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 September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number 001-36306

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

50 Tice Boulevard, Suite 315
Woodcliff Lake, NJ 07677
(201) 326-5300
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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

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

Emerging growth company ☐

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

Indicate by check mark whether the registrant 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 November 2, 2022: 13,015,856 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," " "prospects," "outlook," "goal," 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:

- statements related to our expectations with respect to the potential benefits to us from our acquisition of Acacia Pharma Group plc;
- the potential benefits and commercial potential of our approved products, including rapidly infused bendamustine RTD, or Bendeka, Ryanodex® (dantrolene sodium), or Ryanodex, bendamustine ready-to-dilute, or RTD, 500ml solution, or Belrapzo, BARHEMSYS® and BYFAVO® TREAKISYM®, a lyophilized powder formulation of bendamustine hydrochloride, PEMFEXY®, and vasopressin, for approved indications and any expanded uses;
- statements related to our expectations with respect to our investment in Enalare Therapeutics, Inc., or Enalare, including with respect to the anticipated financial impact on us of the agreement with Enalare, potential benefits to us, the achievement of related milestones and timing thereof, our potential further investment in Enalare pursuant to the terms of the agreement, the commercial potential of Enalare's product candidates and Enalare's development program, including with respect to current and future clinical trials and timing thereof, and expectations regarding our future growth and the expansion of our growth possibilities as a result of the investment in Enalare;
- 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 number and timing of potential product launches, development initiatives or new indications for the Company's product candidates, and the commercial potential of additional indications for our products;
- the initiation, timing, design, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our plans to research, develop and commercialize our products and product candidates and our ability to successfully commercialize our products and product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the impact of the ongoing coronavirus 2019, or COVID-19, pandemic on our business and operations, results of operations and financial performance including: disruption in the sales of our marketed products; delays, interruptions or other adverse effects to clinical trials and patient enrollment; delays in regulatory review; manufacturing and supply chain interruptions; and the adverse effects on healthcare systems, volatility of the financial and credit markets and disruption of the global economy overall;
- the impact of geopolitical events, such as the ongoing conflict between Russia and Ukraine and related sanctions, and macroeconomic conditions, such as rising inflation and interest rates and uncertainty in credit and financial markets, on our business and operations, results operations and financial performance;
- the diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals and doctor offices serving as locations for administration of our products, including Bendeka and hospital staff supporting the conduct of such administration;
- the rate and degree of market acceptance of our products;
- our ability to significantly grow our commercial sales and marketing organization, whether alone or with potential future collaborators;
- the performance of our strategic collaborators and success of our current strategic collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing drugs that are or become available;
- the retention of key scientific or management personnel;
- our ability to obtain additional funding for our operations;

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

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., “Eagle Research Lab” means Eagle Research Lab Limited, and "Acacia Pharma" means Acacia Pharma Group plc.

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, but such references are not intended to indicate in any way that the Company will not assert, to the fullest extent under applicable law, its rights or the rights of the applicable licensor to these trademarks and trade names. The Company does not intend its use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of the Company by, any other entity.

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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)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,384	$ 97,659
Accounts receivable, net	96,932	41,149
Inventories	63,855	21,908
Prepaid expenses and other current assets	8,875	11,890
Total current assets	185,046	172,606
Property and equipment, net	1,297	1,636
Intangible assets, net	108,785	10,671
Goodwill	41,794	39,743
Deferred tax asset, net	23,541	18,798
Other assets	25,986	10,278
Total assets	$ 386,449	$ 253,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,215	$ 16,431
Accrued expenses and other liabilities	73,652	32,338
Current debt	34,961	25,607
Total current liabilities	121,828	74,376
Long-term debt	26,431	—
Deferred tax liability	4,536	—
Other long-term liabilities	1,874	2,903
Total liabilities	154,669	77,279
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 17,568,586 and 16,903,034 shares issued as of September 30, 2022 and December 31, 2021, respectively	18	17
Additional paid in capital	362,161	325,779
Accumulated other comprehensive income (loss)	9,377	(94)
Retained earnings	103,339	75,862
Treasury stock, at cost, 4,552,730 and 4,111,622 shares as of September 30, 2022 and December 31, 2021, respectively	(243,115)	(225,111)
Total stockholders' equity	231,780	176,453
Total liabilities and stockholders' equity	$ 386,449	$ 253,732

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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product sales, net	$ 38,086	$ 12,124	$ 177,375	$ 48,865
Royalty revenue	24,007	27,729	74,728	80,361
License and other revenue	3,808	—	3,808	—
Total revenue	65,901	39,853	255,911	129,226
Operating expenses:				
Cost of product sales	20,869	5,486	67,216	21,835
Cost of royalty revenue	2,782	2,773	7,854	8,036
Research and development	9,326	23,289	26,871	47,488
Selling, general and administrative	23,462	18,482	82,476	54,997
Total operating expenses	56,439	50,030	184,417	132,356
Income (loss) from operations	9,462	(10,177)	71,494	(3,130)
Interest income	(444)	197	(46)	395
Interest expense	(1,147)	(396)	(2,065)	(1,240)
Other expense	(11,534)	(2,284)	(21,254)	(1,797)
Total other expense, net	(13,125)	(2,483)	(23,365)	(2,642)
(Loss) income before income tax (provision) benefit	(3,663)	(12,660)	48,129	(5,772)
Income tax (provision) benefit	(3,468)	7,038	(20,652)	3,341
Net (loss) income	$ (7,131)	$ (5,622)	$ 27,477	$ (2,431)
(Loss) earnings per share attributable to common stockholders:				
Basic	$ (0.54)	$ (0.43)	$ 2.13	$ (0.19)
Diluted	$ (0.54)	$ (0.43)	$ 2.11	$ (0.19)
Weighted average number of common shares outstanding:				
Basic	13,166,931	13,077,298	12,906,235	13,103,203
Diluted	13,166,931	13,077,298	13,051,311	13,103,203

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net (loss) income	$ (7,131)	$ (5,622)	$ 27,477	$ (2,431)
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) for convertible promissory note	(510)	22	94	(882)
Foreign currency translation	7,606	—	9,377	—
Total other comprehensive income (loss)	7,096	22	9,471	(882)
Comprehensive (loss) income	$ (35)	$ (5,600)	$ 36,948	$ (3,313)

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 Income	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount					
Balance as of June 30, 2022	17,549	$ 18	$ 358,377	$ (233,164)	$ 2,281	$ 110,470	$ 237,982
Stock-based compensation expense	—	—	3,537	—	—	—	3,537
Issuance of common stock upon exercise of stock option grants	20	—	247	—	—	—	247
Common stock repurchases	—	—	—	(9,951)	—	—	(9,951)
Other comprehensive income	—	—	—	—	7,096	—	7,096
Net (loss)	—	—	—	—	—	(7,131)	(7,131)
Balance as of September 30, 2022	17,569	$ 18	$ 362,161	$ (243,115)	$ 9,377	$ 103,339	$ 231,780

	Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive (Loss)	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount					
Balance as of June 30, 2021	16,880	$ 17	$ 316,249	$ (208,195)	$ (904)	$ 87,680	$ 194,847
Stock-based compensation expense	—	—	4,084	—	—	—	4,084
Issuance of common stock upon exercise of stock option grants	6	—	233	—	—	—	233
Common stock repurchases	—	—	—	(8,271)	—	—	(8,271)
Other comprehensive income	—	—	—	—	22	—	22
Net (loss)	—	—	—	—	—	(5,622)	(5,622)
Balance as of September 30, 2021	16,886	$ 17	$ 320,566	$ (216,466)	$ (882)	$ 82,058	$ 185,293

See accompanying notes to unaudited condensed consolidated financial statements.

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) Income	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount					
Balance as of December 31, 2021	16,903	$ 17	$ 325,779	$ (225,111)	$ (94)	$ 75,862	$ 176,453
Stock-based compensation expense	—	—	12,332	—	—	—	12,332
Issuance of common stock upon exercise of stock option grants	76	—	1,747	—	—	—	1,747
Issuance of common stock related to business acquisition	516	1	23,644	—	—	—	23,645
Issuance of common stock related to vesting of restricted stock units	74	—	(1,341)	—	—	—	(1,341)
Common stock repurchases	—	—	—	(18,004)	—	—	(18,004)
Other comprehensive income	—	—	—	—	9,471	—	9,471
Net income	—	—	—	—	—	27,477	27,477
Balance as of September 30, 2022	17,569	$ 18	$ 362,161	$ (243,115)	$ 9,377	$ 103,339	$ 231,780

	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	—	—	14,873	—	—	—	14,873
Issuance of common stock upon exercise of stock option grants	84	—	1,841	—	—	—	1,841
Issuance of common stock related to vesting of restricted stock units	63	—	(1,551)	—	—	—	(1,551)
Common stock repurchases	—	—	—	(12,568)	—	—	(12,568)
Other comprehensive (loss)	—	—	—	—	(882)	—	(882)
Net (loss)	—	—	—	—	—	(2,431)	(2,431)
Balance as of September 30, 2021	16,886	$ 17	$ 320,566	$ (216,466)	$ (882)	$ 82,058	$ 185,293

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net income (loss)	$ 27,477	$ (2,431)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Deferred income taxes	(4,743)	(2,533)
Depreciation expense	508	575
Noncash operating lease expense related to right-of-use assets	917	768
Amortization expense of intangible assets	5,886	2,118
Fair value adjustments on equity investment	3,208	1,900
Stock-based compensation expense	12,332	14,873
Amortization of debt issuance costs	354	354
Fair value adjustments related to derivative instruments	962	(254)
Accretion of discount on convertible promissory note	—	(102)
Loss on foreign currency exchange rates	7,309	—
Loss on write-off of promissory note	4,444	150
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(55,325)	5,343
Inventories	(15,006)	(1,240)
Prepaid expenses and other current assets	(831)	(8,821)
Accounts payable	(3,824)	6,449
Accrued expenses and other liabilities	33,888	3,897
Other assets and other long-term liabilities, net	(4,412)	(908)
Net cash provided by operating activities	13,144	20,138
Cash flows from investing activities:		
Purchase of Acacia, net of cash acquired	(74,153)	—
Purchase of equity investment security and options	(12,500)	—
Purchase of property and equipment	(168)	(274)
Purchase of convertible promissory note	—	(5,000)
Net cash used in investing activities	(86,821)	(5,274)
Cash flows from financing activities:		
Proceeds from common stock option exercises	1,747	1,841
Proceeds from revolving credit facility	15,000	—
Employee withholding taxes related to stock-based awards	(1,341)	(1,551)
Payment of debt	(6,000)	(6,000)
Repurchases of common stock	(18,004)	(12,568)
Net cash used in financing activities	(8,598)	(18,278)
Net decrease in cash and cash equivalents	(82,275)	(3,414)
Cash and cash equivalents at beginning of period	97,659	103,155
Cash and cash equivalents at end of period	$ 15,384	$ 99,741
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes	$ 18,855	$ 6,303
Interest	894	917

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, 2021 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 nine months ended September 30, 2022 are not necessarily indicative of the results for the year ending December 31, 2022 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, 2021, filed with the SEC on March 8, 2022.

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 the U.S. Food and Drug Administration ("FDA") approval and commercial launches of six products: PEMFEXY® (pemetrexed for injection), vasopressin, an A-rated generic alternative to Vasostrict®, Ryanodex® (dantrolene sodium) ("Ryanodex"), bendamustine ready-to-dilute ("RTD") 500ml solution ("Belrapzo"), and rapidly infused bendamustine RTD ("Bendeka") and RTD (“Treakisym”). We market our products through marketing partners and/or our internal direct sales force. We market PEMFEXY, vasopressin, Ryanodex and Belrapzo, and Teva Pharmaceutical Industries Ltd. ("Teva") markets Bendeka through its subsidiary Cephalon, Inc. SymBio Pharmaceuticals Limited ("SymBio"), markets Treakisym, a RTD product, in Japan.

On June 9, 2022, we acquired all of the outstanding share capital of Acacia Pharma Group plc (“Acacia”), which added two FDA approved new chemical entities with patent protection, BARHEMSYS® (amisulpride for injection) and BYFAVO® (remimazolam for injection). Refer to Note 14 for further details.

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, 2021 and the notes thereto filed with the SEC on March 8, 2022. Since the date of those consolidated financial statements, there have been no material changes to our significant accounting policies other than as listed below.

Business combinations and asset acquisitions - The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs, process, and output, which would meet the requirements of a business. If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting as indicated in Financial Accounting Standards Board (“FASB”)

Accounting Standards Update ("ASU") 2017-01, “Business Combinations”, which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including any contingent assets and liabilities, and any non-controlling interest in the acquiree based on the fair value estimates as of the date of acquisition. In accordance with Accounting Standards Codification (“ASC”) 805 - Business Combinations, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

The consideration for the Company’s business acquisitions may include future payments that are contingent upon the occurrence of a particular event or events. The obligations for such contingent consideration payments are recorded at fair value on the acquisition date. The contingent consideration obligations are then evaluated each reporting period. Changes in the fair value of contingent consideration, other than changes due to payments, would be recognized as a gain or loss and recorded condensed consolidated statement of operations.

If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50 Business Combinations – Related Issues, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. No gain or loss is recognized as of the date of acquisition unless the fair value of non-cash assets given as consideration differs from the assets’ carrying amounts on the acquiring entity’s financial statements. Consideration transferred that is non-cash will be measured based on either the cost (which shall be measured based on the fair value of the consideration given) or the fair value of the assets acquired and liabilities assumed, whichever is more reliably measurable. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values.

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”). We anticipate that the COVID-19 pandemic may also have an impact on the clinical development timelines for certain of our clinical programs. We also anticipate that the COVID-19 pandemic may have an impact on our supply chain. The COVID-19 pandemic and associated lockdowns have resulted in a decrease in healthcare utilization broadly and specifically lead to a continuing reduction in the utilization of physician-administered oncology products including Belrapzo and Bendeka. In addition, the COVID-19 pandemic has delayed the timing of certain litigation and we anticipate that such delays will continue for the duration of the pandemic. The extent to which the COVID-19 pandemic will continue to impact our business, clinical development and regulatory efforts, supply chain and sales efforts, corporate development objectives and the value of, and market for, our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. The global economic slowdown, the overall disruption of global healthcare systems, including rising inflation and interest rates, volatility in the markets 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, the U.S. government and other nations have imposed significant restrictions on most companies' ability to do business in Russia as a result of the ongoing military conflict between Russia and Ukraine. It is not possible to predict the broader or longer-term consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. Such geopolitical instability and uncertainty could have a negative impact on our ability to further expand our business and to otherwise generate revenues and develop our product candidates. In addition, a significant escalation or expansion of economic disruption or the conflict's current scope could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may opportunistically seek access to additional capital to fund potential licenses, acquisitions or investments to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. As a result of the COVID-19 pandemic, as well as the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia, and countermeasures related thereto in addition to macroeconomic conditions including rising inflation, the global credit and

financial markets have experienced significant volatility and disruption. If these market conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments or acquisitions. An inability to borrow or raise additional capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities, and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds for any such potential acquisition or investment activities, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose. Furthermore, any equity financing would be dilutive to our shareholders, and any financing could require the consent of the lenders under our credit facility.

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, geopolitical and macroeconomic conditions affect our business and results of operations, they may also have the effect of heightening many of the other risks and uncertainties discussed above.

Use of Estimates

These condensed consolidated financial statements are presented in U.S. dollars and are prepared in accordance with U.S. GAAP. The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements including disclosure of gross to net estimates as of the date of the condensed consolidated 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 also 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, although it is not currently expected that any disruption would be significant. As of the date of issuance of these condensed consolidated 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 condensed consolidated financial statements, actual results may materially vary from these estimates, and any such differences may be material to our condensed consolidated financial statements.

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:

	September 30, 2022			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Investment in Syros Pharmaceuticals, Inc. ("Syros")	$ 2,882	$ 2,882	$ —	$ —
Investment in Enalare Therapeutics, Inc.	8,438	—	—	8,438
Acquisition rights of Enalare Therapeutics, Inc.	8,125	—	—	8,125
Liability:				
Forward Liability	4,063	—	—	4,063

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

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 and nine months ended September 30, 2022.

Our investment in Enalare Therapeutics Inc., related acquisition right and forward liability were classified as Level 3. We analyzed and accessed the contractual obligation to invest another $12.5 million within six months from August 2022, along with the purchase option included within the Securities Purchase Agreement (“SPA”). We used a probability factor to value the asset related to the acquired acquisition rights based on management's best estimate, including the probability of completion of certain development milestones. The equity stake was accounted for as non-readily determinable fair value (“RDFV”)

investment. The equity investment and acquisition right was reported at fair value as of September 30, 2022. Refer to Note 15, Investment in Enalare Therapeutics Inc. for further information.

Our investment in restricted shares of common stock of Syros Pharmaceuticals, Inc. ("Syros"), following the merger of Tyme Technologies, Inc. (“Tyme”) and Syros on September 16, 2022, are classified as Level 1. Refer to Note 12, License and Collaboration Agreements for further details.

As of December 31, 2021, our investment in the convertible promissory note and the embedded derivative were 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 was accounted for as available for sale. The convertible promissory note was 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.

In the first quarter of 2022, we entered into a forward contract to purchase euros at a forward rate. The contract settled in the second quarter of 2022 and was used to economically hedge the cost of the acquisition of Acacia.

In second quarter of 2022, we entered into an additional forward contract to purchase euros at a forward rate. The contract was net settled in the third quarter of 2022 and was used to economically hedge the euro-dominated debt of Acacia that we assumed in connection with our acquisition all of the outstanding share capital of Acacia in June 2022. For the three and nine months ended September 30, 2022, the fair value adjustment on the forward contract was a loss of $0.7 million and a loss of $6.3 million, respectively, and the adjustments were recorded in Other (expense) income on our condensed consolidated statement of operations.

The fair value of the previously existing legacy term loan is classified as Level 2 for the periods presented and approximates its book value due to the variable interest rate. The fair value of the euro-denominated loan that we assumed as part of our acquisition of Acacia is classified as Level 2 and was recorded on the balance sheet at fair value upon acquisition.

Refer to Note 14. Business Acquisition for details regarding fair value measurements in connection with our acquisition of Acacia, including the fair value of the euro denominated loan.

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. We determined that no indicators of impairment of finite-lived intangible assets or long-lived assets existed as of September 30, 2022.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired in the Eagle Biologics and Acacia acquisitions. 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

The Company is exposed to risks associated with extending credit to customers related to the sale of products. The Company does not require collateral to secure amounts due from its customers. The Company uses an expected loss methodology to calculate allowances for trade receivables. The Company's measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. The Company does not currently have a material allowance for collectible trade receivables.

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenues				
Teva - See *Revenue Recognition*	39 %	69 %	32 %	66 %
Customer A	8 %	1 %	16 %	6 %
Customer B	15 %	9 %	13 %	8 %
Customer C	14 %	3 %	13 %	4 %
Customer D	10 %	11 %	9 %	10 %
Other	14 %	7 %	17 %	6 %
	100 %	100 %	100 %	100 %

	September 30, 2022	December 31, 2021
Accounts receivable		
Teva - See *Revenue Recognition*	27 %	63 %
Customer A	24 %	13 %
Customer B	16 %	13 %
Customer C	7 %	2 %
Customer D	6 %	2 %
Other	20 %	7 %
	100 %	100 %

Inventories

Inventories are recorded at the lower of cost and net realizable value, with cost determined on a first-in first-out basis. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If these 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 in licensing intellectual property related to new projects, 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 $1.7 million and $0.5 million for the three months ended September 30, 2022 and 2021, respectively, and $5.1 million and $1.3 million for the nine months ended September 30, 2022 and 2021, respectively.

Income Taxes

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

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

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price generally utilizing the expected value method to which the Company expects to be entitled. As such, revenue on sales to end users for vasopressin, Pemfexy, Belrapzo, Ryanodex, Barhemsys, and Byfavo are recorded net of chargebacks, rebates, returns, prompt pay discounts, wholesaler fees and other deductions. Our products are contracted with a limited number of oncology distributors and hospital buying groups with narrow

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

Components of Gross-to-Net (GTN) Estimates

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

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

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

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

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

Company’s distributors. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets.

Wholesaler fees and other incentives: The Company generally provides invoice discounts on vasopressin, Pemfexy, Belrapzo, Ryanodex, Barhemsys, and Byfavo sales to its distributors for prompt payment and fees for distribution services, such as fees for certain data that distributors provide to the Company. The payment terms for sales to distributors generally include a 2% discount for prompt payment which is generally defined in invoice terms as a range from 15 to 45 days, while the fees for distribution services are based on contractual rates agreed with the respective distributors. Based on historical data, the Company expects its distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized. In certain cases, the Company may record the fees as accrued expenses if the Company expects that the fees will be paid rather than deducted by the distributor.

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

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

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

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

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company’s contracts contained a significant financing component as of September 30, 2022.

Stock-Based Compensation

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

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

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

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

Earnings Per Share

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

The anti-dilutive common share equivalents outstanding for the three and nine months ended September 30, 2022 and 2021 were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Stock options	2,627,704	2,446,657	2,546,760	2,777,995
Restricted stock units	241,789	—	238,039	123,600
Total	2,869,493	2,446,657	2,784,799	2,901,595

The following table sets forth the computation for basic and diluted net (loss) earnings per share for the three and nine months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator				
Net (loss) income	$ (7,131)	$ (5,622)	$ 27,477	$ (2,431)
Denominator				
Basic weighted average common shares outstanding	13,166,931	13,077,298	12,906,235	13,103,203
Dilutive effect of stock awards	—	—	145,076	—
Diluted weighted average common shares outstanding	13,166,931	13,077,298	13,051,311	13,103,203
Basic net (loss) earnings per share				
Basic net (loss) earnings per share	$ (0.54)	$ (0.43)	$ 2.13	$ (0.19)
Diluted net (loss) earnings per share				
Diluted net (loss) earnings per share	$ (0.54)	$ (0.43)	$ 2.11	$ (0.19)

All potentially dilutive items were excluded from the diluted share calculation for the three months ended September 30, 2022 and the three months and nine months ended September 30, 2021 because their effect would have been anti-dilutive, as the Company was in a loss position.

Recent Accounting Pronouncements

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.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires an acquirer to recognize and measure contract assets and liabilities acquired in a business combination in accordance with Revenue from Contracts with Customers (Topic 606) rather than adjust them to fair value at the acquisition date. This accounting standard update will be effective for public business entities in fiscal years beginning after December 15, 2022, including interim periods within those fiscal years; therefore for us beginning in the first quarter of 2023. We are currently evaluating the impact of this accounting standard, but do not expect it to have a material impact on our condensed consolidated financial statements.

In March 2022, the FASB issued ASU 2022-01, *Derivatives and Hedging (Topic 801): Fair Value Hedging – Portfolio Layer Method*, which expands the current single-layer hedging model to allow multiple-layer hedges of a single closed portfolio of prepayable financial assets or one or more beneficial interests secured by a portfolio of prepayable financial instruments under

the method. This accounting standards update will be effective for public business entities in fiscal years beginning after December 15, 2022, including interim periods within those fiscal years; therefore for us beginning in the first quarter of 2023. We are currently evaluating the impact of this accounting standard, but do not expect it to have a material impact on our condensed consolidated financial statements.

There are other new accounting pronouncements issued by the FASB that we have adopted or will adopt, as applicable. We do not believe any of these accounting pronouncements have had, or will have, a material impact on our condensed consolidated financial statements or disclosures.

3. Property and Equipment, net

Property and equipment consisted of the following:

	September 30, 2022	December 31, 2021	Estimated Useful Life (years)
Furniture and fixtures	$ 1,525	$ 1,525	7
Office equipment	1,077	1,077	3
Equipment	4,003	3,834	7
Leasehold improvements	1,155	1,155	2
	7,760	7,591	
Less accumulated depreciation	(6,463)	(5,955)	
Property and equipment, net	$ 1,297	$ 1,636	

Depreciation expense related to property and equipment amounted to $0.2 million and $0.2 million for the three months ended September 30, 2022 and 2021, respectively, and $0.5 million and $0.6 million for the nine months ended September 30, 2022 and 2021, respectively.

4. Inventories

Inventories consist of the following:

	September 30, 2022	December 31, 2021
Raw materials (1)	$ 9,704	$ 7,317
Work in process (2)	21,246	9,666
Finished products (3)	32,905	4,925
Total inventories	$ 63,855	$ 21,908

(1) $1.7 million of Raw materials represents inventory acquired with Acacia as detailed in Note 14.

(2) $2.9 million of Work in process represents inventory acquired with Acacia as detailed in Note 14.

(3) $21.8 million of Finished products represents inventory acquired with Acacia as detailed in Note 14.

5. Balance Sheet Accounts

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2022	December 31, 2021
Prepaid income taxes	$ 566	$ 1,173
Prepaid FDA user fee and advances to clinical research organization	—	1,108
Prepaid insurance	537	196
Advances to commercial manufacturers	3,164	2,354
Prepaid R&D	1,445	—
Convertible promissory note, net	—	5,312
Other receivable related to cost sharing arrangement with commercial partner	998	347
All other	2,165	1,400
Total prepaid expenses and other current assets	$ 8,875	$ 11,890

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2022	December 31, 2021
Accrued product sales reserves	$ 21,662	$ 4,390
Income taxes payable	5,750	—
Royalties payable to commercial partners	9,724	5,085
Accrued salary and other compensation	3,702	8,466
Accrued professional fees	7,622	2,013
Accrued research & development	4,233	4,100
Current portion of lease liability	1,508	1,309
Inventory received but not invoiced	14,431	6,177
Forward liability	4,063	—
Accrued other	957	798
Total accrued expenses	$ 73,652	$ 32,338

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, office space located in Indianapolis, Indiana through November 2023, and an office space located in Palm Beach Gardens, Florida. All of our leases are classified as operating leases and have remaining lease terms of approximately 2.3 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):

	September 30, 2022	December 31, 2021
Operating lease cost	$ 1,173	$ 1,407
Total lease cost	$ 1,173	$ 1,407
Other information:		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows for operating leases	$ 1,173	$ 1,407
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 270
Weighted-average remaining lease term - operating leases	2.3 years	3.1 years
Weighted-average discount rate - operating leases	6.0 %	6.0 %

Balance Sheet Classification as of September 30, 2022:	
Current lease liabilities (included with Accrued expenses and other liabilities)	$ 1,508
Long-term lease liabilities (included with Other long-term liabilities)	1,874
Total lease liabilities	$ 3,382

6. Intangible Assets, Net

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

		September 30, 2022		
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Barhemsys intangible *(1)*	9	$ 68,000	$ (2,425)	$ 65,575
Byfavo intangible *(1)*	9	36,000	(1,193)	34,807
Ryanodex intangible *(2)*	9	15,000	(6,821)	8,179
Vasopressin milestone (3)	1	750	(526)	224
Total		$ 119,750	$ (10,965)	$ 108,785

		December 31, 2021		
	Useful Life (In Years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Ryanodex intangible *(2)*	9	$ 15,000	$ (5,079)	$ 9,921
Developed technology	5	8,100	(8,100)	—
Vasopressin milestone (3)	1	750	—	750
Total		$ 23,850	$ (13,179)	$ 10,671

(1) Represents intangible assets acquired in the Acacia acquisition as detailed in Note 14.

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

(3) Represents milestone paid to a third party upon FDA approval of vasopressin.

Amortization expense was $3.7 million and $0.7 million for the three months ended September 30, 2022 and 2021, respectively and $5.9 million and $2.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of September 30, 2022, 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:

	Estimated Amortization Expense
Year Ending December 31,	
2022 (remainder)	3,690
2023	14,405
2024	14,127
2025	13,886
2026	11,584
Thereafter	51,093
Total estimated amortization expense	$ 108,785

7. Common Stock and Stock-Based Compensation

Common Stock

Share Repurchase Program

In March 2020, our board of directors approved our current share repurchase program (the "Share Repurchase Program"), providing for the repurchase of up to an aggregate of $160 million of our outstanding common stock.

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 September 30, 2022, we had repurchased an aggregate of 4,552,730 shares of common stock for an aggregate of $246.1 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.

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

A summary of stock option, RSU and PSU activity under the 2014 Plan during the nine months ended September 30, 2022 and 2021 is presented below:

	Stock Options	RSUs	PSUs
Outstanding as of December 31, 2020	3,331,890	328,396	97,750
Granted	109,000	106,600	159,000
Stock options exercised/RSUs vested/PSUs vested	(100,477)	(94,273)	—
Forfeited or expired	(308,815)	(46,941)	(97,750)
Outstanding as of September 30, 2021	3,031,598	293,782	159,000
Outstanding as of December 31, 2021	2,814,878	263,306	137,300
Granted	123,700	148,000	228,200
Stock options exercised/RSUs vested/PSUs vested	(91,255)	(101,898)	—
Forfeited or expired	(73,983)	(36,616)	(46,400)
Outstanding as of September 30, 2022	2,773,340	272,792	319,100

Stock Options

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.83% - 3.66%	0.82% - 0.93%	1.47% - 3.66%	0.51% - 1.12%
Volatility	46.69%	54.92%	46.83%	56.07%
Expected term (in years)	6.08 years	6.08 years	5.76 years	5.68 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

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

During the first quarter of 2022, we granted 228.2 thousand 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 $70.45 for the CEO and $53.43 for other executives 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 1.6%, an expected volatility of 41%, contractual term of 3 years, and no expected dividend yield.

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 nine months ended September 30, 2022 and 2021 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	$ 1,597	$ 2,515	$ 5,131	$ 8,393
RSUs	989	1,046	3,913	4,051
PSUs	951	523	3,288	2,429
Stock-based compensation expense	$ 3,537	$ 4,084	$ 12,332	$ 14,873
Selling, general and administrative	$ 2,937	$ 3,443	$ 10,488	$ 12,696
Research and development	600	641	1,844	2,177
Stock-based compensation expense	$ 3,537	$ 4,084	$ 12,332	$ 14,873

8. Commitments

Our future material contractual obligations as of September 30, 2022, included the following:

Obligations	Total	2022	2023	2024	2025	Beyond
Operating leases (1)	$ 3,621	$ 414	$ 1,672	$ 1,122	$ 413	$ —
Credit facility and Term Loans (2)	59,324	35,000	4,257	12,162	7,905	—
Investment in Enalare (4)	12,500	—	12,500	—	—	—
Purchase obligations (3)	99,403	99,403	—	—	—	—
Total obligations	$ 174,848	$ 134,817	$ 18,429	$ 13,284	$ 8,318	$ —

(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 through April 2024, office space located in Indianapolis, Indiana through November 2023, and an office space in Palm Beach Gardens, Florida, through October 31, 2024. Rental expense for the operating leases was $0.4 million and $0.3 million, for the three months ended September 30, 2022 and 2021, respectively. Rental expense for the operating leases was $1.2 million and $1.0 million for the nine months ended September 30, 2022 and 2021.The remaining future lease payments under the operating leases are $3.6 million as of September 30, 2022.

(2) Refer to Note 9, “Debt” for further information regarding our Credit Agreement and Term Loans.

(3) As of September 30, 2022, we had purchase obligations in the amount of $99.4 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.

(4) We invested $12.5 million in Enalare at the time of entering the agreement in August 2022, and we are contractually obligated to invest another $12.5 million six months after August 2022. Refer to Note 15 for further details.

9. Debt

As of June 9, 2022, upon closing of our acquisition of Acacia, we guaranteed a term loan facility, dated as of January 10, 2020, by and between Acacia Pharma Limited (“APL”), a direct subsidiary of Acacia, and Cosmo Technologies Ltd. (the “Term Loan Facility”). The Term Loan Facility provides for up to €25 million in loans, all of which was drawn as of closing of the acquisition. See Note 14 Business Acquisition for further information on our acquisition of Acacia. These borrowings were drawn in two tranches; Tranche A for a €15 million term loan with periodic payments through July 31, 2025; and Tranche B for a €10 million term loan with periodic payments through September 30, 2025. Each tranche bears an annual interest rate of 9%. The guarantee provides that we shall guarantee the punctual performance by APL of APL’s obligations pursuant to the terms of the Term Loan Facility (as amended) and that we will immediately on demand pay any amount owed by APL under the Term Loan Facility (as amended) as if we were the principal obligor in the event that such amount is not paid by APL

On November 8, 2019, we entered into the Second Amended and Restated Credit Agreement (the “Prior Credit Agreement”), with JPMorgan Chase Bank, N.A., as administrative agent (the “Administrative Agent”) and the lenders party thereto. The terms and amounts borrowed under the Prior Credit Agreement includes a drawn term loan of $40 million and a revolving credit facility of $110 million. The schedule of principal payments for the new term loan facility was extended to November 8, 2022.

During the third quarter of 2022, we drew down $15 million from our revolving credit facility under the Credit Agreement.

We classified debt related to the pre-existing term loan and revolving credit facility of $35 million as current on our condensed consolidated balance sheet as of September 30, 2022. Per the terms of the Prior Credit Agreement and the Amended and Restated Credit Agreement (as defined herein), we are limited in our ability to pay dividends. As of September 30, 2022, we were in compliance with each of the senior secured net leverage ratio; total net leverage ratio; and fixed charge coverage ratio covenants.

On November 1, 2022, we entered into the Third Amended and Restated Credit Agreement (the “Third Amended Credit Agreement”) with the Administrative Agent and the lenders party thereto, which replaced the Prior Credit Agreement. The terms and amounts borrowed under the Third Amended Credit Agreement includes a drawn term loan of $50 million and a $100 million revolving credit facility of which $15 million was drawn on November 1, 2022. The new maturity date of the schedule of principal payments for each of the revolving credit facility and the term loan facility is October 31, 2025, unless required to mature earlier or extended pursuant to the terms of the Third Amended Credit Agreement. Refer to Note 16, Subsequent Events, for further details on the Third Amended Credit Agreement.

The term loan facility under the Prior Credit Agreement bore 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.

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

As of September 30, 2022, we had $0.1 million of unamortized deferred debt issuance costs as part of current debt in our condensed consolidated balance sheets.

Debt Maturities	As of September 30, 2022
2022 (remainder)	$ 35,000
2023	4,257
2024	12,162
2025	7,905
Total	$ 59,324

10. Income Taxes

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Income tax (provision) benefit	$ (3,468)	$ 7,038	$ (20,652)	$ 3,341
Effective tax rate	(95)%	56 %	43 %	58 %

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 effective tax rate for the three and nine months ended September 30, 2022,reflects an interim tax provision resulting from impact of certain non-deductible executive compensation and the impact of the acquisition of Acacia and of certain non-deductible cost from the acquisition of Acacia, partially offset by credits for research and development activity.

The effective tax rate for the three and nine months ended September 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 we can realize for our 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 Syros may differ from previous estimates, periodic adjustments to our valuation allowances may be necessary.

Deferred income tax assets as of September 30, 2022 consisted of temporary differences primarily related to the net operating losses of Acacia, stock-based compensation and research and development tax credit carryforwards, partially offset by temporary differences related to intangible assets and research and development expenses.

We file income tax returns in the U.S. federal jurisdiction and several states. We are currently under audit by the Internal Revenue Service (IRS) and three State tax jurisdictions. We had no amount recorded for any unrecognized tax benefits as of September 30, 2022. 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.

In Re: Taxotere (Docetaxel)
Beginning in May 2022, the Company was named as a defendant, among various other manufacturers, in several product liability suits that are consolidated in the U.S. District Court for the Eastern District of Louisiana as part of MDL 3023 (Civil Action No 22-1347 H(5)), or the Multidistrict Litigation. The claims are for personal injuries allegedly arising out of the use of docetaxel.

Patent Litigation

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

Bendeka, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Slayback Pharma Limited Liability Company ("Slayback"), Apotex Inc. and Apotex Corp. ("Apotex"), Fresenius Kabi USA, LLC ("Fresenius"), Mylan Laboratories Limited ("Mylan"), Lupin, Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin"), and Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd ("Aurobindo") have filed Abbreviated New Drug Applications ("ANDA's") referencing Bendeka® that include challenges to one or more of the Bendeka® Orange Book-listed patents. Hospira, Inc. ("Hospira") filed a 505(b)(2) NDA.

We, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the "Patentees"), filed separate suits against Slayback, Apotex, Fresenius, Mylan, Hospira, Lupin, and Aurobindo in the United States District Court for the District of Delaware on August 16, 2017 (Slayback ("Slayback I")), August 18, 2017 (Apotex), August 24, 2017 (Fresenius), December 12, 2017 (Mylan), January 19, 2018 (Slayback ("Slayback II")), July 19, 2018 (Hospira), and July 2, 2019 (Lupin) and May 11, 2020 (Aurobindo). In these Complaints, the Patentees allege infringement of the challenged patents, namely U.S. Patent Nos. 8,791,270 and 9,572,887 against Slayback (Slayback I and Slayback II), and of U.S. Patent Nos. 8,609,707, 8,791,270, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399 against Fresenius, Apotex, and Mylan, and of U.S. Patent Nos. 9,572,887, 10,010,533, 9,034,908, 9,144,568, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384 against Hospira, and of U.S. Patent Nos. 8,609,707, 9,000,021, 9,034,908, 9,144,568, 9,265,831, 9,572,796, 9,572,797, 9,572,887, 9,579,384, 9,597,397, 9,597,398, 9,597,399, 10,010,533, and 10,052,385 against Lupin and of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385 against Aurobindo. The parties stipulated to dismiss without prejudice U.S. Patent No. 8,791,270 as to Apotex, Fresenius and Mylan on July 24, 2018, August 2, 2018, and August 3, 2018, respectively. Slayback, Apotex, Fresenius, and Mylan answered their Complaints and some filed various counterclaims on September 29, 2017 (Slayback I), February 12, 2018 (Slayback II), November 27, 2017, September 15, 2017, and February 14, 2018, respectively. The Patentees answered the Slayback I, Slayback II, Fresenius, and Apotex counterclaims on October 20, 2017, March 5, 2018, October 6, 2017, and December 18, 2017, respectively. On October 15, 2018, the Patentees filed a suit against Fresenius and Mylan in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 10,010,533 and 10,052,385. The Slayback I, Slayback II, Apotex, Fresenius and Mylan cases have been consolidated for all purposes (the "Consolidated Bendeka Litigation"), and a bench trial in these cases was held September 9-19, 2019. On April 27, 2020, the district court held that the asserted patents are valid and infringed

by Slayback, Apotex, Fresenius and Mylan. On July 6, 2020, the district court entered a final judgment reflecting this decision, stating that pursuant to 35 U.S.C. § 271(e)(4)(A), the FDA shall not approve Apotex's, Fresenius's, Mylan's, or Slayback's ANDA products on a date which is earlier than January 28, 2031, and enjoining Apotex, Fresenius, Mylan, and Slayback from commercially manufacturing, using, offering to sell, or selling within the US or importing into the US, their ANDA products before that date. On August 4, 2020, Apotex, Fresenius, and Mylan appealed this final judgment, and filed their opening briefs on November 4, 2020. Plaintiffs' responsive appeal brief was filed on February 12, 2021. Defendants' reply briefs were filed April 5, 2021. On August 2, 2021, Fresenius's appeal was dismissed pursuant to a settlement agreement reached with Patentees. Oral argument for the remaining defendants occurred on August 3, 2021. On August 13, 2021, the appeals court affirmed the trial court's decision. The mandate was issued on October 22, 2021. Apotex filed a petition for certiorari on December 14, 2021, which the Supreme Court denied on February 22, 2022.

Hospira filed a motion to dismiss, which was fully briefed on November 16, 2018. On December 16, 2019, the United States District Court for the District of Delaware denied Hospira's motion to dismiss with respect to U.S. Patent No. 9,572,887 and granted that motion with respect to the remaining patents. On December 15, 2020, the Court held a claim construction hearing, ruling in our favor on all claim terms. Fact discovery closed on April 1, 2021. Expert discovery ended on February 10, 2022. The parties reached a settlement on April 19, 2022, resulting in dismissal of the action.

Patentees filed suit against Hospira, Inc. on November 16, 2021. Patentees have asserted U.S. Patent No. 11,103,483. Hospira filed its Answer on December 8, 2021. The parties reached a settlement on April 19, 2022, resulting in dismissal of the action.

On March 10, 2020, the parties filed a stipulation and order of dismissal without prejudice as to Lupin, which the Court entered March 11, 2020.

Aurobindo answered the Complaint on July 20, 2020. The parties exchanged initial disclosures on December 11, 2020. Plaintiffs provided their infringement contentions on March 12, 2021. On October 20, 2021 the Court entered a stipulation of dismissal based on a settlement between the parties.

Patentees filed suit against Dr. Reddy's Laboratories on May 13, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. Dr. Reddy's answer was filed August 16, 2021. On December 27, 2021, Dr. Reddy's moved for judgment on the pleadings, seeking a dismissal of all patents except the '887 patent. On January 27, 2022, the Court entered an agreed stipulation by the parties dismissing all patents except the '887. On February 8, 2022, consistent with that stipulation, Patentees filed an Amended Complaint removing the dismissed patents and adding U.S. Patent No 11,103,483. Dr. Reddy's filed its Answer and Counterclaims to that Amended Complaint on February 22, 2022. Patentees' filed their Counterclaim Answer on March 15, 2022. Fact discovery is ongoing. A claim construction hearing was held on September 15, 2022, and the case is set for trial on May 1, 2023.

Patentees filed suit against Accord Healthcare on June 29, 2021. Patentees have asserted U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797, 9,034,908, 9,144,568, 9,572,887, 9,597,397, 9,597,398, 9,597,399, 9,000,021, 9,579,384, 10,010,533, and 10,052,385. On January 13, 2022, Accord filed a Motion to Dismiss for failure to state a claim. On January 26, 2022, Patentees filed a First Amended Complaint, removing all patents except the '887 patent and additionally asserting U.S. Patent No. 11,103,483. Accord filed its Answer and Counterclaims to that Amended Complaint on February 10, 2022. On February 28, 2022, Patentees filed their Answer to Accord's Counterclaims. On March 29, 2022, the Court entered a schedule and consolidated this case with the above Dr. Reddy's case. Fact discovery is ongoing. A claim construction hearing was held on September 15, 2022, and the case is set for trial on May 1, 2023.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company - (Belrapzo®)

Slayback filed an ANDA referencing Eagle's Belrapzo NDA. Slayback's ANDA includes challenges to one or more of the Belrapzo Orange Book-listed patents. On September 20, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 8,609,707, 9,265,831, 9,572,796, 9,572,797 and 10,010,533. On October 10, 2018, Slayback answered the Complaint and filed various counterclaims. On October 31, 2018, the Company answered Slayback's counterclaims. Pursuant to a stipulation between the parties, Slayback is bound by any final judgment entered in the Consolidated Bendeka Litigation. This case is currently stayed.

Eagle Pharmaceuticals, Inc. v. Slayback Pharma Limited Liability Company, Apotex, Inc. and Apotex Corp., Celerity Pharmaceuticals, LLC - (Belrapzo®)

Slayback, Apotex, and Celerity Pharmaceuticals, LLC ("Celerity") filed NDAs referencing Eagle's Belrapzo NDA. The Company filed suits against Slayback, Apotex, and Celerity in the United States District Court for the District of Delaware on August 31, 2021 (Slayback and Apotex) and on January 11, 2022 (Celerity) alleging infringement of U.S. Patent No. 11,103,483. On September 22, 2021, both Slayback and Apotex filed their Answers. On September 29, 2022, trial was held in the suit against Slayback and Apotex. On October 25, 2022, the Court issued its opinion and entered a judgment of non-infringement with respect to Slayback and Apotex. The Company filed a notice of appeal on October 26, 2022. On February 2, 2022, Celerity moved to dismiss the pending complaint. In response, the Company filed an Amended Complaint on March 1, 2022. Celerity filed its Answer to the Company's Amended Complaint on March 22, 2022. On April 19, 2022, Celerity moved for judgment on the pleadings. Briefing on that motion is closed and a decision is pending. On June 24, 2022, the Court entered a schedule coordinated with the above Accord and Dr. Reddy's cases. Fact discovery is ongoing. A claim construction hearing was held on September 15, 2022. On October 28, 2022, the parties filed a proposed stipulated judgment of non-infringement, which is pending entry by the Court. The case is set for trial on May 1, 2023.

Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd. - (Belrapzo®)

Accord filed an NDA referencing Eagle's Belrapzo NDA. Accord's NDA includes challenges to one or more of the Belrapzo Orange Book-listed patents. On May 27, 2022, the Company filed a suit against Accord 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, 10,010,533, and 11,103,483. On July 6, 2022 the Company filed a First Amended Complaint, removing all patents except the '483 patent. Accord filed its Answer and Counterclaims on July 20, 2022. The Company filed its Answer to Accord's Counterclaims August 9, 2022. On September 20, 2022, the Court entered a schedule consolidating this case with the above Accord and Dr. Reddy's cases. Fact discovery is ongoing. A claim construction hearing was held on September 15, 2022, and the case is set for trial on May 1, 2023.

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 is an alternative to Vasostrict, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The Company answered the complaint on August 6, 2018, and filed an amended answer and counterclaims on October 30, 2019. The court issued a Markman ruling on July 1, 2019. On December 20, 2019, Par dismissed with prejudice claims of three of the patents asserted against Eagle, and the Court entered an Order reflecting that dismissal on December 27, 2019. Mediation took place on March 3, 2020. On April 17, 2020, we submitted a letter requesting leave to file a motion for summary judgment of non-infringement. Par's responsive letter was submitted on May 8, 2020. On May 18, 2020, the court said it would hear non-infringement arguments at trial and not through summary judgment. Fact discovery ended in October 2019, and expert discovery ended in February 2020. Due to the COVID-19 pandemic, the trial, which was scheduled to begin May 18, 2020, was rescheduled to and occurred on July 7-9, 2021. Post-trial briefing was submitted on July 28, 2021. The Court issued an opinion on August 31, 2021 and entered a final judgment of non-infringement in favor of Eagle on September 16, 2021. Par filed a Notice of Appeal of the final judgment on September 22, 2021, and the appeal was docketed with the United States Court of Appeals for the Federal Circuit on September 23, 2021. Par filed its principal appeal brief on December 6, 2021, Eagle filed its responsive appeal brief on February 1, 2022, and Par filed its reply appeal brief on February 22, 2022. Oral argument occurred before the Federal Circuit on July 7, 2022. On August 18, 2022, the Federal Circuit affirmed the District Court's finding of non-infringement, and on September 26, 2022, the Federal Circuit issued the formal mandate. The FDA approved Eagle's ANDA on December 15, 2021. On December 16, 2021, Par filed an emergency motion for temporary restraining order and preliminary injunction in the district court to enjoin Eagle from launching its product, but Par voluntarily withdrew the motion on December 20, 2021. Eagle commercially launched its ANDA product in January 2022. The 30-month stay of FDA approval expired on October 17, 2020.

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. Before the Court ruled on Eagle's Motion to Dismiss, on May 9, 2022, Par provided notice of the dismissal of the action under Rule 41(a)(1)(A)(i), and the Court granted the dismissal of the action on May 10, 2022.

12. License and Collaboration Agreements

License agreement with Combioxin

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

Under the terms of the agreement, we paid $10 million as upfront license consideration that was expensed immediately as research and development and is reflected within the operating activities of the consolidated statements of cash flows as of December 31, 2021. The Company may pay to Combioxin up to $105 million upon achievement of certain development, regulatory and sales based milestone payments plus royalty payments at royalty rates ranging in low double digit percentages on the net sales of all products sold, subject to certain adjustments as provided in the agreement. The Company is also obligated to make certain payments based upon amounts received by sublicensees under the agreement.

License agreement with AOP Orphan

In August 2021, we entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH ("AOP Orphan"), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. We supported the submission of a new drug application ("NDA") in the second quarter of 2022 by AOP Orphan to the FDA seeking approval for landiolol for the short term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter.

Under the terms of the agreement, we paid a $5 million upfront license consideration that was expensed immediately as research and development and is reflected within the operating activities of the consolidated statements of cash flows as of December 31, 2021. We may pay to AOP Orphan up to $25 million upon achievement of certain regulatory milestone payments plus profit share payments, subject to certain adjustments as provided in the agreement. We also entered into a supply agreement at the same time as the licensing agreement.

Collaboration with Tyme (now merged with Syros)

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

In September 2022, Syros announced the closing of its merger with Tyme pursuant to which Syros acquired Tyme. The combined company will be known as Syros going forward.

Under the terms of a related co-promotion agreement, we would be responsible for 25% of the promotional sales effort of SM-88 and would receive 15% royalty on the net revenues of SM-88 in the United States. Syros is responsible for clinical development, regulatory approval, commercial strategy, marketing, reimbursement and manufacturing of SM-88. Syros retains the remaining 85% of net U.S. revenues and reserves the right to repurchase our U.S. co-promotion right for $200.0 million.

Our equity investment in Syros is included in Other assets on our condensed consolidated balance sheet. For the three months ended September 30, 2022 and 2021, the fair value adjustments for the equity investment were a gain of $22.0 thousand and a loss of $2.3 million, respectively. For the nine months ended September 30, 2022 and 2021, the fair value adjustments for the equity investment were a loss of $3.2 million and a loss of $1.9 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 did not have sufficient cash and was unable to obtain additional capital to be able to repay the convertible promissory note with accrued interest at the end of the term. As of September 30, 2022, we impaired the note, accrued interest, as well as the value of the embedded derivative related to the equity conversion feature contained in the note.

The following table summarizes the activity during the three months ended September 30, 2022;

	June 30, 2022	Fair Value Adjustments to the note	Accretion of Discount	Estimated Credit Loss	Interest Income	Fair Value Adjustment to Embedded Derivative	September 30, 2022
Fair value of the note	$ 5,510	$ (5,510)	$ —	$ —	$ —	$ —	$ —
Discount on the note	(36)	36	—	—	—	—	—
Estimated Credit Loss	(820)	—	—	820	—	—	—
Convertible Promissory Note, net	$ 4,654	$ (5,474)	$ —	$ 820	$ —	$ —	$ —
Embedded Derivative	$ 1,026	$ —	$ —	$ —	$ —	$ (1,026)	$ —
Interest Receivable	$ 530	$ —	$ —	$ (530)	$ —	$ —	$ —
Total in Other Current Assets	$ 6,210	$ (5,474)	$ —	$ 290	$ —	$ (1,026)	$ —

The following table summarizes the amounts recorded and activity during the nine months ended September 30, 2022;

	December 31, 2021	Fair Value Adjustments to the note	Accretion of Discount	Estimated Credit Loss	Interest Income	Fair Value Adjustment to Embedded Derivative	September 30, 2022
Fair value of the note	$ 4,906	$ (4,906)	$ —	$ —	$ —	$ —	$ —
Discount on the note	(127)	—	127	—	—	—	—
Estimated Credit Loss	(758)	—	—	758	—	—	—
Convertible Promissory Note, net	$ 4,021	$ (4,906)	$ 127	$ 758	$ —	$ —	$ —
Embedded Derivative	$ 962	$ —	$ —	$ —	$ —	$ (962)	$ —
Interest Receivable	$ 329	$ —	$ —	$ (329)	$ —	$ —	$ —
Total in Other Current Assets	$ 5,312	$ (4,906)	$ 127	$ 429	$ —	$ (962)	$ —

14. Business Acquisition

On June 9, 2022, we completed our previously announced acquisition of the entire issued share capital of Acacia for cash consideration and common stock totaling 94.7 million euros, the equivalent of 0.90 euros per share, and an aggregate of 516,024 shares of our common stock. Each shareholder of Acacia received 0.68 euros in cash and 0.0049 shares of our common stock. Acacia is a hospital pharmaceutical company focused on the development and commercialization of new products aimed at improving the care of patients undergoing significant treatments such as surgery and other invasive procedures. The transaction was entered to expand our current portfolio of FDA approved hospital products with the addition of Barhemsys and Byfavo.

We evaluated the Business Acquisition under ASC 805, Business Combinations and ASU 2017-01, Business Combinations: Clarifying the Definition of a Business. We concluded that substantially all of the fair value of the gross assets acquired is not concentrated in a single identifiable asset or a group of similar identifiable assets. The transaction does not pass the screen test and thus management performed an assessment to determine if the acquired entities met the definition of a business. For the assessment, management considered whether it has acquired (i) inputs, (ii) processes, and (iii) outputs. Under ASC 805, to be considered a business, a set of activities and assets is required to have only the first two of the three elements, which together are or will be used in the future to create outputs. Management determined that the acquired entities met the definition of a business since we acquired inputs, processes capable of producing outputs and outputs.

Therefore, the acquisition has been accounted for under the acquisition method of accounting. Under the acquisition method, the total purchase price of the acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on the fair values as of the date of the acquisition. During the three months ended September 30, 2022, we recorded certain measurement period adjustments that totaled $1.3 million. The impact of these measurement period adjustments were recorded as a reduction to goodwill, reducing the initial goodwill balance of $3.3 million recorded in the three months ended June 30, 2022. The amount recognized will be finalized as the information necessary to complete the analysis is obtained but no later than one year after the acquisition date.

The fair value of the consideration totaled $100.4 million, summarized as follows (in thousands):

	Fair Value of Consideration
Cash consideration	$ 76,708
Fair value of Eagle common stock issued	23,645
	$ 100,353

We recorded the assets acquired and liabilities assumed as of the date of the acquisition based on the information available as of that date. As we finalize the fair values of the assets acquired and liabilities assumed, purchase price adjustments may be recorded during the measurement period and such adjustments could be material. We will reflect measurement period adjustments, if any, in the period in which the adjustments are recognized.

The following table presents the preliminary allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed as of the acquisition date (in thousands):

	Preliminary Purchase Price Allocation as of acquisition date	Measurement Period Adjustments	Preliminary Purchase Price Allocation as of September 30, 2022
Cash	$ 2,556	$ —	$ 2,556
Net working capital, excluding cash	(2,158)	—	(2,158)
Inventory	26,942	—	26,942
Intangible assets	104,000	—	104,000
Debt	(28,503)	—	(28,503)
Deferred tax liability, net	(4,536)	—	(4,536)
Fair value of net assets acquired	98,301	—	98,301
Goodwill	3,315	(1,263)	2,052
	$ 101,616	$ (1,263)	$ 100,353

The fair value of acquired intangible assets was based on the present value of expected future after tax cash flows attributable to the commercialization of Barhemsys and Byfavo, using the net present value approach. The inventory acquired was valued at expected profit margins for the acquired products. The fair value of working capital acquired approximates its book value. The fair value of debt acquired was based on the present value of future cash outflows using the net present value approach and applying an interest rate that is considered to be a market participant equivalent rate.

We incurred approximately $1.1 million and $12.4 million in acquisition-related expenses, which were included in selling, general and administrative expenses in the condensed consolidated statements of operations for the three and nine months ended September 30, 2022. These expenses primarily consist of legal fees and success fees paid to third party advisors. The results of Acacia operations have been included in our condensed consolidated statements of operations beginning on the acquisition date. The acquired business contributed revenues of $0.9 million and net loss of $15.5 million to us for the period from June 9, 2022 to September 30, 2022.

The goodwill recorded related to the acquisition is the excess of the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of acquisition. The goodwill recorded is not deductible for tax purposes.

Pro Forma Financial Information:

The following table provides unaudited pro forma financial information for the three-month and nine-month periods ended September 30, 2022 and 2021 as if the acquisition of Acacia had occurred as of January 1, 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenue	$ 65,901	$ 48,400	$ 257,093	$ 90,090
Net (loss) income	$ (7,131)	$ (14,905)	$ 10,752	$ (41,471)

These amounts have been calculated after applying our accounting policies.

The pro forma results above include the impact of the following adjustments, as necessary: additional amortization expense relating to assets acquired; interest and other financing costs relating to the acquisition transaction; and the elimination of one-time or nonrecurring items. The one-time or nonrecurring items eliminated were primarily comprised of inventory fair value step-up adjustments; transaction costs, as well as certain Acacia-related share based payment charges and employee compensation expenses.

The pro forma results do not include any anticipated cost savings or other effects of the planned integration of Acacia. Accordingly, the pro forma results above are not necessarily indicative of the results that would have been if the acquisition had occurred on the dates indicated, nor are the pro forma results indicative of results which may occur in the future.

15. Investment in Enalare Therapeutics Inc.

On August 8, 2022, we and Enalare Therapeutics Inc. (“Enalare”) entered into a Securities Purchase Agreement, pursuant to the terms of the Shares Purchase Agreement ("SPA"), we are obligated to further invest in Enalare, an additional $12.5 million no later than February 2023 and may invest an additional $30 million, subject to the completion of certain development milestones. Concurrently with the execution of the SPA, we also entered into a Security Purchase Option Agreement ("SPOA"), pursuant to which we were granted an option to acquire all of the remaining outstanding shares of Enalare other than those that we already own, subject to the terms and conditions of the agreement. The term of the Purchase Option (the "Option Period") commenced on August 8, 2022 and will end upon the earlier of (x) 90 days following the FDA communication of proceed to clinical for a Phase 3 clinical study for a Product Candidate or (y) June 30, 2027. Enalare shall not initiate Phase 3 pivotal studies prior to the end of the Option Period and we shall have reasonable access to all relevant data and documents following the Phase 3 Milestone (as defined in the Option Agreement).

Upon entering the Purchase Agreement, we recorded an equity investment in the amount of $8.4 million, an asset related to the acquisition right in the amount of $8.1 million and a forward liability of $4.1 million related to the contractual obligation to

invest another $12.5 million within six months from August 2022 in accordance with ASC 321 *Investments – Equity Securities*. We used a probability factor to value the asset related to the acquired acquisition rights based on management's best estimate, including the probability of completion of certain development milestones. The equity stake was accounted for as an non-RDFV investment. The equity investment, acquisition right, and forward liability was reported at fair value as of September 30, 2022.

Summarized financial information of our investment and equity ownership in Enalare for the three months ending September 30, 2022 is presented below:

	Beginning balance as of June 30, 2022	Additions during period	Adjustments	Ending balance as of September 30, 2022
Non-RDFV Investment (Other assets)	$ —	$ 8,438	$ —	$ 8,438
Acquisition Rights (Other assets)	—	$ 8,125	—	$ 8,125
Forward Liability (Accrued expenses and other liabilities)	—	$ (4,063)	—	$ (4,063)
Total, net	$ —	$ 12,500	$ —	$ 12,500

16. Subsequent Event

On November 1, 2022, we entered into the Third Amended and Restated Credit Agreement ("Third Amended Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative (the "Administrative Agent") and the lenders party thereto, which replaced the Prior Credit Agreement, dated as of November 8, 2019. The terms and amounts borrowed under the Third Amended Credit Agreement includes a drawn term loan of $50 million and a $100 million revolving credit facility of which $15 million was drawn on November 1, 2022. On the effective date for the Third Amended Credit Agreement, we borrowed $15 million under the revolving credit facility and $50 million under the term loan facility. Approximately $35.4 million of the proceeds of the credit facility were used to refinance all amounts outstanding under the Prior Credit Agreement, to repay certain indebtedness of Acacia, and for other corporate purposes. The new maturity date of the schedule of principal payments for each of the revolving credit facility and the term loan facility is October 31, 2025, unless required to mature earlier or extended pursuant to the terms of the Third Amended Credit Agreement.

Loans under the Third Amended Credit Agreement bear interest, at our option, at a rate equal to either (a) the SOFR rate, plus a credit adjustment spread, plus an applicable margin ranging from 2.50% to 3.25% per annum, based upon the total net leverage ratio (as defined in the Third Amended Credit Agreement), or (b) the prime lending rate, plus an applicable margin ranging from 1.50% to 2.25% 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 Third Amended Credit Agreement at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio.

The term loan facility payments will be made in quarterly installments in an amount equal to $1.25 million per fiscal quarter for each fiscal quarter ended after the closing date for the Third Amended Credit Agreement through the fiscal quarter ended September 30, 2023, and in an amount equal to $2.5 million per fiscal quarter for each fiscal quarter thereafter.

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 7, 2022, 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 ("FDA") approval and commercial launches of six products: PEMFEXY® (pemetrexed for injection), vasopressin, an A-rated generic alternative to Vasostrict®, Ryanodex® (dantrolene sodium) ("Ryanodex"), bendamustine ready-to-dilute ("RTD") 500ml solution ("Belrapzo"), and rapidly infused bendamustine RTD ("Bendeka") and RTD ("Treakisym"). We market our products through marketing partners and/or our internal direct sales force. We market PEMFEXY, vasopressin, Ryanodex and Belrapzo, and Teva Pharmaceutical Industries Ltd. ("Teva") markets Bendeka through its subsidiary Cephalon, Inc. SymBio Pharmaceuticals Limited ("SymBio"), markets Treakisym, a RTD product, in Japan.

We acquired Acacia Pharma Group plc ("Acacia") as of June 9, 2022, which added two U.S. Food and Drug Administration ("FDA") approved new chemical entities with patent protection, BARHEMSYS® (amisulpride for injection) and BYFAVO® (remimazolam for injection). The addition of these two products expands our presence in the acute care space, and we believe that our hospital-based salesforce will have success commercializing these assets. Refer to Note 14 for further details.

With several pipeline projects underway and the potential for 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 acute radiation syndrome, traumatic brain injury/concussion and Alzheimer's disease as well as investigations of compounds such as EA-114 (our fulvestrant product candidate) for patients with HR-positive advanced breast cancer. Our clinical development program also includes a license agreement with Combioxin, SA under which the Company was granted exclusive, worldwide development and commercialization rights to CAL02, a novel first-in-class anti-infective agent for Phase 2b/3 development for the treatment of severe pneumonia in combination with traditional antibacterial drugs and a license agreement with AOP Orphan Pharmaceuticals GmbH, a member of the AOP Health Group ("AOP Orphan"), for the commercial rights to its product, landiolol in the United States. Landiolol is a leading hospital emergency use product, which is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias.

Recent Developments

Enalare Investment

On August 8, 2022, we and Enalare Therapeutics Inc. ("Enalare") entered into a Securities Purchase Agreement, pursuant to which we have committed to provide equity investments of up to $55 million in Enalare, subject to the completion of certain development milestones (the "Purchase Agreement"). Concurrently with the execution of the Purchase Agreement, we, Enalare and holders of all of the outstanding capital stock, and any securities or options exercisable for capital stock, of Enalare (the "Securityholders") entered into a Security Purchase Option Agreement, pursuant to which we were granted an option (the "Purchase Option") to acquire all of the remaining outstanding shares of Enalare other than those that we already own, subject to the terms and conditions of the agreement (the "Option Agreement"). The term of the Purchase Option (the "Option Period") commenced on August 8, 2022 and will end upon the earlier of (x) 90 days following the FDA communication of proceed to clinical for a Phase 3 clinical study for a Product Candidate or (y) June 30, 2027. Enalare shall not initiate Phase 3 pivotal studies prior to the end of the Option Period and we shall have reasonable access to all relevant data and documents following the Phase 3 Milestone (as defined in the Option Agreement).

ENA-001 is an investigational, portfolio of novel new chemical entities being developed by Enalare as an agnostic respiratory stimulant for multiple patient populations experiencing acute respiratory depression. The initial targeted indications include post-operative respiratory depression; community drug overdose; and Apnea of Prematurity, a common condition in preterm infants. FDA granted Orphan Drug Designation to ENA-001 for the treatment of Apnea of Prematurity ("AoP"). AoP is a development disorder attributed to immaturity of the pulmonary system characterized by either cessation of breathing for more than 20 seconds or cessation of breathing that lasts less than 20 seconds but is accompanied by either bradycardia or hypoxemia.

Third Amended and Restated Credit Agreement
On November 1, 2022, we entered into the Third Amended and Restated Credit Agreement (the "Third Amended Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Administrative Agent") and the lenders party thereto, which replaced our existing credit agreement, dated as of November 8, 2019 (the "Prior Credit Agreement"). The terms and amounts borrowed under the Third Amended Credit Agreement includes a drawn term loan of $50 million and a $100 million revolving credit facility of which $15.0 million was drawn on November 1, 2022. In addition, approximately $35.4 million of the proceeds of the credit facility were used to refinance all amounts outstanding under the Prior Credit Agreement, and we currently intend to use the remaining proceeds to repay certain indebtedness of our wholly-owned subsidiary, Acacia Pharma Group Limited, and for other corporate purposes. The new maturity date of the schedule of principal payments for each of the revolving credit facility and the term loan facility is October 31, 2025, unless required to mature earlier or extended pursuant to the terms of the Third Amended Credit Agreement.

Acacia Acquisition

On June 9, 2022, we completed the acquisition of Acacia Pharma Group plc ("Acacia"), formerly a public company organized under the laws of England and Wales. The acquisition added two FDA approved currently marketed, acute care, hospital products, both of which are new chemical entities with strong patent protection:

- BARHEMSYS (amisulpride for injection), the first and only antiemetic approved by the FDA for rescue treatment of postoperative nausea and vomiting, and
- BYFAVO (remimazolam for injection), indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Landiolol
On June 1, 2022, we announced that AOP Orphan, with whom we entered into a licensing agreement in August 2021, submitted an NDA to the FDA for landiolol, a short-acting, intravenous ("IV"), cardio-selective beta-1 adrenergic blocker. The submission seeks approval for landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter. The FDA's decision with respect to approval is expected in mid-2023. Patient enrollment for a study of pediatric patients with supraventricular tachycardia is underway in Europe.

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

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

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

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

TREAKISYM

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

Fulvestrant

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

CAL02

We submitted an IND to the FDA for CAL02, a novel first-in-class broad-spectrum anti-virulence agent for the treatment of severe community-acquired bacterial pneumonia ("SCABP"). The IND filing includes a protocol for a global Phase 2 study to evaluate the efficacy and safety of CAL02 when added to standard of care therapy in patients with SCABP.

We expect to start a Phase 2b/3 clinical trial for CAL02 patients later in 2022, during pneumonia season. In August 2021, we entered into a license agreement with Combioxin SA under which we were granted exclusive, worldwide development and commercialization rights to CAL02, a novel approach to the treatment of severe bacterial pneumonia.

Bendeka Settlement

On April 19, 2022, we entered into a definitive settlement agreement, or the Settlement Agreement, with Hospira, Inc., or Hospira, relating to our product BENDEKA® (rapidly infused bendamustine hydrochloride). This settlement resolves patent litigation brought by us and our marketing partners Teva Pharmaceuticals International, GmbH and Cephalon, Inc. relating to the alleged infringement of Orange Book listed United States Patent Nos. 11,103,483 and 9,572,887, or the Asserted Patents, with respect to Hospira's 505(b)(2) NDA, No. 211530. Pursuant to the terms of the Settlement Agreement, we will grant Hospira a license to market Hospira's product made under NDA No. 211530 in the United States beginning on January 17, 2028 (subject to FDA approval), or earlier under certain circumstances. Additionally, in accordance with the Agreement, the parties will terminate all ongoing litigation among us, Teva Pharmaceuticals International, GmbH and Cephalon, Inc. and Hospira regarding the Asserted Patents pending in the United States District Court for the District of Delaware. The Agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

COVID-19 Business Update

In response to the ongoing COVID-19 pandemic, we have taken and continue to take active measures designed to address and mitigate the impact of the COVID-19 pandemic on its business, such as remote working policies, facilitating management's daily communication to address employee and business concerns and providing frequent updates to the Board. While we have experienced variable financial and operational 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*.

In addition, we continue to monitor the impacts of other global and worsening macroeconomic conditions, such as global geopolitical tension, increasing inflation and interest rates, exchange rate fluctuations, supply chain disruptions and increases in commodity, energy and fuel prices.

Other Business Update

In addition, the U.S. government and other nations have imposed significant restrictions on most companies' ability to do business in Russia as a result of the ongoing military conflict between Russia and Ukraine. It is not possible to predict the broader or longer-term consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. Such geopolitical instability and uncertainty could have a negative impact on our ability to further expand our business and to otherwise generate revenues and develop our product candidates. In addition, a significant escalation or expansion of economic disruption or the conflict's current scope could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Financial Operations Overview

Revenue

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

Product Sales. Through September 30, 2022, we have recognized revenues from product sales including Pemfexy, vasopressin, Ryanodex, Belrapzo, Bendeka, Treakisym, BARHEMSYS and BYFAVO. Sales of Bendeka and Treakisym were made to our commercial partners, Teva and SymBio, respectively. Sales to our commercial partners are typically made at little or no profit for resale. Pemfexy, vasopressin, Ryanodex Belrapzo, BARHEMSYS and BYFAVO 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 for which 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 to Teva by wholesalers, hospitals and surgery centers.

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

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

The primary factors that may determine our revenues derived from Pemfexy, vasopressin, Ryanodex, Belrapzo, BARHEMSYS, BYFAVO 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 three months ended September 30, 2022 reflects certain non-deductible executive compensation, partially offset by credits for research and development activity. The effective tax rate for the three months ended September 30, 2021 reflects the impact of a valuation allowance established and adjusted for the fair value adjustments on our investment in Syros Pharmaceuticals, Inc. ("Syros"), following the merger of Tyme Technologies, Inc. (“Tyme”) and Syros on September 16, 2022, 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 September 30, 2022 and 2021

Revenues

	Three Months Ended September 30,		Increase / (Decrease)
	2022	2021	
	(in thousands)		
Product sales, net	$ 38,086	$ 12,124	$ 25,962
Royalty revenue	24,007	27,729	(3,722)
License and other revenue	3,808	—	3,808
Total revenue	$ 65,901	$ 39,853	$ 26,048

Our product sales increased $26 million during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. The increase was primarily attributable to product sales of $13.8 million for vasopressin and product sales of Pemfexy of $1.7 million, each of which launched in the first quarter of 2022. We also had higher product sales for Ryanodex, Bendeka, and Belrapzo of $3.1 million, $3.0 million and $3.6 million, respectively, primarily driven by volume increases. Product sales for the three months ended September 30, 2022 also included our recently acquired Barhemsys and Byfavo products, which totaled $0.8 million.

Our royalty revenue decreased $3.7 million during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021, primarily as a result of a decrease in royalty revenue from our share of Teva's Bendeka sales.

During the three months ended September 30, 2022, we earned a sales milestone of $3.8 million from Symbio related to a contractual milestone for aggregate net sales of Treakisym.

Cost of revenue

	Three Months Ended September 30,		
	2022	2021	Increase
	(in thousands)		
Cost of product sales	$ 20,869	$ 5,486	$ 15,383
Cost of royalty revenue	2,782	2,773	9
Total cost of revenue	$ 23,651	$ 8,259	$ 15,392

Our cost of product sales increased by $15.4 million during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. This was primarily attributable to the cost of product sales of vasopressin of $7.1 million, which launched in 2022. There were also increases of $2.7 million in Bendeka and $1.2 million in Belrapzo cost of product sales resulting from higher unit sales. We also recorded $2.9 million of amortization expenses related to intangible assets acquired with Acacia in June 2022.

Our cost of royalty revenue was almost unchanged during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021 and included royalties we paid on our bendamustine franchise products. This was primarily attributable to costs related to the royalty revenue for Treakisym.

Research and development

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

	Three Months Ended September 30,		Increase / (Decrease)
	2022	2021	
	(in thousands)		
Fulvestrant	$ 1,676	$ 729	$ 947
Vasopressin	13	2,086	(2,073)
Ryanodex related projects	80	—	80
CAL02	3,351	10,000	(6,649)
Landiolol	214	5,000	(4,786)
Pemfexy	—	1,386	(1,386)
All other projects	690	602	88
Salary and other personnel related costs	3,302	3,486	(184)
Research and development	$ 9,326	$ 23,289	$ (13,963)

Our research and development expenses decreased $14.0 million during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. The decrease was primarily due to lower spend of $6.6 million on CAL02 and $4.8 million on landiolol due to the upfront license fees paid in Q3 2021 and non-recurrence of development costs of $2.1 million on vasopressin and $1.4 million on PEMFEXY. This was partially offset by an increase in spend on fulvestrant of $0.9 million compared to the three months ended September 30, 2021.

Selling, general and administrative

	Three Months Ended September 30,		
	2022	2021	Increase
	(in thousands)		
Selling, general and administrative	$ 23,462	$ 18,482	$ 4,980

Our selling, general and administrative expenses increased $5.0 million during the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. This increase was primarily related to $1.1 million of external sales and marketing and $1.2 million of headcount costs for BARHEMSYS and BYFAVO re-launches, $1.1 million of financial and

other professional fees, $0.6 million of severance related to the integration of Acacia, $0.5 million of external legal costs, and $0.2 million of sales and marketing costs for PEMFEXY, partially offset by lower general and administrative head count costs.

Other expense, net

	Three Months Ended September 30,		
	2022	2021	Increase
	(in thousands)		
Interest income	$ (444)	$ 197	$ (641)
Interest expense	(1,147)	(396)	(751)
Other expense	(11,534)	(2,284)	(9,250)
Total other expense, net	$ (13,125)	$ (2,483)	$ (10,642)

Our interest income decreased by $0.6 million for the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. This increase was primarily due to write-off $0.5 million of interest receivable associated with the convertible promissory note which was written-off during the third quarter 2022.

Our interest expense increased by $0.8 million for the three months ended September 30, 2022 as compared to the three months ended September 30, 2021. This increase was due to our higher level of outstanding debt during the three months ended September 30, 2022.

Our other expense was a net expense of $11.5 million for the three months ended September 30, 2022 as compared to a net expense of $2.3 million for the three months ended September 30, 2021. The change was primarily due to a $6.4 million loss related to foreign exchange losses and forward contracts settled during the period, and a $4.2 million loss related to fair value adjustments related to a promissory note write off, partially offset by small gain related to fair value adjustments on our investment in Syros during the three months ended September 30, 2022.

Income tax provision

	Three Months Ended September 30,	
	2022	2021
	(in thousands)	
(Provision) benefit for income taxes	$ (3,468)	$ 7,038
Effective tax rate	(95)%	56 %

Our effective tax rate for the three months ended September 30, 2022, reflects an interim tax provision resulting from the impact of certain non-deductible executive compensation and the impact of certain non-deductible costs from the acquisition of Acacia. The effective tax rate for the three months ended September 30, 2021 reflects the impact of a valuation allowance established and certain non-deductible executive compensation, partially offset by credits for research and development activity.

Comparison of Nine Months Ended September 30, 2022 and 2021

Revenues

	Nine Months Ended September 30,		Increase / (Decrease)
	2022	2021	
	(in thousands)		
Product sales, net	$ 177,375	$ 48,865	$ 128,510
Royalty revenue	74,728	80,361	(5,633)
License and other revenue	3,808	—	3,808
Total revenue	$ 255,911	$ 129,226	$ 126,685

Our product sales increased $128.5 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. The increase was primarily attributable to product sales of Pemfexy and vasopressin, which each launched in the first quarter of 2022, which combined for $114.9 million of product sales, net. We also had higher product sales of Bendeka of $4.5 million, Belrapzo of $4.2 million, each due to unit volume, and Ryanodex of $3.6 million due to volume and price increases.

Our royalty revenue decreased $5.6 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021, primarily as a result of lower royalties on Teva's sales of Bendeka of $9.3 million, which were partially offset by royalties on Symbio's sales of Treakisym of $3.7 million.

During the nine months ended September 30, 2022, we earned a sales milestone of $3.8 million from Symbio related to sales of Treakisym.

Cost of revenue

	Nine Months Ended September 30,		Increase / (Decrease)
	2022	2021	
	(in thousands)		
Cost of product sales	$ 67,216	$ 21,835	$ 45,381
Cost of royalty revenue	7,854	8,036	(182)
Total cost of revenue	$ 75,070	$ 29,871	$ 45,199

Our cost of product sales increased $45.4 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. This was primarily attributable to the product launches of Pemfexy and vasopressin in 2022, which combined for cost of sales of $34.4 million in the nine months ended September 30, 2022, as well as increases of $4.4 million for Bendeka and $1.8 million for Belrapzo, each related to higher unit sales. We also recorded $3.6 million of amortization expenses related to intangible assets acquired with Acacia in June 2022.

Our cost of royalty revenue decreased $0.2 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021, primarily as a result of a decrease in royalty revenue on Teva’s sales of Bendeka. Partially offset by higher cost of royalty associated with Treakisym.

Research and development

	Nine Months Ended September 30,		Increase / (Decrease)
	2022	2021	
	(in thousands)		
Fulvestrant	$ 8,594	$ 5,207	$ 3,387
Vasopressin	(591)	7,297	(7,888)
Ryanodex related projects	512	3,625	(3,113)
CAL02	6,737	10,000	(3,263)
Landiolol	367	5,000	(4,633)
Pemfexy	(56)	2,502	(2,558)
All other projects	1,425	2,475	(1,050)
Salary and other personnel related costs	9,883	11,382	(1,499)
Research and development	$ 26,871	$ 47,488	$ (20,617)

Our research and development expenses decreased $20.6 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. The decrease primarily resulted from non-recurrence of development costs of $7.9 million for vasopressin, $3.1 million for Ryanodex related projects, $2.6 million related to Pemfexy and $1.5 million total decrease in salaries, bonus, severance, included with salary and other personnel related costs. Coupled with decreases for $3.3

million for the CAL02 project and $4.6 million for the Landiolol projects. These decreases were partially offset by an increase of $3.4 million in the fulvestrant project.

Selling, general and administrative

	Nine Months Ended September 30,		
	2022	2021	Increase
	(in thousands)		
Selling, general and administrative	$ 82,476	$ 54,997	$ 27,479

Our selling, general and administrative expenses increased $27.5 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. The increase is primarily related to $9.8 million of professional fees related to the Acacia acquisition, $8.2 million of severance related to the integration of Acacia, $4.7 million of external legal costs, $2.0 million of increased salaries and bonus for increased in salesforce headcount, and $1.9 million of sales and marketing costs for Pemfexy, partially offset by a decrease in stock compensation expense of $2.2 million.

Other expense, net

	Nine Months Ended September 30,		(Decrease) / Increase
	2022	2021	
	(in thousands)		
Interest income	$ (46)	$ 395	$ (441)
Interest expense	(2,065)	(1,240)	825
Other expense	(21,254)	(1,797)	(19,457)
Total other expense, net	$ (23,365)	$ (2,642)	$ (20,723)

Our interest income decreased $0.4 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. This decrease was primarily due to the impairment of $0.5 million of interest receivable associated with the convertible promissory note which was impaired during the third quarter 2022.

Our interest expense increased $0.8 million in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021. This increase was due to higher outstanding debt during the nine months ended September 30, 2022.

Our other expense was a net expense amount of $21.3 million for the nine months ended September 30, 2022 as compared to the net expense of $1.8 million for the nine months ended September 30, 2021. The change was primarily due to a $12.8 million loss related to foreign exchange losses and a forward contract settled during the period and $3.2 million loss related to fair value adjustments on our investment in Syros during the nine months ended September 30, 2022.

Income tax provision

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
(Provision) benefit for income taxes	$ (20,652)	$ 3,341
Effective tax rate	43 %	58 %

The effective tax rate for the nine months ended September 30, 2022, reflects an interim tax provision resulting from impact of certain non-deductible executive compensation and the impact of certain non-deductible costs from the acquisition of Acacia, partially offset by credits for research and development activity.

Liquidity and Capital Resources

Our principal sources of liquidity are our cash and cash equivalents, cash flows from operations and availability of borrowing

under our revolving credit facility. Our primary uses of cash are to fund working capital requirements, including repayment of debt, product development costs and operating expenses. We may also use cash for business acquisitions or other strategic transactions, such as in our acquisition of Acacia. Cash and cash equivalents were $15.4 million and $99.7 million as of September 30, 2022 and September 30, 2021, respectively.

On November 1, 2022, we entered into the Third Amended and Restated Credit Agreement ("Third Amended Credit Agreement"),with the Administrative Agent and the lenders party thereto, which replaced the Prior Credit Agreement. The terms and amounts borrowed under the Third Amended Credit Agreement include a drawn term loan of $50 million and a $100 million revolving credit facility of which $15.0 million was drawn on November 1, 2022. In addition, approximately $35.4 million of the proceeds of the credit facility were used to refinance all amounts outstanding under the Prior Credit Agreement, and we currently intend to use the remaining proceeds to repay certain indebtedness of our wholly-owned subsidiary, Acacia Pharma Group Limited, and for other corporate purposes. The new maturity date of the schedule of principal payments for each of the revolving credit facility and the term loan facility is October 31, 2025, unless required to mature earlier or extended pursuant to the terms of the Third Amended Credit Agreement.

For the nine months ended September 30, 2022, we generated net income of $27.5 million. As of September 30, 2022, our working capital surplus was $63.2 million.

We believe that our cash and cash equivalents and future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for at least the next 12 months. We believe we will be able to meet our expected future cash and working capital requirements through a combination of cash flows from operations, cash and cash equivalents, availability of borrowings under our revolving credit facility and additional funding in the capital markets, if needed. We have based this estimate on assumptions that may prove to be wrong.

We may opportunistically seek access to additional capital to fund potential licenses, acquisitions or investments to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. As a result of the COVID-19 pandemic, as well as the ongoing military conflict between Russia and Ukraine and the related sanctions imposed against Russia and countermeasures related thereto in addition to macroeconomic conditions including rising inflation, the global credit and financial markets have experienced significant volatility and disruption. If these market conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments or acquisitions. An inability to borrow or raise additional capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities, and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds for any such potential acquisition or investment activities, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose. Furthermore, any equity financing would be dilutive to our shareholders, and any financing could require the consent of the lenders under our credit facility.

The COVID-19 pandemic has disrupted and continues to disrupt the U.S. healthcare system, global economies and global capital markets. There are significant uncertainties surrounding the full extent and duration of the impact of the COVID-19 pandemic, geopolitical and macroeconomic conditions 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 used in operating activities for the nine months ended September 30, 2022 was $13.1 million. Net income for the period was $27.5 million enhanced by the net of non-cash adjustments of approximately $31.2 million from deferred income taxes, depreciation expense, 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, foreign exchange gains and losses, and other items. Net changes in working capital decreased cash from operating activities by approximately $46.4 million, due to changes in working capital accounts. The total amount of accounts receivable at September 30, 2022 was approximately $96.9 million, which included $69.1 million related to product sales and $27.8 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 in investing activities for the nine months ended September 30, 2022 was $86.8 million, primarily as a result of our acquisition of Acacia coupled with an equity investment in Enalare of $12.5 million and $0.2 million for purchases of property and equipment.

Financing Activities:

Net cash used in financing activities for the nine months ended September 30, 2022 was $8.6 million, as a result of $6 million of principal payments for debt required by our Prior Credit Agreement, $18 million in payments related to the repurchases of our common stock, $1.3 million of payments associated with employee withholding tax upon vesting of stock-based awards, offset by $15 million from a drawdown from our revolving credit facility under the Credit Agreement coupled with $1.7 million in proceeds received from the exercise of employee stock options.

Trends and Uncertainties

During the three and nine months ended September 30, 2022, we have experienced a variable impact on our business and financial condition due to the COVID-19 pandemic. 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*: During the second quarter of 2021, we developed and implemented plans to resume in-person work practices while adhering to relevant health authority guidance, for certain of our employees, including customer-facing employees, that had been primarily working remotely. We may incur additional expenses in 2022 related to the impact of the COVID-19 pandemic on our operations, including updates to our facilities to align with safety protocols.
- *Manufacturing and Supply Chain:* We are working closely with our commercial partners and third-party manufacturers to mitigate potential disruptions as a result of the COVID-19 pandemic by continuing to monitor the supply and availability of Bendeka, Ryanodex, and Belrapzo, Treskysim, Pemfexy, vasopressin, Barhemsys, and Byfavo for the patients who rely on these products. We anticipate that the COVID-19 pandemic will continue to delay our supply chain and marketing and sales efforts for certain of our products, including Bendeka, although it is not currently expected that any disruption would be material. If the COVID-19 pandemic continues to persist for an extended period of time and impacts essential distribution systems such as FedEx and postal delivery, we could experience future disruptions to our supply chain and operations, and associated delays in the manufacturing and our clinical supply, which would adversely impact our development activities.
- *Marketing and Sale of Products*: In addition to the impact on our product revenues resulting in a decrease in sales from Belrapzo, driven, in part, by the COVID-19 pandemic, we have also observed a reduction in the number of Bendeka patients visiting infusion centers, hospitals and clinics for intravenous administration of Bendeka due to interruptions in healthcare services, and the patients' inability to visit administration sites as well as desire to avoid contact with infected individuals. In addition, our sales and marketing teams have been working remotely and our virtual initiatives with respect to marketing and supporting the sale and administration of our products have not been as effective as our in-person sales and marketing activities.
- *Liquidity and Capital Resources*: We believe that our future cash and cash equivalents and availability of borrowings under our Third Amended Credit Agreement flows from operations will be sufficient to fund our currently anticipated working capital requirements for the next 12 months. We have based this estimate on assumptions that may prove to be wrong 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 evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists or deepens, we could experience an inability to access additional capital when and if needed. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate distribution of our commercialized products, product portfolio expansion or some or all of our research and development programs, which would adversely affect our business prospects. We expect to be able to obtain future funding under the terms of the Third Amended Credit Agreement, for general corporate purposes and any strategic acquisitions.
- *Regulatory Activities*: We may experience further delays in the 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 three and nine months ended September 30, 2022 and, it could have a material adverse impact on our financial condition and results of operations in the future.

In addition, the U.S. government and other nations have imposed significant restrictions on most companies' ability to do business in Russia as a result of the ongoing military conflict between Russia and Ukraine. It is not possible to predict the broader or longer-term consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. Such geopolitical instability and uncertainty could have a negative impact on our ability to further expand our business and to otherwise generate revenues and develop our product candidates. In addition, a significant escalation or expansion of economic disruption or the conflict's current scope could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
We continue to monitor the impacts of other global and worsening macroeconomic conditions, such as global geopolitical tension, increasing inflation and interest rates, exchange rate fluctuations, supply chain disruptions and increases in commodity, energy and fuel prices.

Contractual Obligations

Other than as set forth below, there have been no material changes to our contractual and commercial obligations during the nine months ended September 30, 2022, as compared to the obligations disclosed in our Annual Report.

Our future material contractual obligations included the following as of September 30, 2022 (in thousands):

Obligations	Total	2022	2023	2024	2025	Beyond
Operating leases (1)	$ 3,621	$ 414	$ 1,672	$ 1,122	$ 413	$ —
Credit facility and Term Loans (2)	59,324	35,000	4,257	12,162	7,905	—
Investment in Enalare (4)	12,500	—	12,500	—	—	—
Purchase obligations (3)	99,403	99,403	—	—	—	—
Total obligations	$ 174,848	$ 134,817	$ 18,429	$ 13,284	$ 8,318	$ —

(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, office space located in Indianapolis, Indiana through November 2023, and an office space located in Palm Beach Gardens, Florida, through October 31, 2024.

(2) Refer to Note 9. and Note 16. Subsequent Events for details of our Prior Credit Agreement, and the Third Amended Credit Agreement and term loans.

(3) As of September 30, 2022, we had purchase obligations in the amount of $99.4 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.

(4) We invested $12.5 million in Enalare at the time of entering the agreement in August 2022, and we are contractually obligated to invest another $12.5 million six months after August 2022. Refer to Note 15 for further details.

Critical Accounting Policies and Estimates

Our significant accounting policies and estimates are disclosed in “Note 2. Summary of Significant Accounting Policies” in our audited financial statements for the year ended December 31, 2021 included in our Annual Report. Since the date of such financial statements, there have been no changes to our significant accounting policies and estimates 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

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.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires an acquirer to recognize and measure contract assets and liabilities acquired in a business combination in accordance with Revenue from Contracts with Customers (Topic 606) rather than adjust them to fair value at the acquisition date. This accounting standard update will be effective for public business entities in fiscal years beginning after December 15, 2022, including interim periods within those fiscal years; therefore for us beginning in the first quarter of 2023. We are currently evaluating the impact of this accounting standard, but do not expect it to have a material impact on our condensed consolidated financial statements.

In March 2022, the FASB issued ASU 2022-01, *Derivatives and Hedging (Topic 801): Fair Value Hedging – Portfolio Layer Method*, which expands the current single-layer hedging model to allow multiple-layer hedges of a single closed portfolio of prepayable financial assets or one or more beneficial interests secured by a portfolio of prepayable financial instruments under the method. This accounting standards update will be effective for public business entities in fiscal years beginning after December 15, 2022, including interim periods within those fiscal years; therefore for us beginning in the first quarter of 2023. We are currently evaluating the impact of this accounting standard, but do not expect it to have a material impact on our condensed consolidated financial statements.

There are other new accounting pronouncements issued by the FASB that we have adopted or will adopt, as applicable. We do not believe any of these accounting pronouncements have had, or will have, a material impact on our condensed consolidated financial statements or disclosures.

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 nine months ended September 30, 2022, 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 September 30, 2022, 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

On June 9, 2022, we completed the acquisition of Acacia. We have extended our oversight and monitoring processes that support our internal control over financial reporting, as well as our disclosure controls and procedures, to include Acacia's operations. We continue to integrate the acquired operations of Acacia. There were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2022 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. For a discussion of our risk factors, please see "Part I, Item 1A. Risk Factors" of our Annual Report in addition to our updated risk factors set forth below.

We may fail to realize all of the anticipated benefits of the Acacia acquisition, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of our Acacia acquisition will depend, to a large extent, on our ability to integrate Acacia Pharma and BARHEMSYS and BYFAVO, into our business and realize anticipated growth opportunities and synergies. We will need to devote significant management attention and resources to integrating these products into our business. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the transaction could adversely affect our business, financial condition and results of operations.

Our ability to realize the anticipated benefits of the transaction is expected to entail numerous material potential difficulties, including, among others:

- the diversion of management attention to integration matters;
- difficulties in achieving anticipated business opportunities and growth prospects from the acquisition;
- difficulties in assimilating employees; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the transaction.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially impact our business, financial condition and results of operations.

In addition, we now possess not only the rights to BARHEMSYS and BYFAVO, but also certain corresponding liabilities and obligations, including the contractual liabilities and regulatory obligations that we have assumed upon closing of the transaction, including certain post-marketing commitments. Failure to satisfy any such requirements could delay our realization of, or prevent us from ever realizing, the anticipated benefits from the transaction. Further, it is possible that undisclosed, contingent, or other liabilities or problems may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

All of these factors could decrease or delay the expected accretive effect of the transaction and negatively impact our stock price. As a result, it cannot be assured that our Acacia acquisition will result in the full realization of the benefits anticipated from the transaction within the anticipated time frames or at all.

In addition, we may not realize some or all of the anticipated benefits of our investment in Enalare. Our ability to realize the anticipated benefits of our investment in Enalare will depend, to a large extent, on potential FDA submission, partnership with Biomedical Advanced Research and Development Authority and Orphan Drug Designation of ENA-001. There is no assurance that these development programs and regulatory activities will be completed successfully. In addition, pursuant to the terms of the Purchase Agreement, we are obligated to further invest in Enalare, including an additional $12.5 million no later than February 2023 and two additional $15.0 million milestone payments upon achievement of the milestones specified in the Purchase Agreement. The first $15.0 million investment shall occur upon the dosing of the first patient in a Phase 2 human clinical trial of any product containing the active ingredient ENA-001. The second $15.0 million investment shall occur when patient enrollment in the Phase 2 human clinical trial of a Product Candidate reaches 50%. We also have the option to to acquire all of the remaining outstanding shares of Enalare other than those already owned by us subject to the terms and conditions of the agreement. Given our rights and obligations under the Enalare agreement, we may forego or delay pursuit of

other opportunities that may have proven to have greater commercial potential. In addition, we may forego our option to acquire Enalare. There is no assurance that Enalare's development programs will be successful and that the milestones will be achieved in the expected timeframe, or at all, or that we will exercise the option to purchase the remaining Enalare shares if and when such option were to become available. All of these factors could negatively impact our stock price.

We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.

As part of our business strategy, we may engage in additional strategic transactions to expand and diversify our product pipeline, including through the acquisition of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, similar to our acquisition of Acacia Pharma and investment in Enalare. We may not identify suitable strategic transactions, or complete such transactions in a timely manner, on a cost-effective basis, or at all. Moreover, we may devote resources to potential opportunities that are never completed or we may incorrectly judge the value or worth of such opportunities. Even if we successfully execute a strategic transaction, we may not be able to realize the anticipated benefits of such transaction, may incur additional debt or assume unknown or contingent liabilities in connection therewith, and may experience losses related to our investments in such transactions. Integration of an acquired company or assets into our existing business may not be successful and may disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long-term benefits of a strategic transaction, our expenses and short-term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a detrimental effect on our business, results of operations and financial condition.

In addition, potential future strategic transactions may entail numerous operational, financial and legal risks, including:

- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;
- higher than expected acquisition and integration costs;
- difficulty in integrating operations and personnel of any acquired business;
- increased amortization expenses or, in the event that we write-down the value of acquired assets, impairment losses;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain personnel, customers, distributors, vendors and other business partners integral to an in-licensed or acquired product, product candidate or technology;
- potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges;
- entry into indications or markets in which we have no or limited direct prior development or commercial experience and where competitors in such markets have stronger market positions; and
- other challenges associated with managing an increasingly diversified business.

If we are unable to successfully manage any strategic transaction in which we may engage, our ability to develop and commercialize new products and continue to expand and diversify our product pipeline may be limited.

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations and/or in connection with potential business development transactions we may determine to pursue. For example, in June 2022, we completed our Acacia acquisition, pursuant to which Acacia Pharma shareholders received €0.68 in cash and 0.0049 shares of our common stock for each Acacia Pharma share. To the extent we raise additional capital or pursue potential business development transactions by issuing equity securities, our stockholders may experience substantial dilution. We currently have on file with the SEC a shelf registration statement, which allows us to offer and sell certain registered securities, such as common stock, preferred stock, debt securities and warrants, from time to time pursuant to one or more offerings at prices and

terms to be determined at the time of sale. We may sell common stock, convertible securities or other equity or debt securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity or debt securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

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 and Education 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 Trump administration signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes
under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the 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 remained 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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. 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 until 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

Additionally, 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, the Centers for Medicare & Medicaid Services, or 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 concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The 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, 2032.
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 concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The 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, 2032. 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It

is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these laws, as well as other new laws and reform measures that may be proposed and adopted in the future remains uncertain but may result in additional reductions in Medicare and other health care funding, or higher production costs which could have a material adverse effect on our customers and, accordingly, our financial operations.

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

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

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

As of September 30, 2022, we had a total of 113 employees in the United States and one employee in the United Kingdom. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities.

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

The COVID-19 pandemic has adversely impacted, and may continue to adversely impact, our business, including the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities. In addition, our business, financial condition and results of operations have been and may in the future be adversely affected by macroeconomic conditions and by geopolitical events.

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

to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

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

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

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

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

The COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 continues to impact the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our access to capital and our business development activities, depends on future developments, which are highly uncertain and cannot be predicted with confidence, such as the

ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions, any re-opening plans, additional closures and spikes or surges in COVID-19 infection, and the impact on the economy and capital markets.

In addition, our financial condition, results of operations, business and cash flow may be negatively affected by general economic, industry and market conditions in the global economy and in the global financial markets, such as rising inflation and interest rates, increased costs of goods, supply chain disruptions and uncertainty about economic stability and the financial markets. The global economy has experienced extreme volatility and disruptions from international conflicts, terrorism or other geopolitical events, such as the ongoing conflict between Russian and Ukraine, and related sanctions and other economic disruptions or concerns. On February 24, 2022, Russia initiated significant military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions if the conflict continues or worsens. It is not possible to predict the broader consequences of the conflict, including related geo-political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia may take in response, are likely to cause regional instability and geo-political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. Additional actions that we or others may take in response to the conflict could increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products or products or our partners and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon our plans and programs. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business

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

On November 1, 2022, we entered into the Third Amended and Restated Credit Agreement (the "Third Amended Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Administrative Agent") and the lenders party thereto, which replaced our existing credit agreement, dated as of November 8, 2019 (the "Prior Credit Agreement"). The terms and amounts borrowed under the Third Amended Credit Agreement includes a drawn term loan of $50 million and a $100 million revolving credit facility of which $15.0 million was drawn on November 1, 2022. In addition, approximately $35.4 million of the proceeds of the credit facility were used to refinance all amounts outstanding under the Prior Credit Agreement. The new maturity date of the schedule of principal payments for each of the revolving credit facility and the term loan facility is October 31, 2025, unless required to mature earlier or extended pursuant to the terms of the Third Amended Credit Agreement.

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

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

In addition, our obligations under the Third Amended Credit Agreement are secured by a pledge of substantially all of our assets. If we are unable to pay our obligations when due, the Administrative Agent on behalf of the lenders could proceed to protect and enforce their rights under the Third Amended Credit Agreement, including by foreclosure on the assets securing our obligations under the Third Amended Credit Agreement). The foregoing would materially and adversely affect our business.

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

Issuer Purchases of Equity Securities

Share Repurchase Program

In March 2020, our board of directors approved our current share repurchase program (the "Share Repurchase Program"), providing for the repurchase of up to an aggregate of $160 million of our outstanding common stock.

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
				(dollars in thousands)
July 1, 2022 to July 31, 2022	—	N/A	—	95,735
August 1, 2022 to August 31, 2022	273,899	$ 36.38	273,899	85,784
September 1, 2022 to September 30, 2022	—	N/A	—	85,784
Total	273,899		273,899	

(1) All shares repurchased by us during the three months ended September 30, 2022 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)
10.1		Securities Purchase Agreement, by and between the Registrant and Enalare Therapeutics Inc., dated August 8, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 333-36306, filed on August 9, 2022)
10.2		Security Purchase Option Agreement, by and between the Registrant, Enalare Therapeutics Inc. and the other parties thereto, dated August 8, 2022 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, SEC File No. 333-36306, filed on August 9, 2022)
10.3	(1)	Third Amended and Restated Credit Agreement, by and among the Registrant, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto, dated November 1,, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 333-36306, filed on November 3, 2022)
10.4	(1)+	Settlement and License Agreement, by and between Teva Pharmaceuticals International GmbH and Cephalon, Inc. and the Registrant and Hospira, Inc., dated April 18, 2022.
31.1	(1)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and15d-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) and15d-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 black out bars) 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: November 9, 2022

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

DATED: November 9, 2022

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

Exhibit 10.4

Execution Copy

SETTLEMENT AND LICENSE AGREEMENT

This SETTLEMENT AND LICENSE AGREEMENT (this "Agreement") is hereby entered into and made effective on April 18, 2022 (the "Effective Date") by and among, on the one hand, Teva Pharmaceuticals International GmbH ("Teva GmbH") and Cephalon, Inc. ("Cephalon," together with Teva GmbH, "Teva"), and Eagle Pharmaceuticals, Inc., ("Eagle," together with Teva, "Plaintiffs"), and on the other hand, Hospira, Inc. ("Hospira" or "Defendant"). Plaintiffs and Hospira (and Defendant) are referred to herein individually as a "Party" and collectively, as the "Parties."

WHEREAS, Eagle owns United States Patent Nos. 9,034,908 ("the '908 patent"); 9,144,568 ("the '568 patent"); 9,572,887 ("the '887 patent"); 9,597,397 ("the '397 patent"); 9,597,398 ("the '398 patent"); 9,597,399 ("the '399 patent"); 9,000,021 ("the '021 patent"); 9,579,384 ("the '384 patent"); 10,010,533 ("the '533 patent"); and 11,103,483 ("the '483 patent") (collectively, the "Asserted Patents");

WHEREAS, Eagle also owns United States Patent Nos. 8,609,707 ("the '707 patent"); 9,265,831 ("the '831 patent"); 9,572,796 ("the '796 patent"); 9,572,797 ("the '797 patent"); 10,052,385 ("the '385 patent") (collectively, with the Asserted Patents, the "Eagle Patents");

WHEREAS, Teva owns United States Patent No. 8,791,270 ("the '270 patent") (collectively, with the Eagle Patents, the "Orange Book Patents");

WHEREAS, Eagle is the holder of New Drug Application No. 208194, which is approved by the Food and Drug Administration ("FDA") for the manufacture and sale of bendamustine hydrochloride injection solution in a 100 mg/4 mL (25 mg/mL) dosage strength for intravenous infusion over ten (10) minutes from a 50 mL infusion bag and used for the treatment of chronic lymphocytic leukemia ("CLL") and non-Hodgkin's lymphoma ("NHL") which Teva and its Affiliates market in the Territory under the brand name BENDEKA®;

WHEREAS, Eagle and Cephalon entered into an Exclusive License Agreement on February 13, 2015, as amended (the "Exclusive License Agreement"), pursuant to which Eagle granted Cephalon an exclusive license under certain patents, including the Eagle Patents, for the commercialization of the Bendeka® NDA Product (as defined below) in the Territory (as defined below), including the right to sue for patent infringement;

WHEREAS, on or around October 14, 2015, Cephalon assigned its rights in the Exclusive License Agreement to Teva GmbH;

[redacted]WHEREAS, Hospira is the holder of New Drug Application No. 211530, which was submitted to the FDA pursuant to 21 U.S.C. § 355(b)(2) seeking approval to market in the United States a generic bendamustine hydrochloride injection solution in a 25 mg/1 mL, 100 mg/4 mL, and 200 mg/8 mL (25 mg/mL) dosage strength

containing a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the Orange Book Patents are not infringed or invalid;

WHEREAS, Plaintiffs have contended that the Asserted Patents are valid and enforceable and that, but for the license granted to Hospira under this Agreement, the commercial manufacture, use, sale, offering for sale, or importation of Hospira Product (as defined below) in or for the Territory would infringe the Patents-In-Suit;

WHEREAS, Hospira has contended that the product described in the Hospira NDA (as defined below) does not infringe the Asserted Patents and/or that those patents are invalid;

WHEREAS, Plaintiffs and Defendant are involved in two (2) litigations in the United States District Court for the District of Delaware (the "District Court"), namely (i) Civil Action No. 18-cv-01704 (CFC) and (ii) Civil Action No. 21-cv-01619 (CFC) (collectively, the "Lawsuits"), concerning, *inter alia*, the validity of the Asserted Patents, as well as the alleged infringement by Defendant of the Asserted Patents resulting from the filing by Defendant of the Hospira NDA and related certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv);

WHEREAS, on December 16, 2019, the District Court denied Hospira's motion to dismiss with respect to the '887 patent and granted Hospira's motion to dismiss with respect to all other patents asserted in Civil Action No. 18-cv-01704 (CFC), as a result of which the '887 patent and the '483 patent asserted in the second of the two (2) Lawsuits referenced in the immediately foregoing recital are the remaining asserted patents in the Lawsuits (the "Patents-In- Suit");

WHEREAS, Plaintiffs have previously sued other defendant ANDA filers Apotex Inc. and Apotex Corp. (collectively, "Apotex"), Fresenius Kabi USA, LLC ("Fresenius Kabi"), Mylan Laboratories Ltd. ("Mylan"), and Slayback Pharma LLC ("Slayback") for infringement of certain of the Orange Book Patents;

WHEREAS, on July 6, 2020, the district court entered judgment for Plaintiffs and against Apotex, Fresenius Kabi, Mylan, and Slayback for infringement and non-invalidity of one or more of the Orange Book Patents in Civil Action No. 15-cv-01154 (CFC);

WHEREAS, Apotex, Fresenius Kabi, and Mylan appealed this Court's judgment of non- invalidity to the United States Court of Appeals for the Federal Circuit, which affirmed the district court's judgement in Case No. 20-2134 on August 13, 2021, and denied Apotex and Mylan's Petition for Rehearing En Banc on October 15, 2021;

WHEREAS, Apotex filed a petition for a writ of certiorari with the United States Supreme Court in Case No. 21-893 on December 14, 2021, which the Supreme Court denied on February 22, 2022;

WHEREAS, Plaintiffs are involved in litigations in the District Court for infringement of the Patents-In-Suit, pursuant to which Plaintiffs have sued (i) Accord Healthcare Inc. in Civil Action No. 21-952-952 (CFC) (the "Accord Litigation") and (ii) Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. in Civil Action No. 21-cv-00695 (CFC) (the "DRL Litigation");

WHEREAS, the Parties desire and agree to enter into this Agreement to avoid the costs, uncertainty, and risk associated with continued litigation of this matter, including the pending

Lawsuits, and to pennit entiy of generic competition prior to the expiration of the Patents-In-Suit upon the tenns and subject to the conditions set fo1th herein, and Defendant agrees not to make, have made, use, sell, offer for sale or impo1i the Hospira Product in the Te1Tito1y before the License Effective Date (as defined below) except as expressly pennitted by the tenns and conditions of this Agreement;

WHEREAS, other than the stipulation dismissing Hospira from the Lawsuits, this Agreement is the only agreement between the Paiiies related to the settlement of the Lawsuits with respect to the Hospira NDA and the Hospira Product; and

WHEREAS, no Paiiy has received any consideration from any other Pa1iy for its entiy into this Agreement other than that which is described in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants herein contained and the consideration described herein, the sufficiency and receipt of which ai·e hereby acknowledged, the Paiiies hereto, intending to be legally bound hereby, agree as follows:

1. **DEFINITIONS**

1.1 "Affiliates" means, with respect to a Pa1iy, any entity that, directly or indirectly, through one or more inte1mediai·ies, conu-ols, is conti·olled by, or is under common conu-ol with, such Paiiy. For purposes of this definition, "conti·ol" (including the tenns "conu-olled by" and "under common conti·ol with") of a business entity means the direct or indirect ownership of more than fifty percent (50%) of the voting stock or other ownership interest in such entity; or the direct or indirect ownership of the power to direct the management and policies of the other entity by any means whatsoever. For clai·ity, legal counsel for a Party ai·e not Affiliates.

1.2 "ANDA" means an abbreviated new diug application filed pursuant to 21 U.S.C. § 355(j).

1.3 "ANDA Product" means a phaimaceutical product that (a)(i) is a bendamustine hydi·ochloride solution, and (ii) is therapeutically equivalent to the Bendeka®

NDA Product, as manufactured or sold for use in the Te1Tito1y in a 100 mg/4 mL

[redacted]

25 m /mL

[redacted]

for the u-eatment of CLL and NHL

Product and ANDA Product does not in[redacted]clude 1

[redacted]or (2)[redacted] and

(b) is sold, offered for sale or disu-ibuted under an ANDA that references the Bendeka®NDA Product as the reference-listed diug and is filed or othe1wise conu-olled by a person or entity other than Plaintiffs or their Affiliates. For the avoidance of doubt, the Hos ira Product is not an ANDA

[redacted]

1.1 "Bendeka®NDA" means NDA No. 208194, and any amendments or supplements thereto, including additional indications, additional dosage strengths, or additional infusion bag volumes between 25 to 100 mL that are added to NDA No. 208194 after the Effective Date.

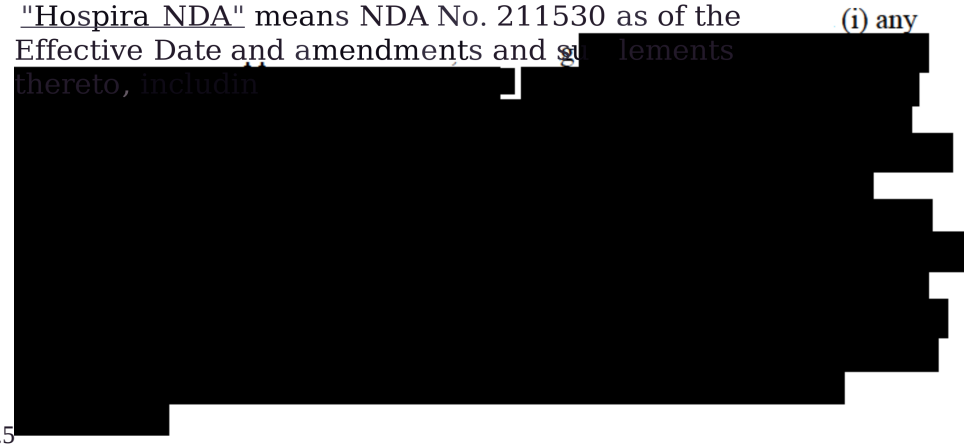
[redacted]

1.2 "Bendeka®NDA Product" means the bendamustine hydrochloride solution product that is the subject of the Bendeka®NDA and marketed in the Tenito1y under the BENDEKA® trademark or any successor trademark thereto in a 100 mg/4 mL (25 mg/mL) dosage strength for intravenous infusion over ten (10) minutes from a 50 mL infusion ba and used for the treatment of CLL and NHL,

1.3 "Controlled" means, with respect to any patent right granted to Defendant, and/or regulato1y exclusivity waived by the relevant Plaintiff, under this Agreement, the ownership of, or exclusive license rights to, such patent right and/or regulato1y exclusivity by the relevant Plaintiff or its Affiliates that pennits such Plaintiff or its Affiliates to grant such patent right or waive such regulato1y exclusivity to Defendant without violating the tenns of any agreement or other aiTangement with any Third Paiiy or being obligated to pay any royalties or other consideration therefor. Notwithstanding the foregoing, with respect to any patent right and/or regulato1y exclusivity Controlled by an Affiliate of a Plaintiff, such patent right and/or regulato1y exclusivity will only be treated as "Controlled" under this Agreement for so long as such Affiliate remains an Affiliate of such Plaintiff.

1.4 "Final Comi Decision" means a decision by a comi on the merits (e.g., after a trial or summaiy judgment motion) whereby such court enters final judgment from which no appeal (other than a petition to the United States Supreme Comi for a writ of ce1iiorai·i) has been or can be taken.

"Hospira NDA" means NDA No. 211530 as of the Effective Date and amendments and supplements thereto, including



1.5

1.4 "Hospira Product" means the NDA Product that is the subject of the Hospira NDA.

1.5 "License Effective Date" means the earliest to occur of the following:

(a) the date of a Final Comt Decision in favor of a Third g all of Paity, holdin the ad'udicated and unex ired claims of the Licensed Patents [redacted] Januaiy 17, 2028; (b) [redacted] § A)(iv) or § 355(j)(2)(A)(vii)(IV), respectively (a "PIV Certification"), [redacted] (ii) occur or be deemed to occur in the event of a Final Court Decision [redacted] and (iii) in no event occur or be deemed to occur (x) prior to [redacted] or (y) in the event of a Final Court Decision involving [redacted] *provided, however*, that a License Effective Date under this clause (b) shall (i) occur only if the Third Pa1ty against whom the Licensed Patents or a subset thereof were asserted in connection with such Final Court Decision included in its NDA or ANDA for its NDA Product or ANDA Product, respectively, a ce1tification pursuant to 21 U.S.C.

(c) the date of a decision by the United States Patent Trial and Appeal Boai·d ("PTAB") from which no appeal (other than a petition to the United States Supreme Comt for a writ of ce1tiorari) has been or can be taken, that all of the adjudicated and unexpired claims of the Licensed Patents ai·e unpatentable; *provided, however,* that a License Effective Date under this clause c shall occur or be deemed to occur [redacted] if (i) the Third Party in whose favor the PTAB decides is a Third Party PIV Filer and (ii) [redacted] and

(d) the date on which all of the Patents-In-Suit have expired, become pennanently abandoned or disclaimed, withdrawn, or delisted from the Orange Book.

[redacted]

1.6 "Licensed Patents" means the Patents-In-Suit, any conections, extensions (including pediatric exclusivities), reissues, or reexaminations of such patents, and any amended claims of such patents arising out of an *inter partes* review, post grant review, or other patent proceeding.

1.7 "NDA" means a new drng application filed pursuant to 21 U.S.C. § 355(b)(2).

1.8 "NDA Product" means a phannaceutical product that (a)(i) is a bendamustine hydrochloride solution, (ii) is therapeutically equivalent to the Bendeka®NDA Product, as manufactured or sold for use in the Tenito1y in a 100 mg/4 mL (25 __g/mL) dosage strength in a multiple-dose vial, and (iii) has an FDA approved label [redacted] for the treatment of CLL and NHL [redacted] Ill [redacted] or (2) [redacted] and (b) is sold, offered for sale or distributed under an NDA that references the Bendeka®NDA Product as the reference-listed drng and is filed or othe1wise controlled by a person or entity other than Plaintiffs or their Affiliates. For the avoidance of doubt an NDA Product does not include 1

1.9 "Orange Book" means FDA's publication entitled Approved Drng Products with Therapeutic Equivalence Evaluations.

1.10 "Other Patents" means, other than the Licensed Patents, any other patent, including but not limited to Orange Book Patents that are not Patents-In-Suit, or patent application, and any conections, extensions (including pediatric exclusivities),

reissues, or reexaminations of such other patents or amended claims of such other patents arising out of an *inter partes* review, post-grant review, or other patent proceeding Controlled now or in the future by a Plaintiff or any of its Affiliates that claim or cover the making, using, selling, offering for sale or impo1iation of the Hospira Product in the Tenito1y.

1.11 "Territory" means [redacted]

1.1 "Third Party" means any entity or person that is not a Party or an Affiliate of a Party.

2. **SETTLEMENT; DISMISSAL; RELEASE**

2.1 All of the terms and conditions set forth in this Agreement shall be binding on the Parties and their Affiliates as of the Effective Date.

2.2 Dismissal. In consideration of the mutual benefits of entering into this Agreement, the Parties shall enter into and cause to be filed with the District Court, within five (5) days of the Effective Date, a joint motion to dismiss with prejudice all claims, defenses, and counterclaims as between Plaintiffs and Defendant in the Lawsuits, substantially in the forms attached hereto as Exhibit A.

2.3 Release. In settlement of the disputed claims in the Lawsuits, and in consideration of the mutual execution of this Agreement and the mutual agreement to be legally bound by the terms hereof, each Plaintiff, on the one hand, and Defendant, on the other hand, on behalf of itself and its predecessors, successors, assigns, shareholders, officers, directors, employees, trustees, agents, representatives, licensees, licensors, parents, subsidiaries and Affiliates and all others claiming by, through and under them, hereby fully, finally, irrevocably and forever (but subject to this Section 2.3) releases, relinquishes, acquits and discharges the other Party and its predecessors, successors, assigns, shareholders, officers, directors, employees, agents, representatives, licensees, licensors, parents, subsidiaries, Affiliates, customers, suppliers, importers, manufacturers, and distributors, if any, from any and all claims, demands, causes of action, liabilities, losses, all manner of actions, judgments, settlements, interest, damages, punitive damages and other damages or costs of whatever nature (including costs, expenses, and attorneys' fees), whether known or unknown, foreseen or unforeseen, certain or contingent, accruing before the Effective Date, arising out of, derived from, predicated upon, or relating to the Hospira Product and Hospira NDA or its filing; provided, however, that nothing herein shall (i) constitute a release of any obligations of Plaintiffs or Defendant (or their respective Affiliates) under this Agreement or prevent a Party from invoking the continuing jurisdiction of the District Court in the Lawsuits to enforce the terms and provisions of this Agreement or (ii) prevent or impair the right of any Party to bring a proceeding in court or any other forum for a breach of this Agreement or any representation, warranty, or covenant herein, or with respect to any product other than the Hospira Product, or any proceeding outside of the Territory. Notwithstanding anything to the contrary, nothing included herein is intended to restrict, limit, or otherwise abrogate any rights Hospira and its Affiliates have under 35 U.S.C. § 271(e)(1).

2.4 Unknown Claims. Each Party, on behalf of itself and its Affiliates, hereby expressly waives and relinquishes any and all provisions, rights and benefits conferred by Section 1542 of the California Civil Code, which provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN TO HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Further, each Paiiy, on behalf of itself and its Affiliates, and its and their respective directors, officers, members, managers, paitners, employees, agents, representatives, assigns, predecessors, successors or other related persons or entities, expressly waive and relinquish all rights and benefits afforded by any law in any other jurisdiction similai·to Section 1542 of the California Civil Code.

1.1 [redacted]

1.2 [redacted]

1.3 No Assignment of Claims. Each Paiiy represents and wanants and covenants that it has not heretofore assigned or ti·ansfe1Ted, and will not assign or othe1wise ti·ansfer, to any

person or entity any matters released by such Paiiy in Section 2.3, and each such Paiiy agrees to indemnify and hold haimless the other Paiiies and the other persons and entities released under Section 2.3 from and against all such released matters ai·ising from any such alleged or actual assignment or ti·ansfer.

1.4 Reliance on Agreement. For the avoidance of doubt, nothing herein shall be construed as an admission or waiver as to any factual or legal matter by any Paiiy or its Affiliates with respect to (a) any jurisdiction outside of the Tenito1y, (b) any products other than the Hospira Product or (c) any patents other than the Licensed Patents or Other Patents solely with respect to the Hospira Product and Hospira NDA. No Pai·ty shall seek to rely upon or enter this Agreement or any admission

herein into evidence in any proceeding other than a proceeding relating to a claimed breach of this Agreement.

3. **LICENSE; RESTRICTIONS**

greement, Pl aintiffs (except

1.5 [redacted]

License Grant. Subject to the tenns and conditions of this A hereby grant to Hospira and its Affiliates as permitted under Section 8.10), non-exc us1ve, revoca e ursuant to Section 5.4) license under the Licensed Patents to manufacture, have

[redacted] manufactured, use, sell, offer to sell, and impo1i the Hospira Product in the Tenito1 as of and followin the License Effective Date.

Plaintiffs shall impose the foregoing license on its Affiliates and any Third Party to which Plaintiffs may assign, license, sublicense, or othe1wise transfer any rights to or under (in each case, that includes the right to asse1i) the Licensed Patents.

1.1

1.2 No Other Licenses: Disclaimer. Other than the license and other rights expressly granted or pennitted in Sections 3.1, 3.2, 3.5, and 3.6, respectively, nothing in this

Agreement will or shall be construed as granting Defendant any other license or other rights. Notwithstanding anything to the contl'aiy in this Agreement, nothing

[redacted] or (e) granting by implication, estoppel or otherwise, any licenses or rights with respect to (i) [redacted] in this Agreement will, or be construed as: (a) creating an obligation by Plaintiffs (or confening a right by Defendant) to bring or prosecute actions or suits against any Third Party for infringement of the Licensed Patents; (b) confening a right to use any ti-ademark or ti·ade name of any Party; (c) granting by implication, estoppel or othe1wise, any licenses or rights under any patent rights, except as expressly described in this Agreement; (d) granting b im lication, esto el or othe1wise an waiver or other ri hts with res ect to

or (ii) any bendamustine product in any dosage fonn other than the rights expressly granted in Sections 3.1, 3.2, 3.5, and 3.6, with respect to the Hospira Product.

1.3 Covenant Not to Challenge and Assist Challenges to the Licensed Patents and Other Patents.

(a) Except to the extent required by law or order of a comi or administi·ative agency of competent jurisdiction, Hospira hereby covenants and agrees that, from and after the Effective Date, it shall not, and shall cause its Affiliates not to: (i)(A) challenge, dispute or contest the validity, enforceability, patentability, priority of invention or other claim to priority, or patent te1m adjust:Inent of the Licensed Patents or Other Patents, or (B) assert the non-infringement of the Licensed Patents or Other Patents with respect to the manufacture, use, sale, offer to sell, impo1iation or disti·ibution of any NDA Product or ANDA Product, in each case ((A) or (B)), in any reexamination, *inter partes* proceeding, protest, observation, comment, opposition, third-paiiy submission, post grant proceeding, *inter partes* review, post grant review, covered business method review, derivation proceeding, interference or other action or proceeding in the United States Patent and Trademark Office ("USPTO") or any United States comi proceedings or ti-ibunal, or submit or cause, in any manner, to be submitted, any conespondence or communication with the USPTO with respect to the Licensed Patents and Other Patents; or (ii) assist, encourage, finance, or join any proceeding with any Third Pa1iy challenging, disputing or contesting, or who may challenge, dispute or contest, the validity, enforceability, patentability, priority of invention or other claim to priority, or patent tenn adjustment of the Licensed Patents or Other Patents, or asse1iing the non-infringement of any of the Licensed Patents or Other Patents in connection with an NDA Product or ANDA Product.

[redacted]

(b)

[redacted]

(a) Without limiting the generality of the foregoing, Defendant shall instrnct the attorneys and expe1ts engaged by or on its behalf in connection with the Lawsuits not to use or transfer to any Third Party any confidential infonnation of Hospira or its Affiliates or any work product or other materials generated in connection with the Lawsuits, unless such disclosure is compelled by law.

[redacted] (b) [redacted]

1.6 Covenant Not to Sue. As pait of the license rights granted in this Section 3, with respect to the Hospira Product, and effective on the License Effective Date, Plaintiffs and their Affiliates nTevocably covenant not to sue (provided HospiI·a has not materially breached this Agreement, and subject to Section 5.3), asse1t any claim or othe1wise paiticipate in any action or proceeding against, Defendant and its Affiliates, and their impo1ters, suppliers, manufacturers, distributors, and customers for infringement of the Licensed Patents and Other Patents solely with respect to Defendant's or its Affiliates' (a) making, having made, using, selling, offering for sale, and nnpo1tation of Hospira Product in the TeITito1 as of and followin the License Effective Date ursuant to Section 3.1

b

Plaintiffs shall impose the foregoing covenant not to sue on its Affiliates and any Thn·d Party to which Plaintiffs may assign license, sublicense, or othe1wise transfer any rights to or under (in each case, that includes the right to asse1t) the Licensed Patents or Other Patents.

1.7 [redacted]

Regulato1y Approval. (a)

to waive with res ect to the

[redacted]

ate and Controlled by that
ursuant to

Product,

at may s of

(b) Each Plaintiff hereby agrees any regulato1y exclusivities existing as of the Effective D prevent approval or marketi the License Effective Date p

.1

- For the avoidance of doubt, each Plaintiff shall cause any Affiliates to waive as a licable with res ect to the Hos ira Product, any regulato1y exclusivitie existing as

-

of the Effective Date, Controlled by that Plaintiff that may prevent approval or marketing of the Hospira Product he
License Effective Date pursuant to Section 3

[redacted]

(c) If requested by Hospira, Plaintiffs and their Affiliates shall reasonably promptly provide written notice to FDA evidencing the license rights, covenant not to sue and waiver of regulato1y exclusivities granted to Hospira as set fo1ih in this Agreement with respect to the Hospira NDA and Hospira Product and indicating that Plaintiffs and their Affiliates have no objection to final approval of the Hospira NDA, and shall confinn to Hospira that it has done so and Hospira shall then also provide a copy of Plaintiffs' cones ondence to the FDA if re uired b the FDA.

1.4 Impact of Granting Certain Licenses to Third Parties. [redacted]

[redacted]

Plaintiffs' Regulatory Covenants. [redacted]

1.8

4. **FTC REVIEW**

4.1 This Agreement shall be submitted to the federal antitmst agencies pmsuant to the Medicare Modernization Act within ten (10) business days of its execution. Each Party shall notify the other Paiiies when it has submitted this Agreement to such agencies. The Paiiies hereby agree that they will work in good faith to resolve any

related issues and endeavor to modify this Agreement in view of any objections from such federal antitiust agencies, but no Paiiy shall be required to accept any tenns that materially change or modify the pmposes of this Agreement.

5. **TERM AND TERMINATION**

5.1 Tenn. Unless eai·lier terminated in accordance with the te1ms of this Section 5, the te1m of this Agreement will commence on the Effective Date and will remain in effect until the expiration of the last to expire of the Licensed Patents. For the avoidance of doubt, the respective te1ms of the Licensed Patents include any te1m extensions or adjust:Inents to which the Licensed Patents are entitled, in each case whether granted or allowed before, on, or after the Effective Date, and the tenn of

this Agreement shall nm until the last to expire of such extensions and pediatric exclusivities, whenever granted.

1.1 Termination for Cause. [redacted] each of [redacted] Plaintiffs and Defendant may tenninate this Agreement at any time in the event that the other Pru or an of its Affiliates materiall breaches this A ·eement

1.2 [redacted] shall survive Effect of Expiration or Te1mination. Expiration or te1mination of this Agreement will not relieve the Pruiies of an obli ation accrnin rior to such ex iration or tennination.

- In addition,

expiration or te1mination of this Agreement.

not be subject to cure and is automatically terminated.

1.3 Te1mination for Breach. tor an of its Affiliates materiall breac 11 E uitable Remedies·

6. **CONFIDENTIALITY; PUBLICITY**

6.1 The Pa1iies hereby agree that, except to enforce this Agreement or lmless othe1wise agreed to by the Pruties in writing or as required by law, the Parties, their Affiliates and their respective employees, officers, directors and other

representatives shall not publish or otherwise disclose the contents of this Agreement, except that (a) each Party may disclose this Agreement (i) to its attorneys, advisors, consultants, agents (including Defendant's manufacturer(s)), and representatives who in each case are subject to obligations of confidentiality consistent with this Agreement, and (ii) if any Party becomes required to disclose this Agreement by law, regulation or order of a court or administrative agency, including reporting requirements to the U.S. Securities and Exchange Commission or by the rules or regulations of any stock exchange to which the Parties are subject, (b) the Parties may communicate with the FDA on a confidential basis prior to the License Effective Date concerning the approval of the Hospira NDA and the licenses and waivers provided for herein, and (c) Plaintiffs may disclose such terms as may be necessary or useful in connection with any proceeding, agreement or settlement discussions relating to the Licensed Patents, Other Patents, or any bendamustine hydrochloride product, including the License Effective Date defined in this Agreement and the fact that the License Effective Date belongs to Defendant. In the event disclosure is required under the foregoing clause (a)(ii), the Party making such disclosure shall (1) provide the other Parties with as much advance notice as reasonably practicable of the required disclosure, (2) cooperate with the other Parties in an attempt to prevent or limit the disclosure, and (3) limit any disclosure to the specific purpose at issue.

1.4 Each Party may, with the prior written approval of the other Party (such approval not to be unreasonably withheld), issue a press release or make a public announcement at any time following the Effective Date indicating that the Parties have settled the Lawsuits, and that Hospira has the right to market the Hospira Product in the Territory beginning January 17, 2028, or earlier based on certain circumstances.

7. REPRESENTATIONS AND WARRANTIES

7.1 Each Party represents and warrants to the other, as of the Effective Date of this Agreement, that:

(a) Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) Such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(c) This Agreement has been duly executed by such Party and constitutes a valid and legally binding obligation of such Party, enforceable in accordance with its terms;

(a) To the knowledge of the Parties, the execution, delivery, and performance of this Agreement does not conflict with any agreement, instrument, or understanding, oral or written, to which such Party is bound nor violate any law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it;

(b) Such Party represents and warrants that it has been advised by its counsel of its rights and obligations under this Agreement and enters into this Agreement freely, voluntarily, and without duress; and

(c) Such Party represents and warrants that it is not relying on any promises, inducements, or representations other than those provided herein.

1.5 Defendant Representations and Warranties. As of the Effective Date, Defendant represents and warrants that: (a) Defendant is the true owner of the Hospira NDA; and (b) Defendant has received no notice or claim and knows of no reason for the assertion of any notice or claim contesting clause (a).

1.6 Plaintiffs Representations and Warranties. As of the Effective Date, Plaintiffs represent and warrant that they have the right and authority to (a) enter into this Agreement, (b) settle the Lawsuits between the Parties, and (c) grant the license rights to Defendant as set forth in this Agreement.

1.7 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NO PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF APPLICABLE LAW.

8. GENERAL PROVISIONS

8.1 Waiver. None of the provisions of this Agreement will be considered waived by any Party unless such waiver is agreed to, in writing, by authorized agents of such Party. The failure of a Party to insist upon strict conformance to any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law will not be deemed a waiver of any rights of any Party.

8.2 Choice of Law and Remedies. The law of the State of Delaware shall govern this Agreement, the interpretation and enforcement of its terms and any claim or cause of action (in law or equity), controversy or dispute arising out of or related to it or its negotiation, execution or performance, whether based on contract, tort, statutory or other law, in each case without giving effect to any conflicts-of-law or other principle requiring the application of the law of any other jurisdiction. The United States District Court for the District of Delaware shall have exclusive jurisdiction in all matters arising under this Agreement, and the Parties hereto expressly consent and submit to the personal and subject matter jurisdiction of the United States District Court for the District of Delaware in connection with matters arising out of or related to this Agreement, and if jurisdiction in the

United States District Comi for the District of Delaware is not possible, will submit any dispute arising out of or related to this Agreement to another comi of competent jmisdiction in the State of Delaware. This Agreement does not limit or restrict the remedies available to any Paiiy for the breach of another Pa1iy, and the Paiiies expressly reserve any and all remedies available to them, at law or in equity, for breach of this Agreement or othe1wise.

8.3 Costs. Each Pai·ty shall each beai·its own costs and legal fees associated with the negotiation and prepai·ation of, and perfonnance under, this Agreement and any activities related to the implementation of this Agreement.

8.4 Entire Agreement. This Agreement constitutes the entire agreement among the Paiiies relating to the subject matter hereof and supersedes all previous agxeements and understandings, oral or written, with respect to such matters.

8.5 Notice. All notices or other communications hereunder shall be deemed to have been duly given and made if in writing and if served by personal delive1y upon a Paiiy, if delivered by a reputable overnight express comier service (charges prepaid), or if sent by email (with confinnation receipt) to the person at the address set fo1ih below, or such other address as may be designated in writing hereafter, in the same manner, by such person as follows:

Ifto **Teva:** Teva Phaimaceuticals Monis Co1porate Center III
400 Inte1pace Pai-Icway, Bldg. A
Pai·si 054 Attn:_, Chief Legal Officer

with copies to:
[redacted]; and
[redacted]

with a copy to (with such copy not constituting notice):

Williains & Connolly LLP 725 Twelfth St. NW Washin
ton DC 20005
Attn: [redacted]

Ifto **Eagle:** Eagle Phaimaceuticals, Inc.
50 Tice Blvd, Suite 315 Woodcliff Lake NJ 07677
[redacted]Attn: General Counsel

with a copy to:
[redacted]

with a copy to (with such copy not constituting notice):

Latham & Watkins LLP 555 Eleventh Street, NW Suite 1000
[redacted]Washington, DC 20004-1304 Attn:

If to **Defendant:** Hospira, Inc.
[redacted]275 North Field Drive Lake Forest, IL 60045 Attn:

Executive Vice President, General Counsel with a copy to (with such copy not constituting notice):

Willkie Farr & Gallagher LLP 300 North LaSalle Dr.
[redacted]Chicago, IL 60654-3406 Attn:

Such notices will be deemed to have been given on the date delivered in the case of delivery by personal delivery or overnight courier or on the date actually received in the case of email delivery.

1.8 Severability. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. If, however, any provision of this Agreement is held to be invalid, illegal, or unenforceable for any reason, the Parties shall negotiate in good faith for a substitute provision to continue the intent and purpose of such invalid provisions, and the validity, legality, and enforceability of the remaining provisions shall not be in any way impaired thereby.

1.9 Amendments. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

1.10 Descriptive Headings. The captions and descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

1.11 Third-Party Benefit. None of the provisions of this Agreement shall be for the benefit of, or enforceable by, any Third Party except as otherwise expressly provided herein.

1.12 Assignment. Defendant will not assign this Agreement or any part hereof or any interest herein (whether by operation of law or otherwise) without the prior

written consent of Plaintiffs (such consent not to be unreasonably withheld, conditioned, or delayed); provided, however, that Defendant may assign this Agreement in whole without such prior consent (a) to any Affiliate of Defendant (for as long as such assignee remains an Affiliate of Defendant); or (b) to any successor entity in the case of a merger, consolidation, change in control or sale of all or substantially all of the assets related to this Agreement. Plaintiffs may assign this Agreement or any part hereof or any interest herein (whether by operation of law or otherwise) without the prior written consent of Defendant, provided that in either case, (i) each assigning party shall provide written notice to the other Parties of any permitted assignment of this Agreement, and (ii) such successor agrees in writing for the benefit of the non-assigning Party to assume all of the obligations of the assigning Party. No assignment will be valid unless the permitted assignee(s) assumes all obligations of its assignor under this Agreement. No assignment will relieve any assigning Party of responsibility for the performance of its obligations hereunder. Any purported assignment in violation of this Section 8.10 will be null and void *ab initio*. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns. For clarity, any successors or permitted assigns to this Agreement are permitted to assign the Agreement as if they were an original Party or Parties to this Agreement, subject to the same terms and obligations regarding assignment under this Section 8.10 that apply to the original Party or Parties to the Agreement.

1.5 Counterparts; Electronic Delivery. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of electronic mail, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any Party hereto or to any such agreement or instrument, each other Party hereto or thereto shall re-execute original forms thereof and deliver them to all other Parties.

[SIGNATURES FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

CEPHALON, INC. **HOSPIRA, INC.**

By: ,S Name: f;. Diclf/2. ,1/4:,v;:f' Name:

Director, Vaccines & Oncology Marketing Title:

Title:

By:

Name:

LEGAL AFFAIRS

Title:

TEVA PHARMACEUTICALS INTERNATIONAL GMBH

By: Name:

Title:

By: Name:

Title:

EAGLE PHARMACEUTICALS, INC.

By: Name:

Title:

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duJy authorized representative as of the Effective Date.

CEPHALON, INC. **HOSPIRA, INC.**

By: __

Name: _____

Title:

By: ____ Name: __ _

Title: __

By:

Name:

Title: \IP 1 '9C.. #0t ,4. cl

:i:P'-,h:qafiCV'\

TEVA PHARMACEU'tICALS INTERNATIONAL GMBH

By: __

Name:

Title:

By:

Name: __

Naama saram _

General Manager

Pascal Guichard

Associate Director Accounting

Title:

EAGLE PHARMACEUTICALS, INC.

_____

By:

Name:

Title:

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

CEPHALON, INC. **HOSPIRA, INC.**

By: __

Name: __

Title: __

By: __

Name: __

Title: __

By: __ Name: __ Title: __

TEVA PHARMACEUTICALS INTERNATIONAL GMBH

By: __ Name: __ Title: __

By: ___Name: _____ Title: ___ **EAGLE PHARMACEUTICALS,**

INC.

By:

Namer*f1/;WJ 0Jrt.Jk:r.*

Title: £V *f (rC i CC* 0

fN WlTNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

CEPHALON, INC. **HOSPIRA, INC.**

By: __

Name: ----------

Title: __

By: ____ Name: ...::J:e•ft'q__ /41.. Afye-,v..;

Title: Al/ulflt1v :Cn ff;(i –/

Exhibit 10.4

_____By: ____ Name: __ Title:

TEVA PHARMACEUTICALS INTERNATIONAL GMBH

_____By: ____ Name: ____ Title:

_____By: ____ Name: ____ Title:

EAGLE PHARMACEUTICALS, INC.

_____By:

Name: __ Title: ____

EXHIBIT A

[Attached]

Exhibit 10.4

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS INTERNATIONAL GMBH, and CEPHALON, INC., Plaintiffs, v. HOSPIRA, INC., Defendant.

C.A. No. 18-cv-01704

STIPULATION AND [PROPOSED] ORDER

By virtue of a settlement agreement between the parties, and pursuant to Federal Rules of Civil Procedure 41(a)(l) and 41(c), Plaintiffs Teva Pharmaceuticals International GmbH, Cephalon, Inc., and Eagle Pharmaceuticals, Inc. (collectively, "Plaintiffs") and Defendant Hospira, Inc. ("Hospira") hereby stipulate and agree that Plaintiffs' action against Hospira with respect to Hospira's NDA Product, including all claims and defenses asserted by Plaintiffs against Hospira and all claims and defenses asserted by Hospira against Plaintiffs with respect to Hospira's NDA Product, are hereby dismissed with prejudice and without costs, disbursements, or attorneys' fees to any party. It is further stipulated that the U.S. District Court for the District of Delaware retains jurisdiction to enforce and resolve any disputes arising under the Agreement.

Respectfully submitted, [Signature Block]

IT IS SO ORDERED this __day of __, 2022

_____

The Honorable Colm F. Connolly

Exhibit 10.4

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS INTERNATIONAL GMBH, and CEPHALON, INC., Plaintiffs, v. HOSPIRA, INC., Defendant.

C.A. No. 21-cv-01619

STIPULATION AND [PROPOSED] ORDER

By virtue of a settlement agreement between the parties, and pursuant to Federal Rules of Civil Procedure 41(a)(l) and 41(c), Plaintiffs Teva Pharmaceuticals International GmbH, Cephalon, Inc., and Eagle Pharmaceuticals, Inc. (collectively, "Plaintiffs") and Defendant Hospira, Inc. ("Hospira") hereby stipulate and agree that Plaintiffs' action against Hospira with respect to Hospira's NDA Product, including all claims and defenses asserted by Plaintiffs against Hospira and all claims and defenses asserted by Hospira against Plaintiffs with respect to Hospira's NDA Product, are hereby dismissed with prejudice and without costs, disbursements, or attorneys' fees to any party. It is further stipulated that the U.S. District Court for the District of Delaware retains jurisdiction to enforce and resolve any disputes arising under the Agreement.

Respectfully submitted, [Signature Block]

IT IS SO ORDERED this __day of __, 2022

_____

The Honorable Colm F. Connolly

Exhibit 31.1

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: November 9, 2022

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: November 9, 2022

/s/ Brian J. Cahill

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

Exhibit 32.1

Certification Pursuant to

18 U.S.C. Section 1350,

As Adopted Pursuant to

Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), **Scott Tarriff**, 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 September 30, 2022, (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 November 2022.

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.