

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number **001-36306**

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

20-8179278
(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 Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this Chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

The number of shares outstanding of the registrant's common stock as of August 2, 2021: 13,097,113 shares.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains “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 Quarterly 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), 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, 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 clinical trial, development plan and litigation matters for vasopressin; and
 - our expectations regarding our submission of formal protocols for clinical study on fulvestrant (EA-114).
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Any forward-looking statements in this Quarterly 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 Quarterly 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 such as “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 Quarterly 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 Lab” means Eagle Research Lab Limited.

NOTE REGARDING TRADEMARKS

All trademarks, trade names and service marks appearing in this Quarterly Report are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Quarterly Report may appear without the ® or TM symbols.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 108,717	\$ 103,155
Accounts receivable, net	52,659	50,678
Inventories	8,294	8,075
Prepaid expenses and other current assets	5,834	4,157
Total current assets	175,504	166,065
Property and equipment, net	1,967	2,077
Intangible assets, net	11,505	12,917
Goodwill	39,743	39,743
Deferred tax asset, net	14,061	15,180
Other assets	21,462	17,208
Total assets	\$ 264,242	\$ 253,190
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 11,136	\$ 6,268
Accrued expenses and other liabilities	25,528	23,817
Current portion of long-term debt	8,000	8,000
Total current liabilities	44,664	38,085
Other long-term liabilities	3,360	3,959
Long-term debt, less current portion	21,371	25,135
Total liabilities	69,395	67,179
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,879,974 and 16,739,203 shares issued as of June 30, 2021 and December 31, 2020, respectively	17	17
Additional paid in capital	316,249	305,403
Accumulated other comprehensive loss	(904)	—
Retained earnings	87,680	84,489
Treasury stock, at cost, 3,782,861 and 3,682,176 shares as of June 30, 2021 and December 31, 2020, respectively	(208,195)	(203,898)
Total stockholders' equity	194,847	186,011
Total liabilities and stockholders' equity	\$ 264,242	\$ 253,190

See accompanying notes to condensed consolidated financial statements (unaudited).

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product sales, net	\$ 19,621	\$ 14,376	\$ 36,741	\$ 32,070
Royalty revenue	28,503	27,562	52,632	55,888
Total revenue	48,124	41,938	89,373	87,958
Operating expenses:				
Cost of product sales	7,907	10,313	16,349	15,078
Cost of royalty revenue	2,850	2,822	5,263	5,860
Research and development	9,911	7,135	24,199	16,562
Selling, general and administrative	16,636	17,959	36,515	42,714
Total operating expenses	37,304	38,229	82,326	80,214
Income from operations	10,820	3,709	7,047	7,744
Interest income	163	150	198	496
Interest expense	(422)	(786)	(844)	(1,675)
Other (expense) income	(5,013)	2,300	487	(4,200)
Total other (expense) income, net	(5,272)	1,664	(159)	(5,379)
Income before income tax provision	5,548	5,373	6,888	2,365
Income tax provision	(1,936)	(5,629)	(3,697)	(5,492)
Net Income (Loss)	<u>\$ 3,612</u>	<u>\$ (256)</u>	<u>\$ 3,191</u>	<u>\$ (3,127)</u>
Earnings (Loss) per share attributable to common stockholders:				
Basic	\$ 0.28	\$ (0.02)	\$ 0.24	\$ (0.23)
Diluted	\$ 0.27	\$ (0.02)	\$ 0.24	\$ (0.23)
Weighted average number of common shares outstanding:				
Basic	13,108,998	13,664,951	13,116,370	13,666,279
Diluted	13,262,164	13,664,951	13,293,920	13,666,279

See accompanying notes to condensed consolidated financial statements (unaudited).

EAGLE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (UNAUDITED)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net income (loss)	\$ 3,612	\$ (256)	\$ 3,191	\$ (3,127)
Other comprehensive loss, net of tax:				
Unrealized loss for convertible promissory note	(904)	—	(904)	—
Total other comprehensive loss	(904)	—	(904)	—
Comprehensive income (loss)	\$ 2,708	\$ (256)	\$ 2,287	\$ (3,127)

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

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount					
Balance at March 31, 2021	16,858	\$ 17	\$ 312,323	\$ (205,330)	\$ —	\$ 84,068	\$ 191,078
Stock-based compensation expense	—	—	4,281	—	—	—	4,281
Issuance of common stock upon exercise of stock option grants	22	—	(355)	—	—	—	(355)
Payment of employee withholding tax upon vesting of stock-based awards	—	—	—	—	—	—	—
Common stock repurchases	—	—	—	(2,865)	—	—	(2,865)
Other comprehensive loss	—	—	—	—	(904)	—	(904)
Net income	—	—	—	—	—	3,612	3,612
Balance at June 30, 2021	<u>16,880</u>	<u>\$ 17</u>	<u>\$ 316,249</u>	<u>\$ (208,195)</u>	<u>\$ (904)</u>	<u>\$ 87,680</u>	<u>\$ 194,847</u>

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount					
Balance as of December 31, 2020	16,739	\$ 17	\$ 305,403	\$ (203,898)	\$ —	\$ 84,489	\$ 186,011
Stock-based compensation expense	—	—	10,789	—	—	—	10,789
Issuance of common stock upon exercise of stock option grants	78	—	1,608	—	—	—	1,608
Issuance of common stock related to vesting of restricted stock units	63	—	(1,551)	—	—	—	(1,551)
Common stock repurchases	—	—	—	(4,297)	—	—	(4,297)
Other comprehensive loss	—	—	—	—	(904)	—	(904)
Net income	—	—	—	—	—	3,191	3,191
Balance as of June 30, 2021	<u>16,880</u>	<u>\$ 17</u>	<u>\$ 316,249</u>	<u>\$ (208,195)</u>	<u>\$ (904)</u>	<u>\$ 87,680</u>	<u>\$ 194,847</u>

	Common Stock			Treasury Stock	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount	Additional Paid-In Capital			
Balance at March 31, 2020	16,598	\$ 17	\$ 285,044	\$ (172,860)	\$ 69,629	\$ 181,830
Stock-based compensation expense	—	—	6,241	—	—	6,241
Issuance of common stock upon exercise of stock option grants	23	—	183	—	—	183
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(34)	—	—	(34)
Issuance of common stock related to vesting of restricted stock units	1	—	—	—	—	—
Common stock repurchases	—	—	—	(4,000)	—	(4,000)
Net loss	—	—	—	—	(256)	(256)
Balance at June 30, 2020	<u>16,622</u>	<u>\$ 17</u>	<u>\$ 291,434</u>	<u>\$ (176,860)</u>	<u>\$ 69,373</u>	<u>\$ 183,964</u>

	Common Stock			Treasury Stock	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount	Additional Paid-In Capital			
Balance at December 31, 2019	16,538	\$ 17	\$ 278,518	\$ (171,861)	\$ 72,500	\$ 179,174
Stock-based compensation expense	—	—	13,713	—	—	13,713
Issuance of common stock upon exercise of stock option grants	39	—	513	—	—	513
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(1,310)	—	—	(1,310)
Issuance of common stock related to vesting of restricted stock units	45	—	—	—	—	—
Common stock repurchases	—	—	—	(4,999)	—	(4,999)
Net loss	—	—	—	—	(3,127)	(3,127)
Balance at June 30, 2020	<u>16,622</u>	<u>\$ 17</u>	<u>\$ 291,434</u>	<u>\$ (176,860)</u>	<u>\$ 69,373</u>	<u>\$ 183,964</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net income (loss)	\$ 3,191	\$ (3,127)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Deferred income taxes	1,119	(916)
Depreciation expense	378	460
Noncash operating lease expense related to right-of-use assets	508	471
Amortization expense of intangible assets	1,412	1,333
Fair value adjustments on equity investment	(400)	4,200
Stock-based compensation expense	10,789	13,713
Convertible promissory note related credit losses	100	—
Amortization of debt issuance costs	236	183
Fair value adjustments related to derivative instrument	(188)	—
Accretion of discount on convertible promissory note	(56)	—
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(1,981)	1,223
Inventories	(219)	(1,325)
Prepaid expenses and other current assets	(1,802)	9,553
Accounts payable	4,868	8,246
Accrued expenses and other liabilities	1,710	(8,583)
Other assets and other long-term liabilities, net	(594)	(1,321)
Net cash provided by operating activities	<u>19,071</u>	<u>24,110</u>
Cash flows from investing activities:		
Purchase of equity investment security	—	(17,500)
Purchase of property and equipment	(269)	(376)
Purchase of convertible promissory note	(5,000)	—
Net cash used in investing activities	<u>(5,269)</u>	<u>(17,876)</u>
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,608	513
Employee withholding taxes related to stock-based awards	(1,551)	(1,310)
Proceeds from existing revolving credit facility	—	110,000
Repayment of existing revolving credit facility	—	(110,000)
Payment of debt	(4,000)	(2,000)
Repurchases of common stock	(4,297)	(4,999)
Net cash used in financing activities	<u>(8,240)</u>	<u>(7,796)</u>
Net increase (decrease) in cash and cash equivalents	<u>5,562</u>	<u>(1,562)</u>
Cash and cash equivalents at beginning of period	<u>103,155</u>	<u>109,775</u>
Cash and cash equivalents at end of period	<u>\$ 108,717</u>	<u>\$ 108,213</u>
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	\$ 4,300	\$ 502
Interest	625	1,458
Right-of-use asset obtained in exchange for lease obligation - lease amendment	—	842

See accompanying notes to condensed consolidated financial statements (unaudited).

EAGLE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(In thousands, except share and per share amounts)

1. Basis of Presentation and Other Company Information

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for reporting quarterly information. Accordingly, certain information and footnote disclosures required for complete financial statements are not included herein. The condensed consolidated balance sheet at December 31, 2020 was derived from audited financial statements, but certain information and footnote disclosures normally included in our annual consolidated financial statements have been condensed or omitted. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary for the fair presentation of the financial information for the interim periods reported have been made. Results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results for the year ending December 31, 2021 or any period thereafter. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 5, 2021.

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

2. Summary of Significant Accounting Policies

Significant Accounting Policies

Our significant accounting policies are described in the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020 and the notes thereto filed with the SEC on March 5, 2021. Since the date of those consolidated financial statements, there have been no material changes to our significant accounting policies other than as listed below.

Significant Risks and Uncertainties

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

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

Use of Estimates

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

Reclassifications

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

Cash and Cash Equivalents

We consider 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.

We, at times, maintain balances with financial institutions in excess of the Federal Deposit Insurance Corporation (“FDIC”) limit.

Fair Value Measurements

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

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

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

Financial assets and liabilities measured and recognized at fair value are as follows:

	June 30, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 104,614	\$ 104,614	\$ —	\$ —
Convertible Promissory Note	3,776	—	—	3,776
Embedded Derivative Asset in Convertible Promissory Note	464	—	—	464
Investment in Tyme	12,600	12,600	—	—
Total financial assets	\$ 121,454	\$ 117,214	\$ —	\$ 4,240

	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	\$ —	\$ —

We recognize 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 three months or six months ended June 30, 2021 and 2020, respectively.

Our investment in the convertible promissory note and the embedded derivative are classified as Level 3. We analyzed and accessed the embedded derivative feature contained in the convertible promissory note agreement. We used a probability factor to value the embedded derivative asset based on management's best estimate, including the principal and estimated accrued interest among other contractual terms. The convertible promissory note is accounted for as available for sale. The convertible promissory note is reported at fair value with unrealized gains and losses included in Accumulated other comprehensive income (loss). Refer to Note 13, Convertible Promissory Note for further details.

Our investment in restricted shares of common stock of Tyme Technologies, Inc. are classified as Level 1. Refer to Note 12, Collaboration with Tyme 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

We review the recoverability of our 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, we 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, we measure 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 as of June 30, 2021.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics acquisition. Goodwill is not amortized, but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if events or changes in circumstances indicate that the reporting unit's goodwill is less than its carrying amount. We did not identify any impairment to goodwill during the periods presented.

Concentration of Major Customers and Vendors

We are dependent on our commercial partner, Teva, who markets and sells Bendeka. Our customer for Bendeka is our commercial and licensing partner; therefore, our future revenues are highly dependent on the related exclusive license and distribution arrangement.

In March 2019, we entered into an agreement with Teva, or the Bendeka License Agreement, pursuant to which Teva has agreed to market Bendeka through its subsidiary, Cephalon, Inc. Pursuant to the Bendeka License Agreement, Teva pays us a royalty based on net sales of the product and also purchases Bendeka from us.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Total revenues				
Teva - See Revenue Recognition	64 %	78 %	65 %	71 %
Other	36 %	22 %	35 %	29 %
	<u>100 %</u>	<u>100 %</u>	<u>100 %</u>	<u>100 %</u>

	June 30,	December 31,
	2021	2020
Accounts receivable		
Teva - See Revenue Recognition	59 %	58 %
Other	41 %	42 %
	<u>100 %</u>	<u>100 %</u>

Inventories

Inventories are recorded at the lower of cost and net realizable value, with cost determined on a first-in first-out basis. We periodically review the composition of inventory 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 inventory, we will record a write-down to lower of cost and net realizable value in the period that the decline in value is first recognized.

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 us by our vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the condensed 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.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs were \$0.4 million and \$0.8 million for the three months ended June 30, 2021 and 2020, respectively, and \$0.7 million and \$1.9 million for the six months ended June 30, 2021 and 2020, respectively.

Income Taxes

We account for income taxes using the liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), 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 (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 a 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 - Revenue from Contracts with Customers (“ASC 606”), we perform 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. We only apply 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, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize 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. 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.

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

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

Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing the expected value method to which we expect to be entitled. As such, revenue on sales to customers 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. We have a product return policy on some of our 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. Our 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. We have terms on sales of Ryanodex by which we do not accept returns. Variable consideration is included in the transaction price if, in our 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 our anticipated performance and all information (historical, current and forecasted) that is reasonably available. We believe that the estimates we have 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 our distributors. Our 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 our 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: We contract 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. We estimate the rebates we 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. We estimate the rebates that we will provide to third-party payors based upon (i) our 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 our distributors.

The information that we also consider when establishing our 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. We regularly review and monitor estimated or actual customer inventory information at our largest distributors for our key products to ascertain whether customer inventories are in excess of ordinary course of business levels.

Product Returns: Our 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. We estimate future product returns on sales of Belrapzo based on: (i) data provided to us by our distributors (including weekly reporting of distributors’ sales and inventory held by distributors that provided us with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to us from retail pharmacies, (iii) data provided to us 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 our 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 condensed consolidated balance sheets.

Our 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. Our commercial returns policy and terms with certain customers also states that certain products are sold as non-returnable.

Wholesaler fees and other incentives: We generally provide invoice discounts on Belrapzo and Ryanodex sales to our distributors for prompt payment and fees for distribution services, such as fees for certain data that distributors provide to us. 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, we expect our distributors to earn these discounts and fees, and deducts the

full amount of these discounts and fees from our 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.

Royalty Revenue — We recognize revenue from license arrangements with our commercial partners' net sales of products. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us within 25 days for Bendeka. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter and subsequently determine a true-up when we receive royalty reports from our commercial partners. Historically, these true-up adjustments have been immaterial.

License and other revenue — We analyze each element of our 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. We recognize 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. We determine 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, we estimate the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

We recognize 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, we 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, we assess each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty of the occurrence of these future events, we 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, we do not assess whether a significant financing component exists if the period between when we perform our obligations under the contract and when the customer pays is one year or less. None of our contracts contained a significant financing component as of June 30, 2021.

Stock-Based Compensation

We account 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.

We account 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 our stock option awards to employees and directors is estimated using the Black-Scholes valuation model and a Monte Carlo simulation model is used to estimate the fair value for market condition share units. These models require the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, historical 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. The fair value of RSUs granted are estimated based on the trading price of our common stock on the date of grant. The fair value of performance condition PSUs granted are also estimated based on the trading price of our common stock on the date of grant and adjusted for the probability of achievement of the performance conditions. Forfeitures are estimated for all stock-based awards.

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.

The anti-dilutive common share equivalents outstanding for the three and six months ended June 30, 2021 and 2020 were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	2,844,961	2,909,289	1,622,046	2,909,289
Restricted stock units	223,103	229,100	1,413,687	253,677
Total	3,068,064	3,138,389	3,035,733	3,162,966

The following table sets forth the computation for basic and diluted net earnings (loss) per share for the three and six months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator				
Numerator for basic and diluted earnings (loss) per share-net earnings (loss)	\$ 3,612	\$ (256)	\$ 3,191	\$ (3,127)
Denominator				
Basic weighted average common shares outstanding	13,108,998	13,664,951	13,116,370	13,666,279
Dilutive effect of stock awards	153,166	—	177,550	—
Diluted weighted average common shares outstanding	13,262,164	13,664,951	13,293,920	13,666,279
Basic net earnings (loss) per share				
Basic net earnings (loss) per share	\$ 0.28	\$ (0.02)	\$ 0.24	\$ (0.23)
Diluted net earnings (loss) per share				
Diluted net earnings (loss) per share	\$ 0.27	\$ (0.02)	\$ 0.24	\$ (0.23)

All potentially dilutive items were excluded from the diluted share calculation for the three months and six months ended June 30, 2020 because their effect would have been anti-dilutive, as the Company was in a loss position.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

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

3. Property and Equipment, net

Property and equipment consisted of the following:

	June 30, 2021	December 31, 2020	Estimated Useful Life (years)
Furniture and fixtures	\$ 1,476	\$ 1,476	7
Office equipment	1,077	1,152	3
Equipment	3,829	3,485	7
Leasehold improvements	1,155	1,155	2
	7,537	7,268	
Less accumulated depreciation	(5,570)	(5,191)	
Property and equipment, net	<u>\$ 1,967</u>	<u>\$ 2,077</u>	

Depreciation expense related to property and equipment amounted to \$188 and \$209 for the three months ended June 30, 2021 and 2020, respectively, and \$378 and \$460 for the six months ended June 30, 2021 and 2020, respectively.

4. Inventories

Inventories consist of the following:

	June 30, 2021	December 31, 2020
Raw materials	\$ 1,977	\$ 3,515
Work in process	4,578	2,589
Finished products	1,739	1,971
Total Inventories	<u>\$ 8,294</u>	<u>\$ 8,075</u>

5. Balance Sheet Accounts

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	June 30, 2021	December 31, 2020
Prepaid FDA user fee and advances to clinical research organization	\$ 421	\$ 1,262
Prepaid insurance	743	191
Advances to commercial manufacturers	212	660
All other	4,458	2,044
Total Prepaid expenses and other current assets	<u>\$ 5,834</u>	<u>\$ 4,157</u>

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2021	December 31, 2020
Accrued sales reserves	\$ 4,339	\$ 4,966
Royalties payable to commercial partners	5,910	5,996
Accrued salary and other compensation	3,909	4,686
Accrued professional fees	2,307	2,370
Accrued research & development	3,968	2,724
Current portion of lease liability	1,174	1,123
Accrued other	3,921	1,952
Total Accrued expenses	<u>\$ 25,528</u>	<u>\$ 23,817</u>

Leases

We lease office space in Woodcliff Lake, New Jersey for our principal office under an amended lease agreement through June 2025. We also lease a lab space in Cambridge, Massachusetts under a lease agreement through April 2024. Both of our leases are classified as operating leases and have remaining lease terms of approximately 3.6 years. The principal office and the lab space leases include renewal options to extend the lease for up to 5 years. Furthermore, we have not elected the practical expedient to separate lease and non-lease components for all classes of underlying assets.

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

	June 30, 2021	December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	\$ 346	\$ 1,323
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ —	\$ 855
Weighted-average remaining lease term - operating leases	3.6 years	4.1 years
Weighted-average discount rate - operating leases	6.0 %	6.0 %

Balance Sheet Classification at June 30:

Current lease liabilities	\$ 1,174
Long-term lease liabilities	3,360
Total lease liabilities	<u>\$ 4,534</u>

6. Intangible Assets, Net

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

	Useful Life (In Years)	June 30, 2021		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value
Ryanodex intangible (i)	20	\$ 15,000	\$ (4,103)	\$ 10,897
Developed technology	5	8,100	(7,492)	608
Total		<u>\$ 23,100</u>	<u>\$ (11,595)</u>	<u>\$ 11,505</u>

	Useful Life (In Years)	December 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value
Ryanodex intangible (i)	20	15,000	(3,500)	11,500
Developed technology	5	8,100	(6,683)	1,417
Total		<u>\$ 23,100</u>	<u>\$ (10,183)</u>	<u>\$ 12,917</u>

(i) Represents a one-time payment made to reduce the royalties payable to a third party on Ryanodex net sales.

Amortization expense was \$706 and \$667 for the three months ended June 30, 2021 and 2020, respectively and \$1,412 and \$1,333 for the six months ended June 30, 2021 and 2020, respectively.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of June 30, 2021, and assuming that the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses are estimated as follows:

Year Ending December 31,	Estimated Amortization Expense
2021 (remainder)	1,210
2022	1,369
2023	1,570
2024	1,898
2025	1,520
Thereafter	3,938
Total estimated amortization expense	<u>\$ 11,505</u>

7. Common Stock and Stock-Based Compensation

Common Stock

Share Repurchase Program

On March 17, 2020, we announced that our Board approved a new share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of \$160 million of our outstanding common stock. The Share Repurchase Program replaced our 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, we had repurchased approximately \$68 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, our Board of Directors approved a \$25 million accelerated share repurchase ("ASR") transaction with JPMorgan Chase Bank, National Association ("JP Morgan") as part of our existing \$160 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 our common stock, less a discount, during the term of the ASR program. Under the terms of our agreement with JP Morgan, we paid \$25 million to JP Morgan on September 24, 2020, and received 550,623 shares, representing the notional amount of the ASR, based on the average of the daily volume weighted average share prices of our common stock, less a discount, during the term of the ASR, which was \$45.40. The ASR was completed in the fourth quarter of 2020. We determined the ASR contained a forward contract and therefore we recorded fair value adjustments on the accelerated share repurchase agreement in the amount of \$3 million which was a loss recorded in Other expense on our consolidated statements of operations in the year ended December 31, 2020.

As of June 30, 2021, we had repurchased an aggregate of 3,782,861 shares of common stock for an aggregate of \$211.2 million pursuant to our share repurchase programs in effect since August 2016.

Stock-Based Compensation

In November 2013, our Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. 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 may be 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.

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

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

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

A summary of stock option, RSU and PSU activity under the 2014 Plan during the six months ended June 30, 2021 and 2020 is presented below:

	Stock Options	RSUs	PSUs
Outstanding at December 31, 2019	3,096,161	251,215	116,181
Granted	600,700	231,450	—
Options Exercised/RSUs Vested/PSUs Vested	(38,951)	(67,970)	—
Forfeited or expired	(78,478)	(11,074)	(2,431)
Outstanding at June 30, 2020	<u>3,579,432</u>	<u>403,621</u>	<u>113,750</u>
Outstanding at December 31, 2020	3,331,890	328,396	97,750
Granted	106,000	106,600	159,000
Options Exercised/RSUs Vested/PSUs Vested	(94,328)	(94,273)	—
Forfeited or expired	(283,998)	(29,796)	(97,750)
Outstanding at June 30, 2021	<u>3,059,564</u>	<u>310,927</u>	<u>159,000</u>

Stock Options

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Risk-free interest rate	1.01% - 1.12%	0.44% - 0.44%	0.51% - 1.12%	0.44% - 1.65%
Volatility	55.66%	55.46%	56.10%	54.94%
Expected term (in years)	5.96 years	6.08 years	5.67 years	6.03 years
Expected dividend yield	0.0%	0.0%	0.0%	0.00%

RSUs

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

PSUs

The fair value of market condition PSUs granted to employees was estimated using a Monte Carlo simulation model. Inputs used in the calculation are described above.

The fair value of performance condition PSUs granted to employees was estimated based on the trading price of our common stock on the date of grant adjusted for probability of achievement of the performance conditions as described above.

We did not recognize any expense for performance based PSUs granted to employees based on our estimated probability of achievement as described above.

We recognized stock-based compensation in our condensed consolidated statements of operations for the three and six months ended June 30, 2021 and 2020 as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	\$ 2,547	\$ 4,153	\$ 5,878	\$ 9,146
RSUs	1,217	1,334	3,005	3,186
PSUs	517	754	1,906	1,381
Stock-based compensation expense	\$ 4,281	\$ 6,241	\$ 10,789	\$ 13,713
Selling, general and administrative	\$ 3,640	\$ 5,207	\$ 9,253	\$ 11,129
Research and development	641	1,034	1,536	2,584
Stock-based compensation expense	\$ 4,281	\$ 6,241	\$ 10,789	\$ 13,713

8. Commitments

Our future material contractual obligations as of June 30, 2021, included the following:

Obligations	Total	2021	2022	2023	2024	2025	2026	Beyond
Operating leases (1)	\$ 5,031	\$ 702	\$ 1,423	\$ 1,455	\$ 1,038	\$ 413	\$ —	\$ —
Credit facility (2)	30,000	4,000	26,000	—	—	—	—	—
Purchase obligations (3)	48,213	48,213	—	—	—	—	—	—
Total obligations	\$ 83,244	\$ 52,915	\$ 27,423	\$ 1,455	\$ 1,038	\$ 413	\$ —	\$ —

(1) We lease our corporate office location. The term of our existing lease expires on June 30, 2025. We also lease our lab space under a lease agreement that expires on October 31, 2023. Rental expense for the operating leases was \$325 and \$351, for the three months ended June 30, 2021 and 2020, respectively. Rental expense for the operating leases was \$650 and \$637 for the six months ended June 30, 2021 and 2020. The remaining future lease payments under the operating leases are \$5 million as of June 30, 2021.

(2) Refer to Note 9, "Debt" for further information regarding our Credit Agreement.

(3) As of June 30, 2021, we had purchase obligations in the amount of \$48.2 million which represents the contractual commitments under contract manufacturing and supply agreements with suppliers. The obligations under the supply agreements are primarily for finished product, inventory, and research and development.

9. Debt

On November 8, 2019, we entered into the Second Amended and Restated Credit Agreement (the "Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Agent") and the lenders party thereto. The terms and amounts

borrowed under the 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 was extended to November 8, 2022.

We classified the current portion of long-term debt of \$8 million on the condensed consolidated balance sheet as of June 30, 2021. Per the terms of the Credit Agreement, the Company is limited in its ability to pay dividends. As of June 30 2021, we were in compliance with each of the senior secured net leverage ratio; total net leverage ratio; and fixed charge coverage ratio covenants.

The term loan facility bears 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 us may amend the Credit Agreement to replace the LIBOR with a Benchmark Replacement, described below.

Loans under the 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 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.

We are required to pay a commitment fee on the unused portion of the new revolving credit facility in the Credit Agreement at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio.

As of June 30, 2021, we had \$0.6 million of unamortized deferred debt issuance costs as part of long-term debt in its condensed consolidated balance sheets.

Debt Maturities		As of June 30, 2021	
2021 (remainder)	\$		4,000
2022			26,000
Total	\$		30,000

10. Income Taxes

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021		2020		2021		2020	
Income tax provision	\$	(1,936)	\$	(5,629)	\$	(3,697)	\$	(5,492)
Effective tax rate		35 %		105 %		54 %		232 %

For interim periods, we recognize an income tax provision based on our estimated annual effective tax rate expected for the entire year plus the effects of certain discrete items occurring in the quarter. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for changes in estimated permanent differences, and certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur.

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the three and six months ended June 30, 2021 reflects the impact of certain non-deductible executive compensation and expired stock compensation, partially offset by credits for research and development activity and excess tax deduction the Company can realize for its stock based awards. We review the realizability of our deferred tax assets on a quarterly basis, or whenever events or changes in circumstances indicate that a review is required. In determining the requirement for a valuation allowance, the historical and projected financial results of the legal entity or consolidated group recording the net deferred tax asset are considered, along with any other positive or negative evidence. Since future financial results, including the fair value adjustment on our investment in Tyme may differ from previous estimates, periodic adjustments to our valuation allowances may be necessary.

Deferred income tax assets as of June 30, 2021 consisted of temporary differences primarily related to stock-based compensation and research and development tax credit carryforwards, partially offset by temporary differences related to intangible assets.

We file income tax returns in the U.S. federal jurisdiction and several states. Given that we have incurred tax losses in most years since our inception, all of our tax years are effectively open to examination. We are currently under audit by three State tax jurisdictions. We had no amount recorded for any unrecognized tax benefits as of June 30, 2021. We regularly evaluate our 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. We reflect interest and penalties attributable to income taxes, to the extent they arise, as a component of income tax provision or benefit.

11. Legal Proceedings

In addition to the below legal proceedings, from time to time, we may be a party to litigation and subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters, or matters discussed below, will not have a material adverse effect on our business nor have we recorded any loss in connection with these matters because we believe that loss is neither probable nor estimable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Commercial Litigation

Cipla v. Eagle

On April 16, 2020, Cipla Limited (“Cipla”) filed a request for arbitration against Eagle with the London Court of International Arbitration. The request alleges that Eagle’s refusal to take delivery of several batches of Argatroban finished drug product constitutes a breach of the parties’ December 14, 2012 supply agreement. Eagle believes that the allegations against it are without merit and is vigorously defending itself in the Arbitration, which was scheduled for June 2021, has been rescheduled for November 2021.

Patent Litigation

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

On December 23, 2020, we, 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 had accepted service. On February 11, 2021, Shilpa amended its NDA to withdraw its exclusivity statement referencing Pemfexy™ and its patent certification to the ‘990 patent. A joint stipulation of dismissal was filed March 26, 2021, and dismissal was ordered April 19, 2021.

Eagle Pharmaceuticals, Inc., et al. v. Slayback Pharma Limited Liability Company; Eagle Pharmaceuticals, Inc., et al. v. Apotex Inc. and Apotex Corp.; Eagle Pharmaceuticals, Inc., et al. v. Fresenius Kabi USA, LLC; Eagle Pharmaceuticals, Inc., et al. v. Mylan Laboratories Limited; Eagle Pharmaceuticals, Inc. et al. v. Hospira, Inc; Eagle Pharmaceuticals, Inc. et al. v. Lupin, Ltd. and Lupin Pharmaceuticals, Inc.; Teva Pharmaceuticals Int’l GmbH et al v. Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd.; Teva Pharmaceuticals Int’l GmbH et al v. Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd.; Teva Pharmaceuticals Int’l GmbH et al v. Dr. Reddy’s Laboratories, Ltd., and Dr. Reddy’s Laboratories, Inc. - (Bendeka®)

Bendeka, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin’s lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Slayback Pharma Limited Liability Company (“Slayback”), Apotex Inc. and Apotex Corp. (“Apotex”), Fresenius Kabi USA, LLC (“Fresenius”), Mylan Laboratories Limited (“Mylan”), Lupin, Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”), and Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd (“Aurobindo”) have filed Abbreviated New Drug

Applications (“ANDA’s”) referencing Bendeka[®] that include challenges to one or more of the Bendeka[®] Orange Book-listed patents. Hospira, Inc. (“Hospira”) filed a 505(b)(2) NDA.

We, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the “Patentees”), filed separate suits against Slayback, Apotex, Fresenius, Mylan, Hospira, Lupin, and Aurobindo in the United States District Court for the District of Delaware on August 16, 2017 (Slayback (“Slayback I”)), August 18, 2017 (Apotex), August 24, 2017 (Fresenius), December 12, 2017 (Mylan), January 19, 2018 (Slayback (“Slayback II”)), July 19, 2018 (Hospira), and July 2, 2019 (Lupin) and May 11, 2020 (Aurobindo). In these Complaints, the Patentees allege infringement of the challenged patents, namely U.S. Patent Nos. 8,791,270 and 9,572,887 against Slayback (Slayback I and Slayback II), and of U.S. Patent Nos. 8,609,707, 8,791,270, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399 against Fresenius, Apotex, and Mylan, and of U.S. Patent Nos. 9,572,887, 10,010,533, 9,034,908, 9,144,568, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384 against Hospira, and of U.S. Patent Nos. 8,609,707, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399, 10,010,533, and 10,052,385 against Lupin and of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385 against Aurobindo. The parties stipulated to dismiss without prejudice U.S. Patent No. 8,791,270 as to Apotex, Fresenius and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018, respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively. On October 15, 2018, the Patentees filed a suit against Fresenius and Mylan in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 10,010,533 and 10,052,385. The Slayback I, Slayback II, Apotex, Fresenius and Mylan cases have been consolidated for all purposes (the “Consolidated Bendeka Litigation”), and a bench trial in these cases was held September 9-19, 2019. On April 27, 2020, the district court held that the asserted patents are valid and infringed by Slayback, Apotex, Fresenius and Mylan. On July 6, 2020, the district court entered a final judgment reflecting this decision, stating that pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA shall not approve Apotex’s, Fresenius’s, Mylan’s, or Slayback’s ANDA products on a date which is earlier than January 28, 2031, and enjoining Apotex, Fresenius, Mylan, and Slayback from commercially manufacturing, using, offering to sell, or selling within the US or importing into the US, their ANDA products before that date. On August 4, 2020, Apotex, Fresenius, and Mylan appealed this final judgment, and filed their opening briefs on November 4, 2020. Plaintiffs’ responsive appeal brief was filed on February 12, 2021. Defendants’ reply briefs were filed April 5, 2021. On August 2, 2021, Fresenius’s appeal was dismissed pursuant to a settlement agreement reached with Patentees. Oral argument for the remaining defendants occurred on August 3, 2021.

Hospira filed a motion to dismiss, which was fully briefed on November 16, 2018. On December 16, 2019, the United States District Court for the District of Delaware denied Hospira’s motion to dismiss with respect to U.S. Patent No. 9,572,887 and granted that motion with respect to the remaining patents. On December 15, 2020, the Court held a claim construction hearing, ruling in our favor on all claim terms. Fact discovery closed on April 1, 2021. Expert discovery is expected to close August 23, 2021. 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. Plaintiffs provided their infringement contentions on March 12, 2021. Trial is scheduled for July 18, 2022. The case is currently stayed, pending the outcome of the appeal in the consolidated cases against Mylan and Apotex.

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.

Patentees filed suit against Dr. Reddy’s Laboratories on May 13, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. Dr. Reddy’s answer is due August 16, 2021.

Patentees filed suit against Accord Healthcare on June 29, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. Accord's answer is due September 28, 2021.

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.

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 Vasopressin, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The Company answered the complaint on August 6, 2018, and filed an amended answer and counterclaims on October 30, 2019. The court issued a Markman ruling on July 1, 2019. On December 20, 2019, Par dismissed with prejudice claims of three of the patents asserted against Eagle, and the Court entered an Order reflecting that dismissal on December 27, 2019. Mediation took place on March 3, 2020. On April 17, 2020, we submitted a letter requesting leave to file a motion for summary judgment of non-infringement. Par's responsive letter was submitted on May 8, 2020. On May 18, 2020, the court said it would hear non-infringement arguments at trial and not through summary judgment. Fact discovery ended in October 2019, and expert discovery ended in February 2020. Due to the COVID-19 pandemic, the trial, which was scheduled to begin May 18, 2020, was rescheduled to and occurred on July 7-9, 2021. Post-trial briefing was submitted on July 28, 2021. The 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 us in the United States District Court for the District of New Jersey, asserting patent infringement of U.S. Patent No. 10,844,435, based on the filing of our ANDA seeking approval to manufacture and sell our vasopressin product. Eagle moved to dismiss Par's complaint on March 2, 2021. On March 22, 2021, Par amended its complaint to additionally assert U.S. Patent No. 10,920,278, and on April 5, 2021, Eagle moved to dismiss Par's amended complaint. This suit is pending.

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, we 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 October 8, 2020, Accord withdrew its July 10, 2019 motion for judgment on the pleadings. On March 31, 2021, pursuant to the parties' joint stipulation, the court dismissed all claims and affirmative defenses asserted by the parties against one another in the New Jersey suit, without costs, disbursements, or attorneys' fees to any party.

12. Collaboration with Tyme

As of June 30, 2021, we included our investment in Tyme in Other Assets (non-current) on our condensed consolidated balance sheet. For the three months ended June 30, 2021 and 2020, the fair value adjustments for the equity investment was a loss of \$5.2 million and a gain \$2.3 million, respectively. For the six months ended June 30, 2021 and 2020, the fair value adjustments for the equity investment was a gain of \$0.4 million and a loss of \$4.2 million, respectively. These adjustments were recorded in Other (expense) income on our condensed consolidated statements of operations.

13. Convertible Promissory Note

During the first quarter of 2021, we invested \$5 million in a convertible promissory note ("the note") of a privately held clinical-stage biotechnology company (the "issuer"). The note bears an 8% annual interest rate and has an 18-month term. The issuer is not required to make any principal or interest payments until the end of the term. The note, along with any accrued interest, may automatically convert into equity securities of the issuer under either a financing event or a change in control event as defined in the convertible promissory note agreement. The issuer's product development efforts could encounter technical or other difficulties that could increase their development costs more than expected. The issuer will likely require additional capital prior to obtaining certain regulatory approval or to be able to repay the convertible promissory note with accrued interest at the end of the term.

As of June 30, 2021, we recorded the following: i) \$0.9 million fair value adjustment related to the investment in the note which is recorded on statement of comprehensive loss as unrealized loss; ii) a \$0.1 million estimated credit loss related to the note; iii) during the three months ended March 31, 2021, an initial \$0.3 million fair value adjustment was recorded associated with an embedded derivative contained in the note, with a corresponding discount recorded to the investment in the note; a subsequent adjustment of \$0.2 million to increase fair value of the derivative asset was recorded during the three months ended June 30, 2021, for a total \$0.5 million derivative asset on our condensed consolidated balance sheet as of June 30, 2021; initial discount on the promissory note of \$0.3 million is being accreted over the term of the note and as such, we recorded \$0.1 million of interest income during the period ended June 30, 2021; and iv) we recorded \$0.1 million of accrued interest income related to the note during the three and six months ended June 30, 2021 in our condensed consolidated statement of operations.

14. Subsequent Event

On August 6, 2021, we entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH (“AOP Orphan”), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, Landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We will support the submission of a new drug application (“NDA”) by AOP Orphan to the FDA seeking approval for Landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia (“SVT”), including atrial fibrillation and atrial flutter. We anticipate the filing of such NDA in the first quarter of 2022, with an expected ten-month review, based on feedback from the FDA provided during AOP Orphan’s Type C meeting with the FDA.

Under the terms of the agreement, we will facilitate the U.S. regulatory pathway for the approval of Landiolol. In addition, we will be responsible for the U.S. commercialization of the product upon approval. Landiolol, which has not previously been marketed in the U.S., is covered by several patents, and we anticipate five years of new chemical entity (“NCE”) exclusivity.

The agreement is subject to regulatory clearance. Under the terms of the agreement, we will make an upfront payment of \$5 million, followed by additional payments upon regulatory approval(s) and based upon commercial sales.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with our unaudited consolidated financial statements and the notes thereto included in this Quarterly Report on Form 10-Q, or the Quarterly Report, and the audited financial information and the notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC, on March 5, 2021, or our Annual Report. This discussion and analysis contains forward-looking statements that involve significant risks and uncertainties. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under “Risk Factors” included elsewhere in this Quarterly Report. Such factors may be amplified by the COVID-19 pandemic and its current or its potential impact on our business and the global economy. Unless otherwise indicated or required by context, references throughout to “Eagle,” the “Company,” “we,” “our,” or “us” refer to financial information and transactions of Eagle Pharmaceuticals, Inc.

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. Symbio Pharmaceuticals Limited, or Symbio, markets Treakisym, a lyophilized powder formulation of bendamustine hydrochloride, in Japan. Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for Pemfexy, a branded alternative to Alimta for metastatic non-squamous non-small cell lung cancer and malignant pleural mesothelioma. 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 Vasotricin 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. We completed the last study required by the FDA for vasopressin during the first quarter of 2021, and we submitted our response to the CRL on June 15, 2021. The FDA has assigned a Generic Drug User Fee Amendments / Act, or GDUFA, date of December 15, 2021, and we expect a commercial launch prior to year-end. Importantly, we have completed an extensive amount of developmental work and continue to do so for our first-to-file polypeptide, where brand sales of the product are over \$700 million annually. In its communication with us, the FDA restated that it has prioritized our ANDA, and that the ANDA has also been flagged as a COVID-19 priority by FDA. We believe we have fully responded to the questions raised. 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, was rescheduled to July 7, 2021. The trial took place on July 7-9, 2021, and post-trial briefing was submitted on July 28, 2021. We remain confident about this litigation given that Par's asserted patents claim a formulation with a pH of 3.7-3.9 and our proposed ANDA product specifies a pH outside of that range. We are confident that our ANDA will be approved in a reasonable timeframe.

Treakisym (bendamustine) Ready-to-Dilute and Rapid Infusion Formulation

On April 30, 2021, we announced that Treakisym ready-to-dilute, or RTD, (bendamustine hydrochloride 120 mg/m²) liquid formulation was approved for a new indication in combination with rituximab, or BR therapy, as treatment for relapsed or refractory diffuse large B-cell lymphoma, or r/r DLBCL, by the Pharmaceuticals and Medical Devices Agency in Japan.

On May 10, 2021, we announced that an application for Treakisym rapid infusion, or RI, (50ml) liquid formulation was filed with the PMDA in Japan. The application is based on the results of clinical studies investigating the safety and pharmacokinetics of Treakisym RTD administered by 10-minute intravenous infusion.

Pursuant to our license agreement with SymBio, SymBio may develop and commercialize our bendamustine hydrochloride ready-to-dilute injection product and rapid infusion injection product in Japan. SymBio currently markets in Japan Treakisym, a lyophilized powder formulation of bendamustine hydrochloride indicated for CLL, relapsed or refractory low-grade NHL, mantle cell lymphoma, or MCL, and as a first line treatment of low-grade NHL and MCL. Under the license agreement, SymBio may develop and market certain other bendamustine hydrochloride products in Japan for limited indications. As part of the agreement, SymBio assumed responsibility for securing regulatory approval of the Treakisym RTD and RI products using the licensed technology in Japan.

Landiolol Licensing Agreement

On August 9, 2021, we announced that we entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH, or AOP Orphan, a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, Landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We will support the submission of a NDA by AOP Orphan to the FDA seeking approval for Landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter. We anticipate the filing of such NDA in the first quarter of 2022, with an expected ten-month review, based on feedback from the FDA provided during AOP Orphan's Type C meeting with the FDA. We will be responsible for the U.S. commercialization of the product upon approval. Landiolol, which has not previously been marketed in the U.S., is covered by several patents, and we anticipate five years of new chemical entity exclusivity. Landiolol is already commercially available in Japan and several European markets. The licensing agreement is subject to regulatory clearance.

COVID-19 Business Update

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on our business, such as remote working policies, facilitating management's daily communication to address employee and business concerns and providing frequent updates to the Board. During the second quarter of 2021, we implemented a plan to reopen our office to allow employees to return to the office, with a focus on employee safety and optimal work environment. Our management continues to monitor and evaluate such plans as the pandemic continues to evolve. We anticipate that the COVID-19 pandemic may 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 June 30, 2021, we have recognized revenues from product sales including Bendeka, Treakisym, Ryanodex and Belrapzo. Sales of Bendeka were made to our commercial partner, Teva, and are typically made at little or no profit for resale. Sales of Treakisym were made to Symbio pursuant to a supply agreement with Symbio. 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 provide a chargeback, representing the difference between the price invoiced to the wholesaler and the customer contract price.

Royalty Revenue. We recognize revenue from royalties based on a percentage of Teva's net sales of Bendeka and Symbio's net sales of Treakisym, 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 the payment for which 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 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 condensed 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 six months ended June 30, 2021 reflects certain non-deductible executive compensation and expired stock compensation, partially offset by credits for research and development activity and excess tax deduction we can realize for our stock based awards. The effective tax rate for the six months ended June 30, 2020 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Tyme, certain non-deductible executive compensation and changes in state filing positions, partially offset by credits for research and development activity.

Results of Operations

Comparison of Three Months Ended June 30, 2021 and 2020

Revenues

	Three Months Ended June 30,		Increase
	2021	2020	
	(in thousands)		
Product sales, net	\$ 19,621	\$ 14,376	\$ 5,245
Royalty revenue	28,503	27,562	941
Total revenue	\$ 48,124	\$ 41,938	\$ 6,186

Our product sales increased \$5.2 million during the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. The increase was attributable to product sales for Belrapzo and Ryanodex of \$3.5 million and \$3.2 million, respectively, which were primarily due to volume increases and \$1.2 million in product sales of Treakisym, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021. These increases were partially offset with a decrease of \$2.5 million in product sales of Bendeka primarily due to a decrease in unit volume.

Our royalty revenue increased \$0.9 million during the three months ended June 30, 2021 as compared to the three months ended June 30, 2020 primarily as a result of an increase in royalty revenue from our share of Symbio's Treakisym sales of \$0.7 million coupled with an increase in royalty revenue associated with Teva's Bendeka sales.

Cost of Revenue

	Three Months Ended June 30,		(Decrease) / Increase
	2021	2020	
	(in thousands)		
Cost of product sales	\$ 7,907	\$ 10,313	\$ (2,406)
Cost of royalty revenue	2,850	2,822	28
Total cost of revenue	\$ 10,757	\$ 13,135	\$ (2,378)

Our cost of product sales decreased \$2.4 million in the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. This was primarily attributable to a decrease of \$2.8 million in Bendeka cost of revenue resulting from lower product unit sales, coupled with a decrease of \$1.5 million in Ryanodex due to non-recurrence of inventory write-offs of \$0.9 million and a favorable \$0.3 million adjustment to the inventory during the current period. These decreases were partially offset by an increase of \$1.2 million in Treakisym cost of revenue resulting from product unit sales, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021, and an increase of \$0.7 million in Belrapzo cost of revenue resulting from higher product unit sales.

Our cost of royalty revenue increased slightly by \$28 thousand during the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. This was primarily attributable to costs related to the royalty revenue for Bendeka and Treakisym. These increases were partially offset by a decrease in costs as a result of ending royalties related to Argatroban.

Research and Development

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

	Three Months Ended June 30,		(Decrease) / Increase
	2021	2020	
	(in thousands)		
Fulvestrant "EGL-5385-C-1701"	\$ 820	\$ 1,358	\$ (538)
Vasopressin	2,351	891	1,460
Ryanodex related projects	1,535	751	784
All other projects	1,652	706	946
Salary and other personnel related	3,553	3,429	124
Research and development	<u>\$ 9,911</u>	<u>\$ 7,135</u>	<u>\$ 2,776</u>

Our research and development expenses increased \$2.8 million in the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. The increase primarily resulted from a \$1.5 million increase in development cost for the Vasopressin project, a \$1 million increase in other projects primarily due to Pemfexy and \$0.8 million increase in Ryanodex related projects. These increases were partially offset by a \$0.5 million decrease related to the Fulvestrant project.

Selling, General and Administrative

	Three Months Ended June 30,		(Decrease)
	2021	2020	
	(in thousands)		
Selling, general and administrative	\$ 16,636	\$ 17,959	\$ (1,323)

Our selling, general and administrative expenses decreased \$1.3 million for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. This decrease is primarily related to a decrease in stock compensation expense.

Other (Expense) Income, net

	Three Months Ended June 30,		Increase / (Decrease)
	2021	2020	
	(in thousands)		
Interest income	\$ 163	\$ 150	\$ 13
Interest expense	(422)	(786)	(364)
Other (expense) income	(5,013)	2,300	(7,313)
Total other (expense) income, net	<u>\$ (5,272)</u>	<u>\$ 1,664</u>	<u>\$ (6,936)</u>

Our interest income slightly increased \$13 thousand for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. This increase is primarily due to accrued interest recorded on the convertible promissory note agreement entered into in the first quarter of 2021.

Our interest expense decreased \$0.4 million for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020. This decrease is primarily due to lower borrowings from our revolving credit facility during the three months ended June 30, 2021.

Our other (expense) income was a net expense of \$5 million for the three months ended June 30, 2021 as compared to a net income of \$2.3 million the three months ended June 30, 2020. This primarily resulted from fair value adjustments on our equity investment in Tyme, a loss in the amount of \$5.2 million during the three months ended June 30, 2021 as compared to a gain of \$2.3 million in the prior year period.

Income Tax Provision

	Three Months Ended June 30,	
	2021	2020
	(in thousands)	
Provision for income taxes	\$ (1,936)	\$ (5,629)
Effective tax rate	35 %	105 %

Our provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the three months ended June 30, 2021 reflects certain non-deductible executive compensation partially offset by credits for research and development activity. The effective tax rate for the three months ended June 30, 2020 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Tyme, certain non-deductible executive compensation partially offset by credits for research and development activity.

Comparison of Six Months Ended June 30, 2021 and 2020 Revenues

	Six Months Ended June 30,		Increase / (Decrease)
	2021	2020	
	(in thousands)		
Product sales, net	\$ 36,741	\$ 32,070	\$ 4,671
Royalty revenue	52,632	55,888	(3,256)
Total revenue	\$ 89,373	\$ 87,958	\$ 1,415

Our product sales increased \$4.7 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020 primarily driven by an increase in product sales of \$4.6 million in product sales of Belrapzo primarily due to unit volume, coupled with \$2.3 million in product sales of Treakisym, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021. These increases were partially offset by decreases in Ryanodex of \$1.5 million and Bendeka of \$0.6 million primarily due to a decrease in unit volume.

Our royalty revenue decreased \$3.3 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020, primarily as a result of lower royalties on Teva's sales of Bendeka of \$3.9 million, which were partially offset by new royalties on Symbio's sales of Treakisym of \$1 million.

Cost of Revenue

	Six Months Ended June 30,		Increase / (Decrease)
	2021	2020	
	(in thousands)		
Cost of product sales	\$ 16,349	\$ 15,078	\$ 1,271
Cost of royalty revenue	5,263	5,860	(597)
Total cost of revenue	\$ 21,612	\$ 20,938	\$ 674

Our cost of product sales increased \$1.3 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020, primarily as a result of an increase of \$2.4 million in Treakisym cost of product sales resulting from product unit sales, following the launch of Treakisym RTD in Japan by Symbio in the first quarter of 2021, and higher cost of product of sales for Belrapzo of \$1.2 million related to volume increase. These increases were partially offset by decreased cost of product sales of Ryanodex of \$1.3 million related to lower unit sales and decreased cost of product sales of Bendeka of \$1.3 million also related to lower unit sales.

Our cost of royalty revenue decreased \$0.6 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020, primarily as a result of a decrease in royalty revenue on Teva's sales of Bendeka coupled with the ending of royalties related to Argatroban.

Research and Development

	Six Months Ended June 30,		Increase / (Decrease)
	2021	2020	
	(in thousands)		
Fulvestrant "EGL-5385-C-1701"	\$ 4,478	\$ 4,159	\$ 319
Vasopressin	5,211	1,174	4,037
Ryanodex related projects	3,746	2,098	1,648
All other projects	3,033	1,287	1,746
Salary and other personnel related	7,731	7,844	(113)
Research and development	<u>\$ 24,199</u>	<u>\$ 16,562</u>	<u>\$ 7,637</u>

Our research and development expenses increased \$7.6 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020, primarily from an increase in project spending for the Company's Vasopressin initiative, coupled with a net increase in our Ryanodex related projects and an increase in all other projects inclusive of the Pemfexy project of \$1 million.

Selling, General and Administrative

	Six Months Ended June 30,		(Decrease)
	2021	2020	
	(in thousands)		
Selling, general and administrative	<u>\$ 36,515</u>	<u>\$ 42,714</u>	<u>\$ (6,199)</u>

Our selling, general and administrative expenses decreased \$6.2 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020. The decrease is primarily related to the non-recurrence of \$2.5 million of costs related to the collaboration with Tyme in 2020, coupled with decreased stock compensation expense of \$1.9 million, and \$1.2 million of decreased spending on advertising and marketing, primarily related to Ryanodex, and decreased expense related to ongoing litigation matters of \$0.3 million.

Other (Expense) Income, net

	Six Months Ended June 30,		(Decrease) / Increase
	2021	2020	
	(in thousands)		
Interest income	\$ 198	\$ 496	\$ (298)
Interest expense	(844)	(1,675)	(831)
Other income (expense)	487	(4,200)	4,687
Total other (expense) income, net	<u>\$ (159)</u>	<u>\$ (5,379)</u>	<u>\$ 5,220</u>

Our interest income decreased \$0.3 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020. This decrease is primarily due to lower interest rates associated with money market funds as compared to the six months ended June 30, 2020.

Our interest expense decreased \$0.8 million in the six months ended June 30, 2021 as compared to the six months ended June 30, 2020. This decrease is primarily due to lower borrowings from the revolving credit facility during the 2021 year to date period.

Our other (expense) income was an income amount of \$0.5 million for the six months ended June 30, 2021 as compared to an expense amount of \$4.2 million for the six months ended June 30, 2020. This primarily resulted from fair value adjustments on equity investment in Tyme in each period.

Income Tax Provision

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Provision for income taxes	\$ (3,697)	\$ (5,492)
Effective tax rate	54 %	232 %

Our provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the six months ended June 30, 2021 reflects certain non-deductible executive compensation and expired stock compensation, partially offset by credits for research and development activity and excess tax deduction we can realize for our stock based awards. The effective tax rate for the six months ended June 30, 2020 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment on Tyme, certain non-deductible executive compensation and changes in state filing positions, partially offset by credits for research and development activity.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Cash and cash equivalents were \$108.7 million and \$108.2 million as of June 30, 2021 and June 30, 2020, respectively.

For the six months ended June 30, 2021, we realized a net income of \$3.2 million. As of June 30, 2021, our working capital surplus was \$130.8 million. For the six months ended June 30, 2020, we realized net loss of \$3.1 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 12 months.

The COVID-19 pandemic has disrupted and continues to disrupt the U.S. healthcare system, global economies and global capital markets. There remain 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 six months ended June 30, 2021 was \$19.1 million. Net income for the period was \$3.2 million enhanced by the net of non-cash adjustments of approximately \$13.9 million from deferred income taxes, depreciation, amortization expense of right-of-use assets, amortization expense of intangible assets, fair value adjustments on equity investment, stock-based compensation expense, amortization of debt issuance costs and other items. Net changes in working capital increased cash from operating activities by approximately \$2 million, due to changes in working capital accounts. The total amount of accounts receivable at June 30, 2021 was approximately \$52.7 million, which included \$23.4 million related to product sales and \$29.3 million related to royalty revenue. 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.

Investing Activities:

Net cash used by investing activities for the six months ended June 30, 2021 was \$5.3 million, as a result of \$5 million of investment to purchase a convertible promissory note and we spent \$0.3 million for purchases of property and equipment.

Financing Activities:

Net cash used by financing activities for the six months ended June 30, 2021 was \$8.2 million, as a result of \$4 million of principal payments for debt required by our Second Amended and Restated Credit Agreement with JPMorgan Chase Bank, N.A., as administrative agent and the lenders party thereto, or the Credit Agreement, \$4.3 million in payments related to the repurchases of our common stock, \$1.6 million of payments associated with employee withholding tax upon vesting of stock-based awards, partially offset by \$1.6 million of proceeds from common stock exercises of employee stock options.

Trends and Uncertainties

Impact of the COVID-19 Pandemic

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

During the six months ended June 30, 2021, we have experienced a variable impact on our business and financial condition due to the COVID-19 pandemic, which impacts include a decrease in revenue from sales of Belrapzo resulting, in part, from a decrease in inventory stocking and utilization rates, as well as a decrease in research and development expenses partially resulting from preclinical program delays. We also incurred an insignificant amount of incremental administrative costs related to the COVID-19 pandemic. The COVID-19 pandemic, including containment and mitigation measures, has impacted, and is expected to continue to impact, our business and operations in a number of ways, including:

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

related to regulatory approval, or the diversion of FDA's efforts and attention to approval of other therapeutics or other activities related to the COVID-19 pandemic, which could further delay approval decisions with respect to regulatory submissions or obtain new product approvals.

- *Clinical Development Timelines:* The clinical trial timelines for certain of our product candidates have been delayed given difficulties with limited patient enrollment resulting from the impact of the COVID-19 pandemic, and we expect that our clinical trial timelines will continue to be impacted for the duration of the pandemic.

There are significant uncertainties surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations. We continue to evaluate the impact of the COVID-19 pandemic on our operating results and financial condition. The COVID-19 pandemic has had a variable impact on our results of operations during the six months ended June 30, 2021 and, it could have a material adverse impact on our financial condition and results of operations in the future.

Contractual Obligations

Other than as set forth below, there have been no material changes to our contractual and commercial obligations during the six months ended June 30, 2021, as compared to the obligations disclosed in our Annual Report.

Our future material contractual obligations included the following as of June 30, 2021 (in thousands):

Obligations	Total	2021	2022	2023	2024	2025	2026	Beyond
Operating leases (1)	\$ 5,031	\$ 702	\$ 1,423	\$ 1,455	\$ 1,038	\$ 413	\$ —	\$ —
Credit facility (2)	30,000	4,000	26,000	—	—	—	—	—
Purchase obligations (3)	48,213	48,213	—	—	—	—	—	—
Total obligations	\$ 83,244	\$ 52,915	\$ 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. We also lease lab space under a lease agreement that expires on April 1, 2024.

(2) Refer to Note 9 Debt for details of our Credit Agreement.

(3) As of June 30, 2021, we had purchase obligations in the amount of \$48.2 million 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.

Critical Accounting Policies

Our significant accounting policies are disclosed in "Note 2. Summary of Significant Accounting Policies" in our audited financial statements for the year ended December 31, 2020 included in our Annual Report. Since the date of such financial statements, there have been no changes to our significant accounting policies other than those described in Note 2 of the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the six months ended June 30, 2021, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report, except as discussed below.

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 4. Controls and Procedures**Evaluation of Disclosure Controls and Procedures**

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the “Exchange Act”, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation at June 30, 2021, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

The disclosures under Note 11. Legal Proceedings in the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report are incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

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. Except for the updated risk factor set forth immediately below, our risk factors have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report.

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.

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 Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act, or collectively, 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 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”. On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the United States Supreme Court ruling, on January 28, 2021, the current U.S. President issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the current Presidential administration will impact the 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, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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.

Further, under the Drug Supply Chain Security Act signed into law on November 27, 2013, certain drug manufacturers will be subject to product identification, tracing and verification requirements, among others, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

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 former U.S. Presidential administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning on January 1, 2020. The final rule codified a CMS policy change that was effective January 1, 2019. In a final rule issued by CMS on December 31, 2020, CMS established a broader definition for a “line extension” drug such that the line extension of the initial brand name listed drug would not need to be an oral solid dosage form. This final rule, may impact the rebate amounts associated with our products and negatively affect the commercial success of our products. Additionally, on December 2, 2020, CMS published changes to the Medicare Physician Fee Schedule for Calendar Year 2021 that also may adversely impact the coverage and reimbursement of our products. Under the changes, CMS will assign certain 505(b)(2) drug products to existing multiple source drug codes because, according to CMS, some drug products approved under the 505(b)(2) pathway share similar labeling and uses with generic drugs that are assigned to multiple source drug codes. CMS noted that this change is consistent with efforts to “curb drug prices” and encourages competition among products that are described by one billing code and share similar labeling. On July 24, 2020 and September 13, 2020, the former U.S. Presidential administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration’s proposals. As a result, 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, the Department of Health and Human Services 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 current administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing the former President’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 for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the United States District Court of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the United States District Court for the Northern District of California and that performance for any final regulation stemming from the Most Favored Nation Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Additionally, based on a recent executive order, the current U.S. Presidential administration expressed its intent to pursue certain policy initiatives to reduce drug prices. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

Share Repurchase Program

On March 17, 2020, we announced that our Board approved a new share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of \$160 million of the Company’s outstanding common stock. The Share Repurchase Program replaced 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 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.

We made the following purchases of our equity securities during the period covered by this Quarterly Report on Form 10-Q.

Period	Total Number of Shares Purchased (1)	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 <small>(dollars in thousands)</small>
April 1, 2021 to April 30, 2021	48,449	\$ 40.84	48,449	121,586
May 1, 2021 to May 31, 2021	21,841	\$ 40.96	21,841	120,691
June 1, 2021 to June 30, 2021	—	N/A	—	120,691
Total	<u>70,290</u>		<u>70,290</u>	

(1) All shares repurchased by us during the three months ended June 30, 2021 were repurchased pursuant to the Share Repurchase Program, described above.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
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)
31.1	(1) Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	(1) Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	** Certification of Principal 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	XBRL 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	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

(1) Filed herewith.

+ Certain portions of the exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to the Registrant if publicly disclosed.

**The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are 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 hereof), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements 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

EAGLE PHARMACEUTICALS, INC.

DATED: August 9, 2021

By: /s/ Scott Tarriff
Scott Tarriff
(On behalf of the Registrant and as Chief Executive Officer as Principal Executive Officer)

DATED: August 9, 2021

By: /s/ Brian J. Cahill
Brian J. Cahill
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Scott Tarriff, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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: August 9, 2021

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Brian J. Cahill, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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: August 9, 2021

/s/ Brian J. Cahill

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

**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**, Chief Executive Officer of Eagle Pharmaceuticals, Inc. (the "Company"), and **Brian J. Cahill**, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, (the "Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of August 2021.

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

By: /s/ Brian J. Cahill
Brian J. Cahill
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q 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-Q), irrespective of any general incorporation language contained in such filing.