EAGLE PHARMACEUTICALS, INC.
Form 10-K
February 28, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
o 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:
Common Stock (par value $0.001 per share), 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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 x	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o

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

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was approximately $703,596,009 computed by reference to the last reported sale price of $75.66 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, 2018. 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 22, 2019 was 13,924,296 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2019 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

Table of Contents

EAGLE PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
For the fiscal year ended December 31, 2018

Eagle Pharmaceuticals, Inc.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

 References to the "Company," "Eagle Pharmaceuticals," "Eagle," "we," "us" or "our" mean Eagle Pharmaceuticals, Inc., a Delaware corporation and its subsidiary, and references to "Eagle Biologics" mean Eagle Biologics, Inc.

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- 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 ability to obtain funding for our operations;
- 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 rate and degree of market acceptance of our products and product candidates;
- our ability to develop sales and marketing capabilities, 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 loss of key scientific or management personnel;
- our use of the proceeds from our initial public offering; and subsequent follow-on offering;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and
- our ability to prevent or minimize the effects of Paragraph IV patent litigation.

Forward-looking statements are statements that are not historical facts. Words such as “believes,” “potential,” “will,” “could,” “would,” “should,” “may,” “intends,” “anticipates,” “plans,” “enables,” “potential,” “entitles,” “estimates,” “projects,” “predict expressions are intended to identify forward-looking statements.

These forward-looking statements reflect our management’s beliefs and views with respect to future events, are based on estimates and assumptions as of the date of this Annual Report on Form 10-K, and are subject to risks and uncertainties. Additionally, these statements are based upon information available to us as of the date of this Annual Report on Form 10-K, 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. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Some of these important factors include our "critical accounting estimates" described in Item 7 in Part II of this Annual Report on Form 10-K and the factors set forth under the caption "Risk Factors" in Item 1A in Part I of this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation

to do so (unless required by law), even if our estimates change, and readers should not rely on our forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I
Item 1. Business

Company Overview

Organization

Eagle Pharmaceuticals, Inc. is a specialty pharmaceutical company registered at and with principal offices at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. On November 16, 2016, we purchased all of the outstanding capital stock of Arsia Therapeutics, Inc. (“Arsia”), and subsequently changed its name to Eagle Biologics, Inc. ("Eagle Biologics").

Business

Our business model is to develop proprietary innovations to FDA-approved, injectable drugs, that offer commercial and/or functional advantages to currently available alternatives. We have historically been, and will continue to primarily be, focused on developing and commercializing injectable drugs, primarily in the critical care and oncology areas, using the United States Food and Drug Administration (“FDA”)'s 505(b)(2) New Drug Application (“NDA”) regulatory pathway. With our addition of Eagle Biologics, we hope to apply our market strategy to offer “biobetter” formulations, and to develop novel biologic products under the pathway provided by the Biologics Price Competition and Innovation Act ("BPCIA"). In addition, we plan to continue to market and/or commercialize our products through marketing partners and/or through our internal direct sales force.

For each of our current and future pre-commercial products, we target market entry no later than the entry of the first generic or biosimilar drug with the goal of substantially converting the market by addressing the needs of stakeholders who ultimately use our products. We believe we can further extend commercial duration through new intellectual property protection and/or orphan drug exclusivity and three years of non-patent regulatory exclusivity for future product candidates, as provided under applicable law and regulations. We strive to enhance branded reference drugs to optimize their ease and safety of use for healthcare providers, produce less drug waste, lower cost to stakeholders, and create the opportunity for label expansion to additional indications.

Our 505(b)(2) model has been validated by the approval and successful launches of our novel formulations of Argatroban and Ryanodex® (dantrolene sodium) (“Ryanodex”) and Eagle's bendamustine ready-to-dilute ("RTD") 500ml solution (“Big Bag” or "Belrapzo"); marketed by Eagle, and rapidly infused bendamustine RTD (“Bendeka”); marketed by Teva, licensed to and launched jointly with Teva Pharmaceutical Industries Ltd. (“Teva”) in January 2016. We are in the early stages of development with our biologics strategy and do not currently have any commercially approved biologics products.

Our product portfolio now includes four approved products: Argatroban; Ryanodex; Belrapzo; and Bendeka. We have three commercial partners: Teva, which through its subsidiary Cephalon, Inc. ("Cephalon") markets Bendeka, and Chiesi USA, Inc. ("Chiesi") and Sandoz Inc. (“Sandoz”), who pursuant to separate agreements market Argatroban.

We currently have multiple product candidates in advanced stages of development, and/or under review for approval by the FDA. Additionally, we have other exploratory candidates under a collaborative agreement entered into in January 2016 with Albany Molecular Research, Inc. (“AMRI”). Our advanced product candidates are EP-4104 (dantrolene sodium for exertional heat stroke (“EHS”)) (“EP-4104”), EP-5101 (PEMFEXY™), a pemetrexed injection ready-to-dilute formulation (“EP-5101”) and EGL-5385-C-1701 (fulvestrant). EP-5101 has been tentatively approved by the FDA. EGL-5385-C-1701 and EP-4104, both unapproved, may address unmet medical needs in major specialty markets.

In 2018, we accomplished the following with respect to our product portfolio:

- On April 16, 2018, we announced the FDA's acceptance of our Abbreviated New Drug Application ("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 May 15, 2018, the FDA granted final approval for our ready-to-dilute bendamustine hydrochloride solution in a 500ml admixture ("Big Bag") 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. We immediately launched this product upon FDA approval.

- On August 30, 2018, we announced the completion of enrollment of our second clinical study to further evaluate the safety and efficacy of Ryanodex (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke, an investigational new indication for the product.

- On October 3, 2018, we announced we had 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.

- On November 27, 2018, we announced positive results of a pre-clinical study conducted to evaluate the effects of Ryanodex in Acute Radiation Syndrome.

In addition to building our product portfolio, we continue to develop our commercial organization. We have built an internal commercial team consisting of approximately 50 direct sales representatives, support staff and management who are a part of our independent commercial organization.

Product Portfolio

Our product portfolio consists of:

Product	U.S. Brand Reference Drug	Description	Indication	Estimated Market Opportunity (amounts in millions)	Status
Ryanodex® (dantrolene sodium)	Dantrium®/ Revonto®	Muscle relaxant	Malignant hyperthermia	$75[2]	Approved (U.S.)/ launched August 2014; orphan drug exclusivity received for MH (U.S.)
Argatroban	Argatroban	Anti-coagulant; thrombin inhibitor	Heparin-induced thrombocytopenia	$99[2]	Approved (U.S.); marketed by Chiesi USA, Inc. and Sandoz
BENDEKA™	BENDEKA™	Chemotherapeutic agent	CLL; Indolent NHL	$642[1] [3]	Approved (U.S.) in December 2015; licensed to and marketed by Teva; orphan drug designation for CLL and NHL (U.S.)
Belrapzo (bendamustine RTD)	Treanda®	Chemotherapeutic agent	(CLL); Indolent (NHL)	$642[1] [3]	Approved (U.S.) and launched for CLL and NHL in May 2018
EP-4104 (dantrolene sodium)	No drug currently approved	Muscle relaxant	Exertional heat stroke	$400[2]	Orphan drug designation received for heat stroke (U.S.); IND submission in 2015; completed safety and efficacy study in December 2015; FDA granted fast track designation and NDA submitted in January 2016; additional clinical trial requested by FDA in 2017
EP-5101 (PEMFEXY™)	Alimta	Chemotherapeutic agent	Lung cancer and mesothelioma	$1,131[1]	NDA submitted December 2016; tentative approval received in October 2017
EGL-5385-C-1701 (fulvestrant)	Faslodex	Selective estrogen receptor degrader	Metastatic breast cancer	$537[1]	Pre-NDA submission

Vasopressin injection 1ml	Vasostrict	Crash cart item in hospital settings	Indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines	$454 [1]	FDA accepted our ANDA filing

[1]Based on publicly filed reports with the SEC.
[2]Based on independent market research and management's estimates extrapolated there from.
[3]Benedeka and Belrapzo are part of the same estimated market opportunity.

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 believe that our management's unique knowledge of the industry as well as the biopharmaceutics formulation acumen presented by Eagle Biologics combine to enable us to compete effectively in the market for injectable therapeutics in both small and large molecule markets. We look to continue to exploit these strengths in order to build upon our portfolio of attractive assets.

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 no later than 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 estate includes 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, deterring competition and 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 on oncology, critical care, and orphan diseases and includes four approved products, a tentative approval, and several distinct product candidates in advanced development. Additionally, we have other exploratory candidates under our collaborative agreement with AMRI, and are developing a “biobetters” pipeline at our subsidiary, Eagle Biologics. 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 focused on the development and commercialization of injectable

pharmaceutical products for use in acute care settings that represent an improvement over the currently marketed reference drug. Our strategy to achieve this goal includes:

Enter the market no later than the first generic drug. We intend to enter the market no later than the first generic or biosimilar of the branded reference drug. During this period, the number of competitors is lowest and branded drugs are generally at peak or near peak value. This will allow us to influence usage patterns and market our products as improved versions, thereby achieving favorable pricing. Even if we enter the market simultaneously with, or after, the first generic drug, as a 505(b)(2) applicant, we would be able to enter the market without regard to any generic drug's 180-day exclusivity period.

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.

Strengthen our product portfolio. We intend to continue to strengthen our product portfolio in the areas of oncology, critical care and orphan diseases. 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.

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 and Non-Hodgkin's Lymphoma

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.

Big Bag

On May 15, 2018, the FDA granted final approval for Big Bag, 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 - Bendamustine License Agreement, below.

Argatroban for Heparin-Induced Thrombocytopenia