 million.

License and other revenue for the year ended December 31, 2019 represents 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.

***Cost of Revenue***

| | Year Ended December 31, | | Increase / (Decrease) |
|---|---|---|---|
| | 2019 | 2018 | |
| | (in thousands) | | |
| Cost of product sales | $ 47,891 | $ 42,374 | $ 5,517 |
| Cost of royalty revenue | 13,006 | 19,542 | (6,536) |
| Total cost of revenue | $ 60,897 | $ 61,916 | $ (1,019) |

Cost of product sales increased $5.5 million in the year ended December 31, 2019, primarily as a result of increased product sales of Belrapzo and Bendeka, partially offset by the discontinuation of Non-Alcohol Docetaxel Injection in September 2018 and decreased product sales of Ryanodex and Argatroban.

Cost of royalty revenue decreased $6.5 million in the year ended December 31, 2019 due to the decrease in royalty revenue for Bendeka and Argatroban.

***Research and Development***

| | Year Ended December 31, | | (Decrease) / Increase |
|---|---|---|---|
| | 2019 | 2018 | |
| | (in thousands) | | |
| Fulvestrant “EGL-5385-C-1701” | $ 5,053 | $ 21,687 | $ (16,634) |
| Ryanodex EHS “EP-4104” | 5,192 | 3,845 | 1,347 |
| Vasopressin | 7,779 | 1,029 | 6,750 |
| All other projects | 3,980 | 4,437 | (457) |
| Salary and other personnel related | 14,806 | 13,421 | 1,385 |
| Total research and development | **$ 36,810** | **$ 44,419** | **$ (7,609)** |

The decrease primarily resulted from a decrease in project spending for EGL-5385-C-1701 (our fulvestrant formulation) relating to the clinical study which completed randomization of 600 subjects in the first half of 2018. This decrease was partially offset by increased spend related to our vasopressin injection ANDA filing and spending on the resubmitted NDA for Ryanodex® (dantrolene sodium for injectable suspension) for the treatment of EHS.

***Selling, General and Administrative***

| | Year Ended December 31, | | Increase |
|---|---|---|---|
| | 2019 | 2018 | |
| | (in thousands) | | |
| Selling, general and administrative | $ 76,370 | $ 60,509 | $ 15,861 |

This increase is primarily related to an increase of $9.6 million in external legal fees related to ongoing litigation matters, increased compensation costs, including stock compensation expense, of $6.6 million and $0.6 million increase in professional fees. These increases were partially offset by a decrease of $0.9 million in sales and marketing direct costs.

***Other income (expense), net***

| | Year Ended December 31, | | Increase |
|---|---|---|---|
| | 2019 | 2018 | |
| | (in thousands) | | |
| Interest income | $ 2,169 | $ 158 | $ 2,011 |
| Interest expense | (2,686) | (2,736) | 50 |
| Other Income | 700 | — | 700 |
| Total other income, net | $ 183 | $ (2,578) | $ 2,761 |

Interest income increased $2.0 million primarily due to our short term investing initiatives with cash on hand throughout 2019 as compared to 2018.

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

Other income represents an amount we received pursuant to a settlement agreement executed in December 2019 with Lilly related to the Company's product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The agreement provides for a release of all claims by the parties related to an antitrust complaint filed by the Company and an alleged patent infringement based on the filing of the Company's 505(b)(2) NDA. The Settlement also 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.

***Provision for income taxes***

| | Year Ended December 31, | |
|---|---|---|
| | **2019** | **2018** |
| | **(in thousands)** | |
| *Provision for income taxes* | $ 7,685 | $ 2,135 |
| Effective tax rate | 35 % | 6 % |

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity. The effective tax rate for 2018 reflects tax benefits related to stock option exercises in the period as well as credits for research and development activity partially offset by the impact of certain non-deductible executive compensation.

***Net Income***

Net income for the year ended December 31, 2019 was $14.3 million as compared to a net income of $31.9 million for the year ended December 31, 2018, as a result of the factors discussed above.

**Liquidity and Capital Resources**

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 $103.2 million, and $109.8 million as of December 31, 2020 and December 31, 2019, respectively.

For the year ended December 31, 2020, we recorded net income of $12.0 million. As of December 31, 2020, we had a working capital surplus of $128.0 million. For the year ended December 31, 2019, we recorded net income of $14.3 million.

We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for at least the next twelve months.

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, 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, amortization of intangible assets, stock-based compensation expense, fair value adjustments on equity investment, fair value adjustments on ASR, and amortization of debt issuance costs and other items. 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, amortization 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.

Net cash provided by operating activities for the year ended December 31, 2018 was $52.4 million. Net income for the same period was $31.9 million offset by non-cash adjustments of approximately $28.4 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, amortization of debt issuance costs, change in fair value of contingent consideration, asset impairment charge and fair value adjustment related to restructuring. Net changes in working capital decreased cash provided from operating activities by $7.9 million, due to an increase in accounts receivable of $12.7 million, an increase in inventory of $5.6 million, an increase in accrued expenses and other liabilities of $8.1 million, an increase in other assets of $0.6 million partially offset by a decrease in prepaid expenses and other current assets of $4.8 million, and a decrease in accounts payable of $2.1 million. The total amount of accounts receivable at December 31, 2018 was approximately $66.5 million, which included approximately $25.3 million from product sales, $35.7 million from royalty income, and $5.5 million related to cost reimbursements.

*Investing Activities:*

During the years ended December 31, 2020, 2019 and 2018, we invested $0.7 million, $0.8 million, and $0.1 million, respectively, for the purchase of property and equipment.

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 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.

Net cash used in financing activities for the year ended December 31, 2018 was $88.1 million, primarily resulting from a $15 million payment of contingent consideration in connection with our acquisition of Arsia Therapeutics, Inc. in 2018, $73.1 million in cash settlements on repurchases of common stock, $3.7 million payment of debt financing costs and a $4.9 million payment of employee withholding tax for net option exercises. This was offset by the issuance of common stock for stock option exercises of $8.6 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. 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. The extent of and timing for such lifting of government restrictions remains uncertain as the COVID-19 pandemic continues to evolve. 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, 2020, 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, our employees, including customer-facing employees, have been working remotely. The duration and extent of these restrictions are uncertain. We have developed plans to resume in-person work practices as we determine it to be safe to do so and pending relevant health authority guidance. We expect to incur additional expenses in 2021 related to the impact of the COVID-19 pandemic on our operations, including procurement of personal protective equipment for our employees and 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 future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for the next 12 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 use be able to obtain any future funding under the terms of the Revised 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, including EA-114 (our fulvestrant product candidate), 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 our results of operations during the year ended December 31, 2020 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 | 2021 | 2022 | 2023 | 2024 | 2025 |
|---|---|---|---|---|---|---|
| Operating leases (1) | $ 5,720 | $ 1,391 | $ 1,423 | $ 1,455 | $ 1,038 | $ 413 |
| Credit facility | 34,000 | 8,000 | 26,000 | — | — | — |
| Purchase obligations (2) | 68,644 | 68,644 | — | — | — | — |
| Total obligations | $ 108,364 | $ 78,035 | $ 27,423 | $ 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. Rental expense was $1,323, $1,146, and $571, for the year ended December 31, 2020, 2019, and 2018, respectively. The remaining future lease payments under the operating leases, exclusive of any renewal option periods, are $5,720 as of December 31, 2020, payable monthly through June 30, 2025 and April 30, 2024.

(2) As of December 31, 2020, the Company has purchase obligations in the amount of $68,644 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.

*Recently Adopted Accounting Pronouncements*

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. This standard is effective for fiscal years beginning after December 15, 2019 and the Company adopted the standard effective January 1, 2020. The adoption of ASU 2016-13 had no material impact on the Company's financial position and results of operations.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

**Impact of Inflation**

While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we believe the effects of inflation, if any, on our results of operations and financial condition have been immaterial.

**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial

statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a “critical accounting estimate” where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in Note 2 to our financial statements included in this Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are “critical accounting estimates.” We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition described below are “critical accounting estimates.”

*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 Argatroban and Bendeka. 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 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 chargeback 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 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.

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 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 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) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Belrapzo previously shipped and currently being shipped to distributors and (vi) 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.

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. Additionally, we consider other factors when estimating our current period return provision, including levels of inventory in the distribution channel, significant market changes that may impact future expected returns, and actual product returns, and may record additional provisions for specific returns that it believes are not covered by the historical rates. The Company’s commercial returns policy and terms with certain customers also states that certain products are sold as non-returnable.

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.

*Other GTN considerations*

We may at our discretion provide price adjustments due to various competitive factors. There are circumstances under which we may not provide price adjustments to certain customers as a matter of business strategy, and consequently may lose future sales volume to competitors and risk a greater level of product returns.

As detailed above, we have the experience and access to relevant information that we believe are necessary to reasonably estimate the amounts of such deductions from gross revenues. Some of the assumptions we use for certain of these estimates

are based on information received from third parties, such as wholesale customer inventories and market data, or other market factors beyond our control. The estimates that are most critical to the establishment of these reserves, and therefore, would have the largest impact if these estimates were not accurate, are estimates related to contract sales volumes, average contract pricing, customer inventories and return volumes. We regularly review the information related to these estimates and adjust our reserves accordingly, if and when actual experience differs from previous estimates. With the exception of the product returns allowance, the ending balances of accounts receivable reserves and allowances generally are processed during a two-month to four-month period.

**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, 2020, we had cash and cash equivalents of $103.2 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, 2020 and 2019, the aggregate principal amount of such variable-rate indebtedness was $34.0 million and $39.0 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, 2020 and 2019, 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.

We are monitoring the ongoing impacts of the COVID-19 pandemic on our business. While the full extent of the economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact on the global financial markets may reduce our ability to access capital, which could negatively impact our long-term liquidity.

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

Our Financial Statements and Supplementary Data and the Reports of Independent Registered Public Accounting Firms appear beginning on page F-1 attached to 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, 2020, 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, 2020. 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; and
- 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.

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, 2020 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, 2020, 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, 2020. This attestation report appears below.

/s/ Scott Tarriff
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, 2020 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' internal control over financial reporting as of December 31, 2020, 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 (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, 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 sheet of the Company as of December 31, 2020, and the related consolidated statements of income, changes in stockholders' equity and cash flows for the period year December 31, 2020 and the related notes and our report dated March 4, 2021 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 4, 2021

**Item 9B. Other information.**

None.

## PART III

We will file a definitive proxy statement for our 2021 Annual Meeting of Stockholders, or the 2021 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 2021 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 definitive 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 definitive 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 definitive 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 definitive 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 definitive 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. Financial Statements**

See Index to Financial Statements at Item 8 herein.

**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 | | Third Amended and Restated Investor Rights Agreement, dated April 11, 2013, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, SEC File No. 333-192984, filed December 20, 2013) |
| 4.3 | | 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) |

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| 10.7 | † | Offer Letter by and between the Registrant and Adrian Hepner dated December 11, 2014 (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-36306, filed March 15, 2017) as amended by entry into the Eagle Pharmaceuticals, Inc. Officer Severance Benefit Plan on April 29, 2016 (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) |
| 10.8 | | 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) |
| 10.9 | * | 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) |
| 10.10 | * | 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) |
| 10.11 | * | 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) |
| 10.12 | * | 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) |
| 10.13 | * | 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) |
| 10.14 | * | 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) |
| 10.15 | * | 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) |
| 10.16 | * | 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) |
| 10.17 | * | 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) |
| 10.18 | * | 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) |
| 10.19 | * | 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) |
| 10.20 | † | 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). |
| 10.21 | † | 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) |
| 10.22 | * | 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) |
| 10.23 | * | 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) |
| 10.24 | † | Offer Letter by and between the Registrant and David Pernock dated January 2, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed December 19, 2016) |

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| 10.25 | | 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). |
| 10.26 | | 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) |
| 10.27 | * | 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) |
| 10.28 | † | 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) |
| 10.29 | (1) † | Form of Performance Stock Unit Grant Package (2014 Equity Incentive Plan) |
| 10.30 | (1) † + | Form of Performance Stock Unit Grant Package (2014 Equity Incentive Plan) |
| 10.31 | | 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) |
| 10.32 | | 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). |
| 10.33 | | 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). |
| 10.34 | + | 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). |
| 10.35 | + | 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). |
| 10.36 | | 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). |
| 10.37 | † | Consulting Agreement between the Registrant and Adrian J. Hepner, M.D., Ph.D. dated July 31, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 8-K, SEC File No. 001-36306, filed November 2, 2020). |
| 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 4, 2021.

**EAGLE PHARMACEUTICALS, INC.**

By: /s/ Scott Tarriff
Scott Tarriff
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<br>Scott Tarriff | Chief Executive Officer and Director<br>(Principal Executive Officer) | March 4, 2021 |
| /S/ BRIAN CAHILL<br>Brian Cahill | Chief Financial Officer<br>(Principal Accounting and Financial Officer) | March 4, 2021 |
| /S/ MICHAEL GRAVES<br>Michael Graves | Chairman of the Board of Directors | March 4, 2021 |
| /S/ STEVEN RATOFF<br>Steven Ratoff | Member of the Board of Directors | March 4, 2021 |
| /S/ JENNIFER K. SIMPSON<br>Jennifer K. Simpson | Member of the Board of Directors | March 4, 2021 |
| /S/ ROBERT L. GLENNING<br>Robert L. Glenning | Member of the Board of Directors | March 4, 2021 |
| /S/ RICHARD A. EDLIN<br>Richard A. Edlin | Member of the Board of Directors | March 4, 2021 |

**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 sheet of Eagle Pharmaceuticals, Inc. (the Company) as of December 31, 2020, the related consolidated statements of income, changes in stockholders' equity and cash flows for the year ended December 31, 2020, 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, 2020, and the results of its operations and its cash flows for the period ended 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, 2020, 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 4, 2021 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 disclosures to which it relates.

***Revenue Recognition - Chargebacks***

*Description of the Matter*

At December 31, 2020, the Company recorded an allowance for chargebacks totaling $2.3 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 chargeback reserve, 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 and performed analytical procedures to assess the correlation of monthly sales to distributors and monthly chargeback claims. 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 4, 2021

**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 income, changes in stockholders' equity and cash flows for each of the two years in the period 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 each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

**Change in Accounting Principles**

On January 1, 2019, the Company adopted Accounting Standards Update 2016-02, *Leases*. The effects of the adoption are described in Note 2 to the consolidated financial statements.

**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 audits. 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 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 consolidated 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 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 audits 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 audits provide 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, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 103,155 | $ 109,775 |
| Accounts receivable, net | 51,117 | 48,004 |
| Inventories | 8,075 | 6,566 |
| Prepaid expenses and other current assets | 3,718 | 15,104 |
| Total current assets | 166,065 | 179,449 |
| Property and equipment, net | 2,077 | 2,202 |
| Intangible assets, net | 12,917 | 15,583 |
| Goodwill | 39,743 | 39,743 |
| Deferred tax asset, net | 15,180 | 13,669 |
| Other assets | 17,208 | 3,908 |
| Total assets | $ 253,190 | $ 254,554 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 6,268 | $ 5,462 |
| Accrued expenses and other liabilities | 23,817 | 28,361 |
| Current portion of long-term debt | 8,000 | 5,000 |
| Total current liabilities | 38,085 | 38,823 |
| | | |
| Other long-term liabilities | 3,959 | 3,000 |
| Long-term debt, less current portion | 25,135 | 33,557 |
| Total liabilities | 67,179 | 75,380 |
| | | |
| **Commitments and contingencies** | | |
| | | |
| **Stockholders' equity:** | | |
| Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of December 31, 2020 and 2019 | — | — |
| Common stock, $0.001 par value; 50,000,000 shares authorized; 16,739,203 and 16,537,846 shares issued as of December 31, 2020 and 2019, respectively | 17 | 17 |
| Additional paid in capital | 305,403 | 278,518 |
| Retained earnings | 84,489 | 72,500 |
| Treasury stock, at cost, 3,682,176 and 2,907,687 shares as of December 31, 2020 and 2019, respectively | (203,898) | (171,861) |
| Total stockholders' equity | 186,011 | 179,174 |
| Total liabilities and stockholders' equity | $ 253,190 | $ 254,554 |

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, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| **Revenue:** | | | |
| Product sales, net | $ 72,323 | $ 73,989 | $ 70,385 |
| Royalty revenue | 110,479 | 112,903 | 142,927 |
| License and other revenue | 5,000 | 9,000 | — |
| Total revenue | 187,802 | 195,892 | 213,312 |
| **Operating expenses:** | | | |
| Cost of product sales | 33,647 | 47,891 | 42,374 |
| Cost of royalty revenue | 11,818 | 13,006 | 19,542 |
| Research and development | 30,785 | 36,810 | 44,419 |
| Selling, general and administrative | 78,598 | 76,370 | 60,509 |
| Restructuring charge | — | — | 7,911 |
| Asset impairment charge | — | — | 2,704 |
| Change in fair value of contingent consideration | — | — | (763) |
| Total operating expenses | 154,848 | 174,077 | 176,696 |
| Income from operations | 32,954 | 21,815 | 36,616 |
| Interest income | 562 | 2,169 | 158 |
| Interest expense | (2,577) | (2,686) | (2,736) |
| Other (expense) income | (8,262) | 700 | — |
| Total other (expense) income, net | (10,277) | 183 | (2,578) |
| **Income before income tax provision** | 22,677 | 21,998 | 34,038 |
| Income tax provision | 10,688 | 7,685 | 2,135 |
| **Net income** | $ 11,989 | $ 14,313 | $ 31,903 |
| Earnings per share: | | | |
| Basic | $ 0.89 | $ 1.04 | $ 2.16 |
| Diluted | $ 0.87 | $ 1.01 | $ 2.09 |
| Weighted average number of common shares outstanding: | | | |
| Basic | 13,481,525 | 13,754,516 | 14,768,625 |
| Diluted | 13,771,393 | 14,138,733 | 15,278,651 |

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 | Retained Earnings | Total Stockholders' Equity |
| **Balance at December 31, 2017** | **16,089** | **$ 16** | **$ 233,639** | **$ (80,795)** | **$ 26,284** | **$ 179,144** |
| Stock-based compensation expense | — | — | 19,082 | — | — | 19,082 |
| Issuance of common stock upon exercise of stock option grants | 415 | 1 | 8,614 | — | — | 8,615 |
| Payments for employee net option exercises | — | — | (4,877) | — | — | (4,877) |
| Common stock repurchases | — | — | — | (73,105) | — | (73,105) |
| Net income | — | — | — | — | 31,903 | 31,903 |
| **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** |

See accompanying notes to consolidated financial statements

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| **Cash flows from operating activities:** | | | |
| Net income | $ 11,989 | $ 14,313 | $ 31,903 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Deferred income taxes | (1,511) | 152 | (2,468) |
| Depreciation expense | 872 | 972 | 1,155 |
| Amortization expense of right-of-use assets | 1,228 | 1,159 | — |
| Amortization expense of intangible assets | 2,666 | 2,520 | 2,515 |
| Stock-based compensation expense | 24,756 | 21,998 | 19,082 |
| Change in fair value of contingent consideration | — | — | (763) |
| Fair value adjustments on equity investment | 5,300 | — | — |
| Amortization of debt issuance costs | 419 | 480 | 376 |
| Fair value adjustments on settled accelerated share repurchase agreement | 2,962 | — | — |
| Asset impairment charge | — | — | 2,704 |
| Non-cash restructuring charge | — | — | 5,769 |
| **Changes in operating assets and liabilities which provided (used) cash:** | | | |
| Accounts receivable | (3,113) | 18,481 | (12,665) |
| Inventories | (1,509) | 1,739 | (5,556) |
| Prepaid expenses and other current assets | 11,386 | (4,841) | 4,838 |
| Other assets | (2,325) | (599) | (570) |
| Accounts payable | 806 | (4,455) | (2,064) |
| Accrued expenses and other liabilities | (4,429) | 4,067 | 8,128 |
| Net cash provided by operating activities | 49,497 | 55,986 | 52,384 |
| **Cash flows from investing activities:** | | | |
| Purchase of property and equipment | (747) | (777) | (133) |
| Purchase of equity investment security | (17,500) | — | — |
| Net cash used in investing activities | (18,247) | (777) | (133) |
| **Cash flows from financing activities:** | | | |
| Repurchases of common stock | (34,999) | (17,961) | (73,105) |
| Payment of contingent consideration | — | — | (15,000) |
| Proceeds from existing revolving credit facility | 110,000 | — | — |
| Repayment of existing revolving credit facility | (110,000) | — | — |
| Payment of debt | (5,000) | (6,000) | (3,750) |
| Payment of debt financing costs | — | (326) | — |
| Payment of employee withholding tax upon vesting of stock-based awards | (1,525) | (198) | — |
| Payments for employee net option exercises | — | — | (4,877) |
| Proceeds from common stock option exercises | 3,654 | 260 | 8,615 |
| Net cash used in financing activities | (37,870) | (24,225) | (88,117) |
| **Net (decrease) increase in cash and cash equivalents** | (6,620) | 30,984 | (35,866) |

See accompanying notes to consolidated financial statements

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| **Cash and cash equivalents at beginning of period** | 109,775 | 78,791 | 114,657 |
| **Cash and cash equivalents at end of period** | $ 103,155 | $ 109,775 | $ 78,791 |
| | | | |
| **Supplemental disclosures of cash flow information:** | | | |
| **Cash paid during the period for:** | | | |
| Income taxes, net | $ 6,428 | $ 6,673 | $ 2,281 |
| Interest | 2,224 | 2,478 | 2,084 |
| Right-of-use asset obtained in exchange for lease obligation - lease amendment | 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. Eagle 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, Eagle strives 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 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. Eagle markets Ryanodex and Belrapzo, and Teva Pharmaceutical Industries Ltd. ("Teva") markets Bendeka through its subsidiary Cephalon, Inc.

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.

We view our operation and manage our business as one reporting segment because we have a single management team that reports to the Chief Executive Officer that 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, 2020, the Company had repurchased an aggregate of 3,682,176 shares of common stock for an aggregate of $206.9 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.

*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 income.

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.

*Vasopressin*

On April 16, 2018, the Company announced the FDA's acceptance of the Company's ANDA filing for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict® formulation, 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. On February 2, 2021, the Company announced that the FDA issued a complete response letter, or CRL, for the Company’s ANDA for vasopressin.

*PEMFEXY*

On December 13, 2019, we reached a settlement agreement with Eli Lilly and Company related to the Company’s novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®. The 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.

On February 10, 2020, we announced that it has received final approval from the FDA for its novel product, PEMFEXY™ (pemetrexed for injection), a branded alternative to ALIMTA®.

*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 is an investigational agent in two Phase 2 studies for pancreatic cancer and in a Phase 2 study for prostate cancer. Data is expected in 2021.

**2. Summary of Significant Accounting Policies**

***Significant Risks and Uncertainties***

In response to the ongoing COVID-19 pandemic, the Company has taken and continues 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 periodic communication to address employee and business concerns and providing frequent updates to the Company's Board of Directors ("Board"). The Company anticipates that the COVID-19 pandemic may also have an impact on the clinical development timelines for certain of its clinical programs, such as EA-114. The Company also anticipates that the COVID-19 pandemic may have an impact on the Company's 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 ongoing litigation, including the litigation with Par (as defined below) with respect to Vasopressin, and the Company anticipates that such delays will continue for the duration of the pandemic. The extent to which the COVID-19 pandemic will continue to impact the Company's business, its clinical development and regulatory efforts, its supply chain and sales efforts, its corporate development objectives and the value of, and market for, its 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 the Company's operations and could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

In addition, the Company is subject to other challenges and risks specific to its business and its ability to execute on its 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 its 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 its intellectual property rights; and the challenges of complying with applicable regulatory requirements. In addition, as the ongoing COVID-19 pandemic affects the Company's 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. The Company's critical accounting policies are those that are both most important to the Company's 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. The Company anticipates that the COVID-19 pandemic will continue to disrupt the Company's 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 significant. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments or revise the carrying value of its 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 the Company's 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 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.

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

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. 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..

***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.

The following tables present the Company’s hierarchy for its assets measured at fair value as of December 31, 2020 and 2019:

| | 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 | $ — | $ — |

| | December 31, 2019 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| **Assets:** | | | | |
| Money market funds | $ 85,625 | $ 85,625 | $ — | $ — |
| **Total financial assets** | $ 85,625 | $ 85,625 | $ — | $ — |

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, 2020 and 2019, respectively.

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***

*Other Intangible Assets, Net*

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 will evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include 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 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. The impairment test would be based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of income.

*Goodwill*

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition described in Note 11. 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 did not identify any impairment to goodwill during the periods presented.

***Acquisition-Related Contingent Consideration***

Contingent consideration related to a business combination is recorded on the acquisition date at the estimated fair value of the contingent payments. The acquisition date fair value is measured based on the consideration expected to be transferred using probability-weighted assumptions and discounted back to present value. The discount rate used is determined at the time of the acquisition in accordance with accepted valuation methods. The fair value of the acquisition-related contingent consideration is re-measured at the estimated fair value at each reporting period with the change in fair value recognized as income or expense in the consolidated statements of income.

***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.

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| **Net revenues** | | | |
| Cephalon, Inc. (Teva) - See Revenue Recognition | 67 % | 77 % | 75 % |
| Other | 33 % | 23 % | 25 % |
| | 100 % | 100 % | 100 % |

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| **Accounts receivable** | | |
| Cephalon, Inc. (Teva) - See Revenue Recognition | 58 % | 80 % |
| Other | 42 % | 20 % |
| | 100 % | 100 % |

***Inventories***

Inventories are recorded at the lower of cost or 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 $2.7 million, $2.4 million, and $3.3 million for the year ended December 31, 2020, 2019, and 2018, 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 on sales to commercial partners relates primarily to Bendeka. 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 controls the inventory while 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 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 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) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Belrapzo previously shipped and currently being shipped to distributors and (vi) 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.

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. Additionally, we consider other factors when estimating our current period return provision, including levels of inventory in the distribution channel, significant market changes that may impact future expected returns, and actual product returns, and may record additional provisions for specific returns that it believes are not covered by the historical rates. The Company's commercial returns policy and terms with certain customers also states that certain products are sold as non-returnable.

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.

*Other GTN considerations*

We may at our discretion provide price adjustments due to various competitive factors. There are circumstances under which we may not provide price adjustments to certain customers as a matter of business strategy, and consequently may lose future sales volume to competitors and risk a greater level of product returns.

As detailed above, we have the experience and access to relevant information that we believe are necessary to reasonably estimate the amounts of such deductions from gross revenues. Some of the assumptions we use for certain of these estimates are based on information received from third parties, such as wholesale customer inventories and market data, or other market factors beyond our control. The estimates that are most critical to the establishment of these reserves, and therefore, would have the largest impact if these estimates were not accurate, are estimates related to contract sales volumes, average contract pricing, customer inventories and return volumes. We regularly review the information related to these estimates and adjust our reserves accordingly, if and when actual experience differs from previous estimates. With the exception of the product returns allowance, the ending balances of accounts receivable reserves and allowances generally are processed during a two-month to four-month period.

The Company recorded product sales, net as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| | | (in thousands) | |
| Bendeka | $ 15,439 | $ 31,182 | $ 24,568 |
| Belrapzo | 27,527 | 29,665 | 22,853 |
| Ryanodex | 28,268 | 13,039 | 20,195 |
| Other | 1,089 | 103 | 2,769 |
| Product Sales, net | $ 72,323 | $ 73,989 | $ 70,385 |

The following table provides a summary roll-forward of the Company's net product revenue allowances and related reserves and allowances for the years ended December 31, 2020 and 2019, on the consolidated balance sheets (in thousands).

| | Chargebacks | Commercial Rebates | Medicaid Rebates | Product Returns | Wholesaler Fees and Other Incentives | Total |
|---|---|---|---|---|---|---|
| **Balance at December 31, 2018** | $ 6,032 | $ 1,789 | $ 319 | $ 705 | $ 3,614 | $ 12,459 |
| Provisions / Adjustments | 12,599 | 946 | 678 | 1,929 | 7,670 | 23,822 |
| Charges processed / Payments | (15,643) | (1,604) | (430) | (231) | (9,273) | (27,181) |
| **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 |

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 for Bendeka 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, 2020.

***Stock-Based Compensation***

The Company accounts for stock-based compensation using the fair value provisions of ASC 718, Compensation - Stock Compensation that requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based payments including stock options and restricted stock. This topic requires companies to estimate the fair value of the stock-based awards on the date of grant for options issued to employees and directors and record expense over the employees' service periods, which are generally the vesting period of the equity awards.

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. The straight-line method is used to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. The fair value of the Company's stock-based awards to employees and directors is estimated using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate is determined with the implied yield currently available for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options.

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

***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 warrants, options, convertible debt and other such convertible instruments. 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.

The anti-dilutive common shares equivalents outstanding at December 31, 2020, 2019, and 2018 were as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Options | 2,767,501 | 2,454,077 | 1,824,728 |
| Restricted stock units | 207,177 | — | — |
| Total | 2,974,678 | 2,454,077 | 1,824,728 |

The following table sets forth the computation for basic and diluted net income per share for December 31, 2020, 2019, and 2018:

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| **Numerator** | | | |
| Numerator for basic and diluted earnings per share-net income | $ 11,989 | 14,313 | $ 31,903 |
| **Denominator** | | | |
| Basic weighted average common shares outstanding | 13,481,525 | 13,754,516 | 14,768,625 |
| Dilutive effect of stock options | 289,868 | 384,217 | 510,026 |
| Diluted weighted average common shares outstanding | 13,771,393 | 14,138,733 | 15,278,651 |
| **Basic net income per share** | | | |
| Basic net income per share | $ 0.89 | $ 1.04 | $ 2.16 |
| **Diluted net income per share** | | | |
| Diluted net income per share | $ 0.87 | $ 1.01 | $ 2.09 |

***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.

*Recently Adopted Accounting Pronouncements*

The Company adopted FASB ASU No. 2016-02,“Leases (Topic 842)”("ASU 2016-02") as of January 1, 2019 to increase transparency and comparability among organizations, which included recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Lessees are required to recognize a lease liability, which represents the discounted obligation to make future minimum lease payments, and a corresponding right-of-use asset on the balance sheet for most leases. The Company adopted ASU 2016-02 using the modified retrospective approach and did not recognized a cumulative-effect adjustment to the opening balance of Retained earnings. The Company elected a number of optional practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward the historical lease classification and that permits lease agreements that are twelve months or less to be excluded from the balance sheet. The primary impact upon adoption was the recognition, on a discounted basis, of the Company’s minimum commitments under noncancelable operating leases as right of use assets and obligations on the consolidated balance sheets, of approximately $3 million. The Company may enter into future long-term lease agreements or exercise renewal options contained in existing lease agreements that could have a material impact on the right of use assets and obligations reflected on the consolidated balance sheets. Refer to Note 5 - Balance Sheet Accounts for further details.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses which requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected. This standard is effective for fiscal years beginning after December 15, 2019 and the Company adopted the standard effective January 1, 2020. The adoption of ASU 2016-13 had no material impact on the Company's financial position and 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**

Inventories consist of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Raw materials | $ 3,515 | $ 2,460 |
| Work in process | 2,589 | 3,243 |
| Finished products | 1,971 | 863 |
| | $ 8,075 | $ 6,566 |

(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) |
|---|---|---|---|
| | 2020 | 2019 | |
| Furniture and fixtures | $ 1,476 | $ 1,188 | 7 |
| Office equipment | 1,152 | 1,094 | 3 |
| Equipment | 3,485 | 3,095 | 7 |
| Leasehold improvements | 1,155 | 1,144 | 2 |
| | 7,268 | 6,521 | |
| Less accumulated depreciation | (5,191) | (4,319) | |
| Property and equipment, net | $ 2,077 | $ 2,202 | |

Depreciation expense related to property and equipment amounted to $872 and $972 for the year ended December 31, 2020 and 2019, respectively.

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

**5. Balance Sheet Accounts**

***Prepaid and Other Current Assets***

Prepaid and other current assets consist of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Advances to commercial manufacturers | $ 660 | $ 2,462 |
| Prepaid FDA user fee and advances to CROs | 1,262 | 6,345 |
| Prepaid insurance | 191 | 191 |
| Prepaid income taxes | — | 4,661 |
| All other | 1,605 | 1,445 |
| Total Prepaid expenses and other current assets | $ 3,718 | $ 15,104 |

***Accrued Expenses and Other Liabilities***

Accrued expenses and other liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Royalties payable to commercial partners | $ 5,996 | $ 6,004 |
| Accrued research & development | 2,724 | 1,686 |
| Accrued professional fees | 2,370 | 1,926 |
| Accrued salary and other compensation | 4,686 | 8,083 |
| Accrued product sales reserves | 4,966 | 8,364 |
| All other | 3,075 | 2,298 |
| Total Accrued expenses and other liabilities | $ 23,817 | $ 28,361 |

***Leases***

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) in order to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet. ASU 2016-02 requires a lessee to recognize a liability to make lease payments (the lease liability) and a right-of-use (“ROU”) asset representing its right to use the underlying asset for the lease term on the balance sheet.

A lease is a contract, or part of a contract, that conveys the right to control the use of explicitly or implicitly identified property, plant or equipment in exchange for consideration. Control of an asset is conveyed to the Company if the Company obtains the right to obtain substantially all of the economic benefits of the asset or the right to direct the use of the asset. The Company recognizes ROU assets and lease liabilities at the lease commencement date based on the present value of future, fixed lease payments over the term of the arrangement. ROU assets are amortized on a straight-line basis over the term of the lease. Lease liabilities accrete to yield and are reduced at the time when the lease payment is payable to the vendor.

In accordance with Topic 842, leases are measured at present value using the rate implicit in the lease or, if the implicit rate is not determinable, the lessee's incremental borrowing rate. As the implicit rate is not typically available, the Company uses its incremental borrowing rate based on the information available at the lease commencement date to determine the present value of future lease payments. The implicit borrowing rate approximates the rate the Company would pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in similar economic environment.

The Company leases office space in Woodcliff Lake, New Jersey for its principal office under an amended lease agreement through June 2025. The Company also leases a lab space in Cambridge, Massachusetts under a lease agreement through April

2024. Both the Company leases are classified as operating leases and have remaining lease terms ranging from 3.33 years to 4.5 years. The principal office and the lab space leases include renewal option to extend the lease for up to 5 years. Furthermore, the Company has 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):

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Operating lease cost | $ 1,323 | $ 1,146 |
| Total lease cost | $ 1,323 | $ 1,146 |
| | | |
| **Other information:** | | |
| Cash paid for amounts included in the measurement of lease liabilities | | |
| Operating cash flows for operating leases | $ 1,323 | $ 952 |
| Right-of-use assets obtained in exchange for new operating lease liabilities | $ 855 | $ 3,716 |
| Weighted-average remaining lease term - operating leases | 4.1 years | 5.0 years |
| Weighted-average discount rate - operating leases | 6.0 % | 6.0 % |

The table below presents the maturity of lease liabilities on an annual basis for the remaining years for the Company's two lease agreements (in thousands):

| **Year Ending December 31,** | **Operating Leases** |
|---|---|
| 2021 | $ 1,391 |
| 2022 | 1,423 |
| 2023 | 1,455 |
| 2024 | 1,038 |
| 2025 | 413 |
| Thereafter | — |
| Total | 5,720 |
| Less: present value discount | (638) |
| Present value of lease liabilities | $ 5,082 |
| | |
| **Balance Sheet Classification at December 31:** | |
| Current lease liabilities | $ 1,123 |
| Long-term lease liabilities | 3,959 |
| Total lease liabilities | $ 5,082 |

**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

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

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 $8 million on the consolidated balance sheet as of December 31, 2020. Per the terms of the Revised Credit Agreement, the Company is limited in its ability to pay dividends. As of December 31, 2020, 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 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, 2020, the Company had $0.9 million of unamortized deferred debt issuance costs in its consolidated balance sheets.

| **Debt Maturities** | **At December 31, 2020** |
|---|---|
| 2021 | $ 8,000 |
| 2022 | 26,000 |
| Total | $ 34,000 |

On August 8, 2017, the Company entered into an Amended and Restated Credit Agreement (the “Amended Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Agent”) and the lenders party thereto, which amended and restated the Company’s then existing credit agreement, dated as of January 26, 2017. The Amended Credit Agreement provided for a 3-year $50 million revolving credit facility and a 3-year $100 million term loan facility (which are collectively referred to as the “Amended Credit Facility”). The Amended Credit Facility was subject to certain financial covenants.

On the date of the amendment, $50 million of the term loan facility was drawn, and none of the revolving credit facility had been drawn. The Amended Credit Facility included a $5 million letter of credit subfacility. Loans under the Amended Credit Facility bore interest, at the Company’s option, 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 Amended Credit Agreement), or (b) the prime lending rate, plus an applicable margin ranging from 1.25% to 2.0% per annum, based upon the total net leverage ratio. The Company was required to pay a commitment fee on the unused portion of the Amended Credit Facility at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio. The Company was permitted to terminate or reduce the revolving commitments or term commitments of the lenders and to make voluntary prepayments at any time subject to break funding payments. The Company was required to make mandatory prepayments of outstanding indebtedness under the Amended Credit Agreement (a) upon receipt of proceeds from certain sales, transfers or other dispositions, casualty and other condemnation events and the incurrence of certain indebtedness other than indebtedness permitted, subject to customary reinvestment exceptions and (b) in the case that the aggregate amount of all outstanding loans and letters of credit issued under the Amended Credit Facility exceed the aggregate commitment of all lenders under the Amended Credit Facility. The Company

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

was obligated to repay the term loan facility on the last day of each March, June, September and December in an aggregate principal amount equal to 2.5% during the term of the loan.

**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, 2020, the Company had repurchased an aggregate of 3,682,176 shares of common stock for an aggregate of $206.9 million pursuant to the Company's share repurchase programs in effect since August 2016.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Shares of common stock repurchased | 774,489 | 317,429 | 1,348,563 |
| Cash paid for repurchases of common stock | $ 34,999 | $ 17,961 | $ 73,105 |

**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,

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

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, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Risk-free interest rate | 0.37% - 1.65% | 1.42% - 2.61% | 2.30% - 3.07% |
| Volatility | 54.89% - 55.51% | 40.83% - 50.73% | 43.76% |
| Expected term (in years) | 5.50 - 6.08 years | 1.51 - 9.41 years | 5.50 - 6.08 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, 2018** | **2,556,365** | **$ 62.78** | **1,074,456** | **1,481,909** |
| Granted | 628,133 | $ 44.28 | | |
| Exercised | (23,032) | $ 10.33 | | |
| Forfeited or expired | (65,305) | | | |
| **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** |

The weighted-average grant-date fair value of options granted during the year ended December 31, 2020, 2019, and 2018 was $28.98, $22.18, and $26.73, respectively. As of December 31, 2020, there was $19,447 unrecognized stock-based compensation expense related to stock options that is expected to be recognized over a weighted average period of 2.7 years. The total intrinsic value of options exercised during the year ended December 31, 2020 was $3,383.

The weighted average contractual terms of options outstanding as of December 31, 2020, 2019, and 2018 was 6.1, 6.8, and 7.3 years, respectively.

The aggregate pre-tax intrinsic value of options outstanding as of December 31, 2020, 2019, and 2018 was $11.6 million, $31.9 million, and $10.7 million, respectively.

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

*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, 2018** | **54,219** | **$ 59.02** |
| Granted | 211,829 | $ 42.17 |
| Vested | (13,555) | $ 59.02 |
| Forfeited | (1,278) | $ 52.19 |
| **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** |

As of December 31, 2020, there was $10,945 of unrecognized stock-based compensation expense related to non-vested RSUs that is expected to be recognized over a weighted average period of 2.7 years.

*PSUs*

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 2.06%, an expected volatility of 47%, contractual term of 3 years, and no expected dividend yield.

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, 2018** | **117,219** | **$ 90.19** |
| Granted | **—** | **$ —** |
| Vested | **—** | **$ —** |
| Forfeited | (1,038) | $ 90.19 |
| **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** |

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

The Company recognized stock-based compensation in its consolidated statements of income for the year ended December 31, 2020, 2019, and 2018 as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Stock options | $ 17,694 | $ 16,394 | $ 15,333 |
| PSUs | 1,635 | 3,062 | 3,059 |
| RSUs | 5,427 | 2,542 | 690 |
| Stock-based compensation expense | $ 24,756 | $ 21,998 | $ 19,082 |
| Selling, general and administrative | $ 22,074 | $ 17,556 | $ 15,068 |
| Research and development | 2,682 | 4,442 | 4,014 |
| Stock-based compensation expense | $ 24,756 | $ 21,998 | $ 19,082 |

(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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Current: | | | |
| Federal | $ 10,140 | $ 6,689 | $ 4,137 |
| State | 2,059 | 844 | 466 |
| | $ 12,199 | $ 7,533 | $ 4,603 |
| Deferred: | | | |
| Federal | (1,227) | 392 | (2,565) |
| State | (284) | (240) | 97 |
| | $ (1,511) | $ 152 | $ (2,468) |
| | | | |
| Provision for income taxes | $ 10,688 | $ 7,685 | $ 2,135 |

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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Federal statutory tax rate | 21 % | 21 % | 21 % |
| State income taxes, net of federal benefit | 6 % | 2 % | 1 % |
| Tax benefit on stock option exercises, net of forfeitures | 4 % | 1 % | (11)% |
| R&D tax credits and Orphan Drug credits | (2)% | (2)% | (7)% |
| Limitation on executive compensation | 9 % | 10 % | 3 % |
| Change in valuation allowance | 9 % | 4 % | — % |
| Other | — % | (1)% | (1)% |
| **Effective tax rate** | 47 % | 35 % | 6 % |

(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, | |
|---|---|---|
| | 2020 | 2019 |
| Deferred tax assets | | |
| Net operating loss carryforward | $ 841 | $ 243 |
| Stock based compensation | 12,015 | 10,647 |
| Other asset - equity investment with readily determined fair value | 1,771 | — |
| Inventories | 2,338 | 1,539 |
| Employee-related expenses | 51 | 51 |
| Prepaid R&D expenses | 479 | 620 |
| Intangible assets | 708 | 662 |
| ROU asset | 1,154 | 925 |
| Research and development tax credit carryforwards | 86 | — |
| Other | 737 | 1,017 |
| Total deferred tax assets | 20,180 | 15,704 |
| | | |
| Deferred tax liabilities | | |
| Installment sale - Malta | 483 | — |
| Prepaid expenses | 43 | 43 |
| Fixed assets | 315 | 203 |
| Lease liability | 1,092 | 838 |
| Other | — | — |
| Total deferred tax liabilities | 1,933 | 1,084 |
| Valuation allowance | (3,067) | (951) |
| **Net deferred tax assets** | $ 15,180 | $ 13,669 |

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. Given that the company has incurred tax losses in most years since its inception, all of the Company’s tax years are effectively open to examination. The Company is under audit by the Internal Revenue Service and three states tax jurisdiction as of December 31, 2020. The Company has no amount recorded for any unrecognized tax benefits as of December 31, 2020. 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.

**9. License and Collaboration Agreements**

***License Agreements***

On February 13, 2015, the Company submitted a New Drug Application or NDA to the FDA for Bendeka, which was approved by the FDA on December 7, 2015. Also, on February 13, 2015, the Company entered into the Cephalon License 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, Cephalon will be responsible for all U.S. commercial activities for the product including promotion and distribution, and the Company is responsible for obtaining and maintaining all regulatory approvals and conducting post-approval clinical studies. In connection with the Cephalon License, the Company has entered into a supply agreement with Cephalon, pursuant to which the Company is responsible for supplying product to Cephalon. As of March 29, 2019, the Company and TPIG 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 income. On April 13, 2019, we announced an expansion of our Cephalon License. Under the terms of the revised agreement, beginning on October 1, 2019, Eagle'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 revised agreement also extends the U.S. Bendeka royalty term until it is no longer sold in the United States. The previous U.S. royalty term was set to expire in 2025.

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. Under the License Agreement, 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 will bear 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, Eagle 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 the Company's assessment of the probability of additional costs, we have not deferred revenue on the SymBio License Agreement. SymBio is also 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 ("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.

Pursuant to the terms of the SymBio License Agreement, the Company and SymBio will enter into a separate supply agreement, under which the Company 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 Agreement, the Company will retain the right to control the prosecution, maintenance and enforcement of the Company's patents covering the Products, both inside and outside of Japan.

The Company has entered into several product development agreements with development partners whereby the Company acquired the exclusive rights in the United States and, in most cases, worldwide rights to a total of thirty-three products for ten years following first commercial sale of each product. The Company will share varying percentages of the profits after, in most cases, recapturing development, legal and certain operating costs, from the sales of the products with the development partners if the products are commercialized. The Company expenses these costs as incurred.

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

The Company earned a $5.0 million milestone in the year ended December 31, 2020 when its marketing partner, SymBio Pharmaceuticals Limited, received regulatory approval for TREAKISYM ready-to-dilute (250 ml) liquid bendamustine formulation from the Pharmaceuticals and Medical Devices Agency in Japan.

***Collaboration with Tyme***

On January 7, 2020, Tyme and the Company announced a strategic collaboration to advance SM-88, an oral product candidate for the treatment of patients with cancer. SM-88 is an investigational agent in two Phase II studies, one for pancreatic cancer and another for prostate cancer.

Under the terms of the related agreements, Tyme is entitled to receive up to a total $40.0 million as follows:

(a) an initial $20.0 million upfront payment. In return, we received 10 million restricted shares of Tyme's common stock at $2.00 per share. The Company is contractually restricted from selling its investment in Tyme for up to three years; and

(b) a second potential $20.0 million milestone payment upon the earlier of (i) the successful completion of a pivotal trial in pancreatic cancer or (ii) FDA approval of SM-88 in any cancer indication within the United States. Upon occurrence of such milestone event, this payment would be split into a $10.0 million one-time milestone cash payment and a $10.0 million additional investment in Tyme's preferred stock. The preferred shares will be convertible into common stock with a conversion price at a 15% premium to the then-prevailing common stock market price per share.

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 be 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.

Under the terms of the agreement, the initial $20.0 million paid to Tyme, was accounted for as a $17.5 million readily determinable fair value equity investment based on the closing price per share of Tyme's common stock on January 7, 2020. The remainder was treated as an upfront collaboration payment of $2.5 million that was recorded as selling, general and administrative expense in the first quarter of 2020. The investment in Tyme represents approximately 9% of the total shares outstanding of Tyme's common stock.
As of December 31, 2020, the Company included its investment in Tyme in Other Assets (non-current) on its consolidated balance sheet. For the year ended December 31, 2020, the fair value adjustments for the equity investment was a loss of $5.3 million which was recorded in other income (expense) on our consolidated statements of operations.

**10. Commitments**

Our future material contractual obligations include the following:

| Obligation | Total | 2021 | 2022 | 2023 | 2024 | 2025 |
|---|---|---|---|---|---|---|
| Operating leases (1) | $ 5,720 | $ 1,391 | $ 1,423 | $ 1,455 | $ 1,038 | $ 413 |
| Credit facility | 34,000 | 8,000 | 26,000 | — | — | — |
| Purchase obligations (2) | 68,644 | 68,644 | — | — | — | — |
| Total obligations | $ 108,364 | $ 78,035 | $ 27,423 | $ 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. Rental expense was $1,323, $1,146, and $571, for the years ended December 31, 2020, 2019, and 2018, respectively. The remaining future lease payments

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

under the operating leases, exclusive of any renewal option periods, are $5,720 as of December 31, 2020, payable monthly through June 30, 2025 and April 30, 2024.

(2) As of December 31, 2020, the Company has purchase obligations in the amount of $68,644 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 Transactions**

During the year ended December 31, 2018, the Company obtained legal services from Greenberg Traurig, LLP in exchange for $0.2 million. Richard A. Edlin, a member of the Company's Board, is an attorney and shareholder of Greenberg Traurig, LLP.

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.

**12. Intangible Assets, Net**

The gross carrying amounts and net book value of our intangible assets are as follows:

| | | December 31, 2020 | | | |
|---|---|---|---|---|---|
| | Useful Life (In Years) | Gross Carrying Amount | Accumulated Amortization | Accumulated Impairment Charges | 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 |

| | | December 31, 2019 | | | |
|---|---|---|---|---|---|
| | Useful Life (In Years) | Gross Carrying Amount | Accumulated Amortization | Accumulated Impairment Charge | Net Book Value |
| Ryanodex intangible | 20 | 15,000 | (2,454) | — | 12,546 |
| Developed technology | 5 | 8,100 | (5,063) | — | 3,037 |
| Total | | $ 23,100 | $ (7,517) | $ — | $ 15,583 |

Amortization expense amounted to $2.7 million, $2.5 million, and $2.5 million, for the year ended December 31, 2020, 2019, and 2018, respectively.

*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, 2020 and 2019.

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

*Intangible Asset Impairment*

On June 30, 2018, the Company implemented a restructuring initiative based on its assessment of the current product portfolio and made a decision to discontinue manufacture and distribution of Non-Alcohol Docetaxel Injection. The Company ceased selling the product by September 30, 2018. As a result, the Company recognized a pre-tax, non-cash asset impairment charge of $2.7 million during the year ended December 31, 2018.

*Estimated Amortization Expense for Intangible Assets*

Based on definite-lived intangible assets recorded as of December 31, 2020, 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:

| | Estimated Amortization Expense |
|---|---|
| Year Ending December 31, | |
| 2021 | $ 2,622 |
| 2022 | 1,369 |
| 2023 | 1,570 |
| 2024 | 1,898 |
| All other | 5,458 |
| Total estimated amortization expense | $ 12,917 |

**13. Legal Proceedings**

In addition to the below legal proceedings, from time to time, the Company 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, the Company currently believes that the final outcome of these ordinary course matters, or matters discussed below, will not have a material adverse effect on the Company's business nor has the Company recorded any loss in connection with these matters because the Company believes that loss is neither probable nor estimable. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors.

**Commercial Litigation**

*In Re: Taxotere (Docetaxel)*

On February 1, 2017, the Company was named as a defendant, among various other manufacturers, in several product liability suits that are consolidated in the U.S. District Court for the Eastern District of Louisiana as part of MDL 2740 (Civil Action No 2:16 md-2740), or the Multidistrict Litigation. The claims are for personal injuries allegedly arising out of the use of docetaxel.

In March 2017, the Company reached agreements in principle with the Plaintiffs' Steering Committee in this matter to voluntarily dismiss the Company from all of the lawsuits in which it was named and from the master complaint. The Company is in the process of working with the other parties in this matter to have it removed from the Multidistrict litigation entirely. As part of the agreement, in the event a case is brought in the future with facts that justify the Company's inclusion, the plaintiffs reserved the right to include the Company in such matter. The plaintiffs have filed several additional lawsuits since the parties' agreement in principle to dismiss, and the Company is in the process of working with plaintiffs to explore the possibility of dismissing those lawsuits.

*Eagle v. Azar*

On April 27, 2016, the Company filed an action in the U.S. District Court for the District of Columbia (the "District Court") against the FDA and other federal defendants seeking an order requiring the FDA to recognize orphan drug exclusivity for Bendeka for the treatment of CLL and indolent B-cell NHL. On June 8, 2018, the District Court issued a decision requiring the

FDA to recognize seven years of orphan drug exclusivity in the U.S. for Bendeka, and on July 6, 2018 the FDA recognized such ODE until December 7, 2022. In addition, on July 6, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested that the District 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 District Court on August 1, 2018 on the grounds that the FDA had not satisfied the standard for altering or amending the judgment. The FDA and two intervenors appealed the District Court's final judgment to the U.S. Court of Appeals for the District of Columbia Circuit (the "Court of Appeals"). Oral arguments occurred on October 17, 2019, and on February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of exclusivity for Bendeka. On March 13, 2020, a panel of the Court of Appeals affirmed the District Court's decision.

FDA filed a petition for rehearing *en banc* on May 27, 2020, which was denied on August 17, 2020. The deadline for the FDA to file a petition for writ of certiorari with the Supreme Court was January 14, 2021, and Eagle is not aware that any petition was filed and has not received service of any such petition. Pursuant to the District Court's decision, no bendamustine product used to treat the same indications (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka.

*Eagle v. Eli Lilly*

On August 24, 2017, the Company filed an antitrust complaint in the United States District Court for the District of New Jersey ("New Jersey District Court") against Eli Lilly and Company ("Lilly"). The complaint alleges that Lilly engaged in anticompetitive conduct which restrained competition by delaying and blocking the Company's launch of a competing pemetrexed injection product (to compete with Lilly's Alimta). Lilly accepted service and answered the complaint on October 27, 2017. Lilly also filed a motion to transfer this case to Delaware on October 27, 2017. The Company filed a motion to oppose such transfer on November 6, 2017. On July 20, 2018, the New Jersey District Court transferred the case to Delaware. On November 27, 2018, the Delaware Court stayed the case at least until conclusion of the Pemfexy™ patent trial described below. On December 16, 2019, the Delaware Court entered the Company and Lilly's stipulation dismissing this case with prejudice.

*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 Company and Cipla's December 14, 2012 supply agreement. Eagle believes that allegations in the demand for arbitration are without merit and intends to vigorously defend itself in the arbitration, which was scheduled for June 2021, has been rescheduled for November 2021.

**Patent Litigation**

*Eli Lilly and Company v. Eagle Pharmaceuticals, Inc. (Pemfexy™ (Pemetrexed))*

On August 14, 2017, Lilly filed suit against the Company in the United States District Court for the Southern District of Indiana (the "Indiana Suit"). Lilly alleged patent infringement based on the filing of the Company's 505(b)(2) NDA seeking approval to manufacture and sell the Company's EP-5101. EP-5101, if finally approved by FDA, will be a branded alternative to Alimta®.

On September 8, 2017, Eagle moved to dismiss the Indiana Suit for improper venue. On September 11, 2017, Lilly voluntarily dismissed the Indiana Suit. It then filed a complaint in the United States District Court for the District of Delaware, alleging similar patent infringement claims (the "Delaware Suit"). Eagle answered and filed various counterclaims in the Delaware Suit on October 3, 2017. Lilly answered Eagle's counterclaims on October 24, 2017. On May 31, 2018, Eagle filed a Motion for Judgment on the Pleadings, which the Court denied on October 26, 2018. On January 23, 2019, the Court held a Markman hearing. Trial took place from October 28, 2019 to October 31, 2019 and continued on December 12, 2019 through December 13, 2019. On December 13, 2019, the Company and Lilly settled this litigation. The settlement 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. On December 16, 2019, the District Court entered the Company and Lilly's stipulation dismissing this case with prejudice.

*Eagle Pharmaceuticals, Inc. and ScinoPharm Taiwan, Ltd. v. Shilpa Medicare Ltd. (Pemfexy)*

On December 23, 2020, the Company, along with ScinoPharm Taiwan Ltd. (together, "Eagle") brought suit against Shilpa Medicare Limited in the United States District Court for the District of New Jersey. Eagle alleges infringement based on the filing of Shilpa's NDA seeking approval to manufacture and sell Pemetrexed injection prior to the expiration of U.S. Patent No. 9,604,990. Shilpa has accepted service, and its answer to the complaint is due by March 29, 2021 This suit is pending.

*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. - (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.

The Company, 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. Defendents' reply briefs are due April 5, 2021.

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 the Company's favor on all claim terms. Trial is scheduled for November 15, 2021. The case remains pending.

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. Trial is scheduled for July 18, 2022.

The FDA is stayed from approving Aurobindo's ANDA, and Hospira's 505(b)(2) application, until the earlier of (1) October 6, 2022 and December 7, 2020 respectively (the "30-month stay dates"); and (2) a court decision that each of the challenged patents is not infringed, invalid, or unenforceable. The 30-month stay dates may be shortened or lengthened if either party to the action fails to reasonably cooperate in expediting the action.

*Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company*

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*

Slayback filed a 505(b)(2) NDA referencing Eagle's Belrapzo NDA. Slayback's NDA includes challenges to one or more of the Belrapzo Orange Book-listed patents. On December 11, 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. 9,265,831, 9,572,796, 9,572,797, and 10,010,533. On January 4, 2019, Slayback filed a motion for judgment on the pleadings. On May 9, 2019, the United States District Court for the District of Delaware granted Slayback's motion for judgment on the pleadings. On July 23, 2019, the Company filed an appeal of this decision with the United States Court of Appeals for the Federal Circuit. On May 8, 2020, the Federal Circuit upheld the district court's decision.

*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, the Company 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, has been rescheduled to begin on July 7, 2021. The 30-month stay of FDA approval expired on October 17, 2020. This suit is pending.

On December 7, 2020, Par filed a separate suit against the Company 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 the Company's ANDA seeking approval to manufacture and sell the Company's vasopressin product. Eagle's response to the complaint is due by March 1, 2021. This suit is pending.

*Eagle Pharmaceuticals, Inc. et al. v. Accord (Argatroban)*

On March 27, 2019, the Company and Chiesi filed suit against Accord Healthcare, Inc. ("Accord") in the United States District Court for the District of New Jersey (the "New Jersey suit") and in the United States District Court for the Middle District of North Carolina (the "North Carolina suit") (together "the suits"). The suits alleged patent infringement based on Accord's 505(b)(2) NDA seeking approval to manufacture and sell Accord's proposed argatroban product. On May 21, 2019, the Company and Chiesi voluntarily dismissed the North Carolina suit. On July 10, 2019, Accord moved for judgment on the pleadings in the New Jersey suit. On June 30, 2020, the district court held a settlement conference. On October 7, 2020, the Magistrate Judge held a status conference. On October 8, 2020, Accord withdrew its July 10, 2019 motion for judgment on the pleadings. The parties submitted a proposed discovery plan to the Court in the New Jersey suit on October 27, 2020. The Court has not set a schedule or trial date. The New Jersey suit remains pending.

**14. Restructuring**

As part of its ongoing organizational review, the Company engaged in a restructuring initiative to rationalize its product portfolio and focus its physical sites. These measures included the discontinuation of manufacture and distribution of Non-Alcohol Docetaxel Injection in June 2018 and plans to rationalize research and development operations. Charges consist of inventory and related reserves, certain asset impairment charges related to property and equipment, and personnel related costs. The restructuring costs of $7,911 for the year ended December 31, 2018 has been recorded to Restructuring charge on the Consolidated Statements of Income. The Company also recorded an asset impairment charge for the remaining Intangible asset for Non-Alcohol Docetaxel Injection of $2,704 as well as an adjustment to remove the contingent consideration of $763 on the related line items in the Statements of Income for the year ended December 31, 2018. The Company does not expect to incur additional expenses related to this restructuring initiative. There was no liability remaining for the restructuring as of December 31, 2018.

**Eagle Pharmaceuticals, Inc.**
**Performance Stock Unit Grant Notice (2014 Equity Incentive Plan)**

Eagle Pharmaceuticals, Inc. (the "***Company***"), pursuant to its 2014 Equity Incentive Plan (as amended, the "***Plan***"), hereby awards to Participant a Performance Stock Unit Award for the number of shares of the Company's Common Stock ("***Performance Stock Units***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Performance Stock Unit Grant Notice***"), and the Performance Stock Unit Award Agreement (the "***Award Agreement***") (which is attached hereto) and the Plan, both of which are incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Performance Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:
Date of Grant:
Vesting Commencement Date:
Target Number of Performance Stock Units:
Maximum Number of Performance Stock Units:

**Vesting Schedule:** See Exhibit A hereto.

**Issuance Schedule:** Subject to any Capitalization Adjustment, one share of Common Stock (or its cash equivalent, at the discretion of the Company) will be issued for each Performance Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Performance Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Performance Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award (including, but not limited to, the Eagle Pharmaceuticals, Inc. Severance Benefit Plan and any Equity Award Vesting Acceleration Benefit Letter Agreement between Participant and the Company), with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Performance Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**Eagle Pharmaceuticals, Inc. Participant:**
By:
Signature Signature
Title: Date:
Date:

**Attachments**: Award Agreement

**Attachment I**
**Eagle Pharmaceuticals, Inc.**
**2014 Equity Incentive Plan**
**Performance Stock Unit Award Agreement**

Pursuant to the Performance Stock Unit Grant Notice (the "***Grant Notice***") and this Performance Stock Unit Award Agreement (the "***Agreement***"), Eagle Pharmaceuticals, Inc. (the "***Company***") has awarded you ("***Participant***") a Performance Stock Unit Award (the "***Award***") pursuant to the Company's 2014 Equity Incentive Plan (as amended, the "***Plan***") for the number of Performance Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. **Grant of the Award.** This Award represents the right to be issued on a future date one (1) share of Common Stock for each Performance Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Performance Stock Units/shares of Common Stock subject to the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of Common Stock, in part or in full satisfaction of the delivery of Common Stock in connection with the vesting of the Performance Stock Units, and, to the extent applicable, references in this Agreement and the Grant Notice to Common Stock issuable in connection with your Performance Stock Units will include the potential issuance of its cash equivalent pursuant to such right. This Award was granted in consideration of your services to the Company.
2. **Vesting.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Except as otherwise set forth in Exhibit A attached hereto, vesting will cease upon the termination of your Continuous Service and the Performance Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the shares of Common Stock to be issued in respect of such portion of the Award.
3. **Number of Shares.** The number of Performance Stock Units (including the Target Number of Performance Stock Units and the Maximum Number of Performance Stock Units set forth in the Grant Notice) subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Performance Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Performance Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.
4. **Securities Law Compliance**. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Performance Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.
5. **Transfer Restrictions**. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Performance Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Performance Stock Units.

**Death**. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

**Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder,

pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

1. **Date of Issuance.**

The issuance of shares in respect of the Performance Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation set forth in Section 11 of this Agreement, in the event one or more Performance Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Performance Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***".

If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

i. the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Arrangement***")), *and*

ii. either (1) a Withholding Obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Obligation by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer pursuant to Section 11 of this Agreement (including but not limited to a commitment under a 10b5-1 Arrangement) and (C) not to permit you to pay your Withholding Obligation in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

1. **Dividends.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; provided, however, that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.
2. **Restrictive Legends.** The shares of Common Stock issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.
3. **Execution of Documents.** You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.
4. **Award not a Service Contract**.

Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or

affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

1. **Withholding Obligation.**

(a) On each vesting date, and on or before the time you receive a distribution of the shares of Common Stock in respect of your Performance Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision, including in cash, for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Obligation***").

(b) By accepting this Award, you acknowledge and agree that the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Obligation relating to your Performance Stock Units by any of the following means or by a combination of such means: (i) causing you to pay any portion of the Withholding Obligation in cash; (ii) withholding from any compensation otherwise payable to you by the Company; (iii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued pursuant to Section 6) equal to the amount of such Withholding Obligation; provided, however, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Withholding Obligation using the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided*, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or the Company's Compensation Committee; and/or (iv) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***"), pursuant to this authorization and without further consent, whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Performance Stock Units to satisfy the Withholding Obligation and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Obligation directly to the Company and/or its Affiliates. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to you any Common Stock or any other consideration pursuant to this Award.

(c) In the event the Withholding Obligation arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Withholding Obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

1. **Tax Consequences.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible

for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

2. **Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.
3. **Notices**. Any notice or request required or permitted hereunder shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.
4. **Headings**. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.
5. **Miscellaneous**.

The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

1. **Governing Plan Document**. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.
2. **Effect on Other Employee Benefit Plans.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.
3. **Severability**. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

4. **Other Documents**. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.
5. **Amendment.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.
6. **Compliance with Section 409A of the Code**. This Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Performance Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Performance Stock Unit Grant Notice to which it is attached.

**Exhibit A**
**Performance Vesting Terms**

The Performance Stock Units awarded hereunder shall vest, if at all, based on the Company's Relative TSR Ranking (as defined below) during the Performance Period (as defined below), subject to the terms and conditions of the Plan, the Grant Notice, the Agreement and this Exhibit A. Capitalized terms not explicitly defined in this Exhibit A shall have the same meanings given to them in the Plan, the Grant Notice or the Agreement, as applicable.

1. **Determination of Number of Earned Performance Stock Units.** The number of Performance Stock Units that shall be entitled to vest based on the Company's Relative TSR Ranking (the "***Earned Performance Stock Units***") shall be determined in accordance with the following table, with linear interpolation used to determine the number of Earned Performance Stock Units between the applicable achievement levels if the Company's Relative TSR Ranking is greater than the 25th percentile, but less than the 90th percentile, in each case with the resulting number rounded to the nearest whole number; *provided*, *however*, that notwithstanding anything to the contrary in this Exhibit A, if the Company's Total Stockholder Return (as defined below) is below 0%, the number of Earned Performance Stock Units may not exceed 100% of the Target Number of Performance Stock Units (as set forth in the Grant Notice). For clarity, (i) no Performance Stock Units shall be eligible to vest if the Company's Relative TSR Ranking is below the 25th percentile and (ii) the total number of Earned Performance Stock Units may not exceed the Maximum Number of Performance Stock Units (as set forth in the Grant Notice).

| | **Company's Relative TSR Ranking** | **Number of Earned Performance Stock Units (% of Target Number of Performance Stock Units)** |
|---|---|---|
| Maximum | 90th percentile or above | 200% |
| Target | 50th percentile | 100% |
| Threshold | 25th percentile | 50% |
| | Below 25th percentile | 0% |

1. **Vesting Date.** Subject to Section 3 below, the Earned Performance Stock Units shall vest on the date that the Committee (as defined below) certifies the Company's Relative TSR Ranking and determines the number of Earned Performance Stock Units (which will be as soon as administratively practicable following the end of the Performance Period, but in no event later than March 1, 2024). A Participant must remain in Continuous Service with the Company through the end of the Performance Period in order to receive any Earned Performance Stock Units, except as otherwise provided in Section 3 below.
2. **Change in Control and Covered Termination.** Notwithstanding anything to the contrary in this Exhibit A, if a Change in Control occurs during the Performance Period, then:
    i. The number of Earned Performance Stock Units shall be determined by the Committee in accordance with Section 1 above (and for purposes of this Exhibit A, such number shall be the "***CIC Earned Performance Stock Units***"); *provided*, *however*, that (x) solely for purposes of determining the Total Stockholder Return of the Company, "Ending Share Price" shall mean the Fair Market Value of the per-share of Common Stock consideration received by the Company's stockholders in such Change in Control, and (y) solely for purposes of determining the Total Stockholder Return of the other Index Companies (and which companies constitute the Index Companies), the term "Performance Period" as it appears in the definition of "Ending Share Price" shall mean the period commencing on (and including) February 1, 2021 and ending on (and including) the last trading day prior to such Change in Control, provided that the Board shall have the discretion to use any date within the five trading day period prior to such Change in Control;
    ii. If, in connection with such Change in Control, the Award is assumed, substituted for, or continued by the surviving or acquiring company (or its parent entity), then the CIC Earned Performance Stock Units shall vest on the last day of the Performance Period (i.e., February 1, 2024), subject to the Participant's Continuous Service through such vesting date; *provided*, *however*, that if the Participant incurs a Covered Termination (as defined below) within one month prior to or within twelve months following the closing date of such Change in Control, but prior to February 1, 2024, then the CIC Earned Performance Stock Units shall vest on the date of such Covered Termination or upon the closing date of such Change in Control, if later; and
    iii. If, in connection with such Change in Control, the Award is not assumed, substituted for, or continued by the surviving or acquiring company (or its parent entity), then, subject to the

Participant's Continuous Service through the closing date of such Change in Control, the CIC Earned Performance Stock Units shall vest effective immediately prior to, but subject to the consummation of, such Change in Control.

3. **Termination of Performance Stock Units.** Any Performance Stock Units subject to the Award, to the extent unvested and outstanding, shall automatically terminate and be forfeited, without the payment of any consideration to Participant, on the earlier of (i) the date of termination of the Participant's Continuous Service (after giving effect to any accelerated vesting in the event of a Covered Termination) or (ii) the date that any Earned Performance Stock Units or CIC Earned Performance Stock Units, as applicable, become vested.
4. **Definitions.** For purposes of this Exhibit A, the following definitions shall apply to the capitalized terms set forth below (except as otherwise specified in this Exhibit A).
    a. "***Cause***" shall have the meaning ascribed to such term in any written employment agreement, offer letter or similar agreement between the Participant and the Company defining such term, and, in the absence of such agreement, has the meaning ascribed to such term in the Plan. The determination of whether a termination is with or without Cause shall be made by the Company in its sole and exclusive judgment and discretion.
    b. "***Committee***" shall mean the Compensation Committee of the Board.
    c. "***Covered Termination***" shall mean a termination of Participant's employment with the Company that is due to (i) a termination by the Company without Cause (and other than as a result of the Participant's death or Disability) or (ii) the Participant's resignation for Good Reason.
    d. "***Disability***" shall mean the Participant satisfies (i) the requirements for benefits under the Company's long-term disability plan, as determined by the third-party long-term disability insurance carrier or (ii) if the Company does not have a long-term disability plan, the requirements for Social Security disability benefits, as determined by the Social Security Administration.
    e. "***Ending Share Price***" shall mean the average of the daily closing prices per share of an Index Company's common stock, as reported on the stock exchange or market on which such stock is listed, for the thirty (30) Trading Days ending on (and including) the last Trading Day of the Performance Period, as adjusted for any dividends per share that have an ex-dividend date during the Performance Period, assuming the reinvestment of such dividends as of the applicable ex-dividend date.
    f. "***Good Reason***" for the Participant's resignation shall mean, notwithstanding the meaning ascribed to such term (or similar term) in any written agreement between the Participant and the Company, that one or more of the following are undertaken by the Company (or successor to the Company, if applicable) without the Participant's express written consent:
        i. a material reduction in the Participant's annual base salary, which the Participant agrees is a reduction of at least 10% of the Participant's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees);
        ii. a material diminution in the Participant's authority, duties, or responsibilities, including, solely if the Participant is the Company's Chief Executive Officer, a requirement that the Participant report to a corporate officer or employee instead of reporting directly to the board of directors of the Company (or, if applicable, the successor to the Company or similar governing body if such successor is an entity other than a corporation);
        iii. a relocation of the Participant's principal place of employment with the Company (or successor to the Company, if applicable) to a place that increases the Participant's one-way commute by more than fifty (50) miles as compared to the Participant's then-current principal place of employment immediately prior to such relocation (excluding regular travel in the ordinary course of business), provided that if the Participant's principal place of employment is the Participant's personal residence, this clause (iii) shall not apply; or
        iv. a material breach by the Company of any terms of the Award or any other material written agreement between the Participant and the Company concerning the terms and conditions of the Participant's employment with the Company.

In addition, in each case (i) through (iv) described above, in order for the Participant's resignation to be deemed to have been for Good Reason, the Participant must first give the Company written notice of the action or omission giving rise to "Good Reason" within thirty (30) days after the first occurrence thereof, the Company must fail to reasonably cure such action or omission within thirty (30) days after receipt of such notice (the "***Cure Period***"), and the Participant's resignation must be effective not later than thirty (30) days after the expiration of such Cure Period.

a. "***Index Company***" shall mean the Company and each of the other companies in the S&P 600 Biotechnology Select Index for the entirety of the period beginning on the date that is thirty (30) trading days preceding February 1, 2021 and ending on the last day of the Performance Period.

a. "***Initial Share Price***" shall mean the average of the daily closing prices per share of an Index Company's common stock, as reported on the stock exchange or market on which such stock is listed, for the thirty (30) Trading Days prior to the Date of Grant, as adjusted for any dividends per share that have an ex-dividend date during the Performance Period, assuming the reinvestment of such dividends as of the applicable ex-dividend date.
b. "***Performance Period***" shall mean the period commencing on (and including) February 1, 2021 and ending on (and including) February 1, 2024. Notwithstanding the foregoing, the Performance Period may be treated as ending earlier than February 1, 2024 for certain purposes pursuant to Section 3(a)(i) as a result of the occurrence of a Change in Control prior to February 1, 2024.
c. "***Relative TSR Ranking***" shall be determined by ranking the Index Companies from the highest to the lowest according to their respective Total Stockholder Returns and then calculating the Company's percentile ranking within the Index Companies as follows:

where:

"P" represents the Company's percentile ranking within the Index Companies, which shall be rounded to the nearest whole percentile by application of regular rounding;

"N" represents the number of Index Companies; and

"R" represents the Company's ranking among the Index Companies.

For example, if there are 10 Index Companies (including the Company) and the Company's Total Stockholder Return ranks 3rd, the Company's Relative TSR Ranking is equal to the 70th percentile.

a. "***Total Stockholder Return***" shall mean the Ending Share Price divided by the Initial Share Price, minus one (1).
b. "***Trading Day***" shall mean any day on which the stock exchange or market on which shares of an Index Company's common stock is listed is open for trading.

**Eagle Pharmaceuticals, Inc.**
**Performance Stock Unit Grant Notice (2014 Equity Incentive Plan)**

Eagle Pharmaceuticals, Inc. (the "***Company***"), pursuant to its 2014 Equity Incentive Plan (as amended, the "***Plan***"), hereby awards to Participant a Performance Stock Unit Award for the number of shares of the Company's Common Stock ("***Performance Stock Units***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Performance Stock Unit Grant Notice***"), and the Performance Stock Unit Award Agreement (the "***Award Agreement***") (which is attached hereto) and the Plan, both of which are incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Performance Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:
Date of Grant:
Vesting Commencement Date:
Target Number of Performance Stock Units:
Maximum Number of Performance Stock Units:

**Vesting Schedule:** See Exhibit A hereto.

**Issuance Schedule:** Subject to any Capitalization Adjustment, one share of Common Stock (or its cash equivalent, at the discretion of the Company) will be issued for each Performance Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Performance Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Performance Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award (including, but not limited to, the Eagle Pharmaceuticals, Inc. Severance Benefit Plan and any Equity Award Vesting Acceleration Benefit Letter Agreement between Participant and the Company), with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Performance Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**Eagle Pharmaceuticals, Inc.** **Participant:**
By:
Signature Signature
Title: Date:
Date:

**Attachments**: Award Agreement

**Attachment I**
**Eagle Pharmaceuticals, Inc.**
**2014 Equity Incentive Plan**
**Performance Stock Unit Award Agreement**

Pursuant to the Performance Stock Unit Grant Notice (the "***Grant Notice***") and this Performance Stock Unit Award Agreement (the "***Agreement***"), Eagle Pharmaceuticals, Inc. (the "***Company***") has awarded you ("***Participant***") a Performance Stock Unit Award (the "***Award***") pursuant to the Company's 2014 Equity Incentive Plan (as amended, the "***Plan***") for the number of Performance Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. **Grant of the Award.** This Award represents the right to be issued on a future date one (1) share of Common Stock for each Performance Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Performance Stock Units/shares of Common Stock subject to the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of Common Stock, in part or in full satisfaction of the delivery of Common Stock in connection with the vesting of the Performance Stock Units, and, to the extent applicable, references in this Agreement and the Grant Notice to Common Stock issuable in connection with your Performance Stock Units will include the potential issuance of its cash equivalent pursuant to such right. This Award was granted in consideration of your services to the Company.
2. **Vesting.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Except as otherwise set forth in Exhibit A attached hereto, vesting will cease upon the termination of your Continuous Service and the Performance Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the shares of Common Stock to be issued in respect of such portion of the Award.
3. **Number of Shares.** The number of Performance Stock Units (including the Target Number of Performance Stock Units and the Maximum Number of Performance Stock Units set forth in the Grant Notice) subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Performance Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Performance Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.
4. **Securities Law Compliance**. You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Performance Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.
5. **Transfer Restrictions**. Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Performance Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Performance Stock Units.

**Death**. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

**Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

1. **Date of Issuance.**

The issuance of shares in respect of the Performance Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation set forth in Section 11 of this Agreement, in the event one or more Performance Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Performance Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***".

If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

i. the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Arrangement***")), *and*

ii. either (1) a Withholding Obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Obligation by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer pursuant to Section 11 of this Agreement (including but not limited to a commitment under a 10b5-1 Arrangement) and (C) not to permit you to pay your Withholding Obligation in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

1. **Dividends.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; provided, however, that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.
2. **Restrictive Legends.** The shares of Common Stock issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.
3. **Execution of Documents.** You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.
4. **Award not a Service Contract**.

Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions

contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

1. **Withholding Obligation.**

(a) On each vesting date, and on or before the time you receive a distribution of the shares of Common Stock in respect of your Performance Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision, including in cash, for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Obligation***").

(b) By accepting this Award, you acknowledge and agree that the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Obligation relating to your Performance Stock Units by any of the following means or by a combination of such means: (i) causing you to pay any portion of the Withholding Obligation in cash; (ii) withholding from any compensation otherwise payable to you by the Company; (iii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued pursuant to Section 6) equal to the amount of such Withholding Obligation; provided, however, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Withholding Obligation using the maximum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided*, further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or the Company's Compensation Committee; and/or (iv) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***"), pursuant to this authorization and without further consent, whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Performance Stock Units to satisfy the Withholding Obligation and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Obligation directly to the Company and/or its Affiliates. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to you any Common Stock or any other consideration pursuant to this Award.

(c) In the event the Withholding Obligation arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Withholding Obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

1. **Tax Consequences.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.
2. **Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.
3. **Notices**. Any notice or request required or permitted hereunder shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.
4. **Headings**. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.
5. **Miscellaneous**.

The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

1. **Governing Plan Document**. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.
2. **Effect on Other Employee Benefit Plans.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.
3. **Severability**. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.
4. **Other Documents**. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.
5. **Amendment.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.
6. **Compliance with Section 409A of the Code**. This Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse

taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Performance Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Performance Stock Unit Grant Notice to which it is attached.

**Exhibit A**
**Performance Vesting Terms**

The Performance Stock Units awarded hereunder shall vest, if at all, based on the Company's achievement of the Milestones (as defined below) during the Performance Period (as defined below), subject to the terms and conditions of the Plan, the Grant Notice, the Agreement and this Exhibit A. Capitalized terms not explicitly defined in this Exhibit A shall have the same meanings given to them in the Plan, the Grant Notice or the Agreement, as applicable.

1. **Determination of Number of Earned Performance Stock Units.** The number of Performance Stock Units that shall be entitled to vest based on the Company's achievement of the Milestones (the "***Earned Performance Stock Units***") shall be determined in accordance with the following table, with each specified Milestone as defined in Section 6 below. For clarity, (i) the following table sets forth, for each specified Milestone, the percentage of the Target Number of Performance Stock Units (as set forth in the Grant Notice) that will qualify as Earned Performance Stock Units if such Milestone is achieved and (ii) the total number of Earned Performance Stock Units may not exceed the Maximum Number of Performance Stock Units (as set forth in the Grant Notice).

| **Achievement of Milestone** | **Number of Earned Performance Stock Units (% of Target Number of Performance Stock Units)** |
|---|---|
| Fulvestrant FDA Approval Milestone | [X]% |
| Vasopressin Cumulative Sales Milestone | [X]% |
| PEMFEXY Cumulative Sales Milestone | [X]% |

1. **Vesting Date.** Subject to Section 3 below, the Earned Performance Stock Units shall vest on the date that the Committee (as defined below) certifies the Company's achievement of the Milestones and determines the number of Earned Performance Stock Units (which will be as soon as administratively practicable following the end of the Performance Period, but in no event later than [DATE]). A Participant must remain in Continuous Service through the end of the Performance Period in order to receive any Earned Performance Units, except as otherwise provided in Section 3 below.
2. **Change in Control and Covered Termination.**
    a. Notwithstanding anything to the contrary in this Exhibit A, if a Change in Control occurs during the Performance Period, then the Target Number of Performance Stock Units (as set forth in the Grant Notice) shall vest effective immediately prior to, but subject to the consummation of, such Change in Control, subject to the Participant's Continuous Service through the closing date of such Change in Control; *provided*, *however*, that if (i) all of the Milestones have been achieved as of the date of such Change in Control or (ii) the sale (or other applicable transaction) price per share of the Common Stock in such Change in Control is at least $[X], then the Maximum Number of Performance Stock Units (as set forth in the Grant Notice) shall vest effective immediately prior to, but subject to the consummation of, such Change in Control, subject to the Participant's Continuous Service through the closing date of such Change in Control.
    b. Notwithstanding anything to the contrary in this Exhibit A, if the Participant incurs a Covered Termination (as defined below) prior to the date any Performance Stock Units have vested in accordance with the terms of this Exhibit A, then the number of Earned Performance Stock Units, if any, shall be determined in accordance with Section 1 above based on whether the Milestones have been achieved as of the date of such Covered Termination, and any such Earned Performance Stock Units shall vest on the date of such Covered Termination. Notwithstanding the foregoing, if the Participant's Covered Termination occurs within the one month period prior to the closing of a Change in Control, the Participant shall be treated as remaining in Continuous Service as of the closing date of such Change in Control for purposes of Section 3(b) and shall be eligible to receive vesting of Performance Stock Units as described in 3(a) above, rather than the treatment described in this Section 3(b).
3. **Termination of Performance Stock Units.** Any Performance Stock Units subject to the Award, to the extent unvested and outstanding, shall automatically terminate and be forfeited, without the payment of any consideration to Participant, on the earlier of (i) the date of termination of the Participant's Continuous Service (after giving effect to any accelerated vesting in the event of a Covered Termination) or (ii) the date that any Earned Performance Stock Units become vested.
4. **Definitions.** For purposes of this Exhibit A, the following definitions shall apply to the capitalized terms set forth below.
    a. "***Cause***" shall have the meaning ascribed to such term in any written employment agreement, offer letter or similar agreement between the Participant and the Company defining such term, and, in the absence of such agreement, has the meaning ascribed to such term in the Plan. The determination of whether a termination is with or without Cause shall be made by the Company in its sole and exclusive judgment and discretion.
    b. "***Committee***" shall mean the Compensation Committee of the Board.

c. "***Covered Termination***" shall mean a termination of Participant's employment with the Company that is due to (i) a termination by the Company without Cause (and other than as a result of the Participant's death or Disability) or (ii) the Participant's resignation for Good Reason.

d. "***Disability***" shall mean the Participant satisfies (i) the requirements for benefits under the Company's long-term disability plan, as determined by the third-party long-term disability insurance carrier or (ii) if the Company does not have a long-term disability plan, the requirements for Social Security disability benefits, as determined by the Social Security Administration.

e. "***Fulvestrant FDA Approval Milestone***" shall mean the first approval by the U.S. Food and Drug Administration (or any successor entity thereto), on or prior to the last day of the Performance Period, for the commercial sale and marketing of Fulvestrant in the U.S. by the Company.

f. "***Good Reason***" for the Participant's resignation shall mean, notwithstanding the meaning ascribed to such term (or similar term) in any written agreement between the Participant and the Company, that one or more of the following are undertaken by the Company (or successor to the Company, if applicable) without the Participant's express written consent:

i. a material reduction in the Participant's annual base salary, which the Participant agrees is a reduction of at least 10% of the Participant's base salary (unless pursuant to a salary reduction program applicable generally to the Company's similarly situated employees);

ii. a material diminution in the Participant's authority, duties, or responsibilities, including, solely if the Participant is the Company's Chief Executive Officer, a requirement that the Participant report to a corporate officer or employee instead of reporting directly to the board of directors of the Company (or, if applicable, the successor to the Company or similar governing body if such successor is an entity other than a corporation);

iii. a relocation of the Participant's principal place of employment with the Company (or successor to the Company, if applicable) to a place that increases the Participant's one-way commute by more than fifty (50) miles as compared to the Participant's then-current principal place of employment immediately prior to such relocation (excluding regular travel in the ordinary course of business), provided that if the Participant's principal place of employment is the Participant's personal residence, this clause (iii) shall not apply; or

iv. a material breach by the Company of any terms of the Award or any other material written agreement between the Participant and the Company concerning the terms and conditions of the Participant's employment with the Company.

In addition, in each case (i) through (iv) described above, in order for the Participant's resignation to be deemed to have been for Good Reason, the Participant must first give the Company written notice of the action or omission giving rise to "Good Reason" within thirty (30) days after the first occurrence thereof, the Company must fail to reasonably cure such action or omission within thirty (30) days after receipt of such notice (the "***Cure Period***"), and the Participant's resignation must be effective not later than thirty (30) days after the expiration of such Cure Period.

a. "***Milestone***" shall mean the Fulvestrant FDA Approval Milestone, the Vasopressin Cumulative Sales Milestone or the PEMFEXY Cumulative Sales Milestone, as applicable.

b. "***PEMFEXY Cumulative Sales Milestone***" shall mean a total of at least $[XXX] in net sales (as defined by U.S. GAAP) of PEMFEXY™ by the Company during the Performance Period.

c. "***Performance Period***" shall mean the period commencing on (and including) [DATE] and ending on (and including) [DATE].

d. "***Vasopressin Cumulative Sales Milestone***" shall mean a total of at least $[XXX] in net sales (as defined by U.S. GAAP) of Vasopressin by the Company during the Performance Period.

**Exhibit 21.1**

**Subsidiaries of Eagle Pharmaceuticals, Inc.**

| **Name of Subsidiary** | **Jurisdiction of Incorporation** |
| --- | --- |
| Eagle Biologics, Inc. (formerly Arsia Therapeutics, Inc.) | Delaware |
| Eagle Research Lab Limited | Malta |

**Exhibit 23.1**

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement on Form S-3 No. 333-234742 and 333-202592 of Eagle Pharmaceuticals, Inc., and

(2) Registration Statements on Form S-8 Nos. 333-228876, 333-216839, 333-213683, 333-206729 and 333-194056 Eagle Pharmaceuticals, Inc.

of our reports dated March 4, 2021, with respect to the consolidated financial statements of Eagle Pharmaceuticals, Inc. and the effectiveness of internal control over financial reporting of Eagle Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Eagle Pharmaceuticals for the year ended December 31, 2020.

/s/ Ernst & Young, LLP

Stamford, Connecticut
March 4, 2021

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

Eagle Pharmaceuticals, Inc.

Woodcliff Lake, New Jersey

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-234742 and 333-202592) and Form S-8 (Nos. 333-228876, 333-216839, 333-213683, 333-206729 and 333-194056) of Eagle Pharmaceuticals, Inc. (the "Company") of our report dated March 2, 2020, relating to the consolidated financial statements which appears in this Form 10-K.

/s/ BDO USA, LLP

Woodbridge, New Jersey

March 4, 2021

**Exhibit 31.1**

## Certification of Principal Executive Officer

I, Scott Tarriff, certify that:

1. I have reviewed this annual report on Form 10-K of Eagle Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   (d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 4, 2021

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

## Certification of Principal Financial and Accounting Officer

I, Brian Cahill, certify that:

1. I have reviewed this annual report on Form 10-K of Eagle Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   (d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 4, 2021

/s/ Brian Cahill

Brian Cahill
Chief Financial Officer
(Principal Accounting and Financial Officer)

**Exhibit 32.1**

## Certification Pursuant to

## 18 U.S.C. Section 1350,

## As Adopted Pursuant to

## Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), **Scott Tarriff**, President and Chief Executive Officer of Eagle Pharmaceuticals, Inc. (the "Company"), and **Brian Cahill**, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

**1.** The Company's Annual Report on Form 10-K for the period ended December 31, 2020 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

**Dated: March 4, 2021**

| /s/ Scott Tarriff | /s/ Brian Cahill |
|---|---|
| Scott Tarriff | Brian Cahill |
| Chief Executive Officer | Chief Financial Officer |
| (Principal Executive Officer) | (Principal Financial and Accounting Officer) |

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eagle Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.