

**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 March 31, 2020

OR

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

For the transition period from _____ to _____

Commission File Number 001-36306

Eagle Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

2834

(Primary Standard Industrial
Classification Code 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)

20-8179278

(I.R.S. Employer
Identification Number)

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

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

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.

The number of shares outstanding of the registrant's common stock as of May 4, 2020: 13,685,118 shares.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our expectations regarding the impact of the ongoing coronavirus 2019, or COVID-19, pandemic including the expected duration of disruption and immediate and long-term delays, disruption in the sales of our marketed products, interruptions or other adverse effects to clinical trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, and the overall impact of the COVID-19 pandemic on our business, financial condition and results of operations;
- the potential benefits and commercial potential of BENDEKA, RYANODEX® and BELRAPZO for approved indications and any expanded uses;
- the commercial potential of additional indications for our products;
- sales of our products in various markets worldwide, pricing for our products, level of insurance coverage and reimbursement for our products, timing regarding development and regulatory approvals for our products or for additional indications or in additional territories;
- future expansion of our commercial organization and transition to third-parties in certain jurisdictions to perform sales, marketing and distribution functions;
- the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development program;
- our ability to obtain and maintain regulatory approval of our products and product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- our ability to obtain funding for our operations and to expand business and sales;
- our plans to research, develop and commercialize our products and product candidates and our ability to successfully commercialize our products and product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- the size and growth potential of the markets for our products and product candidates, and our ability to serve those markets;
- the diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals and doctor offices serving as locations for administration of our products, including BENDEKA, and hospital staff supporting the conduct of such administration;
- the interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic;
- the rate and degree of market acceptance of our products and product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the performance of our strategic collaborators and success of our current strategic collaborations;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing drugs that are or become available;
- the retention of key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to prevent or minimize the effects of Paragraph IV patent litigation; and
- 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 and other factors 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. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. 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 and its subsidiaries, references to "Eagle Biologics" mean Eagle Biologics, Inc. and references to "Eagle Research Lab" means Eagle Research Lab Limited.

NOTE REGARDING TRADEMARKS

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

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 202,016	\$ 109,775
Accounts receivable, net	54,491	48,004
Inventories	8,434	6,566
Prepaid expenses and other current assets	10,631	15,104
Total current assets	275,572	179,449
Property and equipment, net	2,423	2,202
Intangible assets, net	14,917	15,583
Goodwill	39,743	39,743
Deferred tax asset, net	13,759	13,669
Other assets	15,530	3,908
Total assets	\$ 361,944	\$ 254,554
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,756	\$ 5,462
Accrued expenses and other liabilities	20,123	28,361
Current portion of long-term debt	116,000	5,000
Total current liabilities	145,879	38,823
Other long-term liabilities	3,454	3,000
Long-term debt, less current portion	30,781	33,557
Total liabilities	180,114	75,380
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, 1,500,000 shares authorized and no shares issued or outstanding as of March 31, 2020 and December 31, 2019	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 16,597,814 and 16,537,846 shares issued as of March 31, 2020 and December 31, 2019, respectively	17	17
Additional paid in capital	285,044	278,518
Retained earnings	69,629	72,500
Treasury stock, at cost, 2,933,320 and 2,907,687 shares as of March 31, 2020 and December 31, 2019, respectively	(172,860)	(171,861)
Total stockholders' equity	181,830	179,174
Total liabilities and stockholders' equity	\$ 361,944	\$ 254,554

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended	
	March 31,	
	2020	2019
Revenue:		
Product sales	\$ 17,694	\$ 14,472
Royalty revenue	28,326	26,313
License and other revenue	—	9,000
Total revenue	46,020	49,785
Operating expenses:		
Cost of product sales	4,765	9,554
Cost of royalty revenue	3,038	3,546
Research and development	9,427	6,375
Selling, general and administrative	24,755	18,141
Total operating expenses	41,985	37,616
Income from operations	4,035	12,169
Interest income	346	494
Interest expense	(889)	(686)
Other expense	(6,500)	—
Total other expense, net	(7,043)	(192)
(Loss) Income before income tax benefit (provision)	(3,008)	11,977
Income tax benefit (provision)	137	(3,004)
Net (Loss) Income	\$ (2,871)	\$ 8,973
(Loss) Earnings per share attributable to common stockholders:		
Basic	\$ (0.21)	\$ 0.64
Diluted	\$ (0.21)	\$ 0.62
Weighted average number of common shares outstanding:		
Basic	13,667,606	13,925,227
Diluted	13,667,606	14,418,211

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	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount				
Balance at December 31, 2019	16,538	\$ 17	\$ 278,518	\$ (171,861)	\$ 72,500	\$ 179,174
Stock-based compensation expense	—	—	7,472	—	—	7,472
Issuance of common stock upon exercise of stock option grants	16	—	330	—	—	330
Payment of employee withholding tax upon vesting of stock-based awards	—	—	(1,276)	—	—	(1,276)
Issuance of common stock related to vesting of restricted stock units	44	—	—	—	—	—
Common stock repurchases	—	—	—	(999)	—	(999)
Net loss	—	—	—	—	(2,871)	(2,871)
Balance at March 31, 2020	<u>16,598</u>	<u>\$ 17</u>	<u>\$ 285,044</u>	<u>\$ (172,860)</u>	<u>\$ 69,629</u>	<u>\$ 181,830</u>

	Common Stock		Additional Paid-In Capital	Treasury Stock	Retained Earnings	Total Stockholders' Equity
	Number of Shares	Amount				
Balance at December 31, 2018	16,504	\$ 17	\$ 256,458	\$ (153,900)	\$ 58,187	\$ 160,762
Stock-based compensation expense	—	—	5,782	—	—	5,782
Issuance of common stock upon exercise of stock option grants	7	—	42	—	—	42
Payment of employee withholding tax for net option exercise	—	—	(198)	—	—	(198)
Issuance of common stock related to vesting of restricted stock units	9	—	—	—	—	—
Net income	—	—	—	—	8,973	8,973
Balance at March 31, 2019	<u>16,520</u>	<u>\$ 17</u>	<u>\$ 262,084</u>	<u>\$ (153,900)</u>	<u>\$ 67,160</u>	<u>\$ 175,361</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net (loss) income	\$ (2,871)	\$ 8,973
Adjustments to reconcile net income to net cash provided by operating activities:		
Deferred income taxes	(90)	(287)
Depreciation expense	472	503
Amortization expense	666	630
Fair value adjustments on equity investment	6,500	—
Stock-based compensation expense	7,472	5,782
Amortization of debt issuance costs	65	94
Changes in operating assets and liabilities which provided (used) cash:		
Accounts receivable	(6,487)	2,556
Inventories	(1,868)	(1,961)
Prepaid expenses and other current assets	4,473	4,368
Accounts payable	4,294	6,869
Accrued expenses and other liabilities	(8,238)	(1,083)
Other assets and other long-term liabilities, net	(1,230)	(263)
Net cash provided by operating activities	<u>3,158</u>	<u>26,181</u>
Cash flows from investing activities:		
Purchase of equity investment security	(17,500)	—
Purchase of property and equipment	(472)	(177)
Net cash used in investing activities	<u>(17,972)</u>	<u>(177)</u>
Cash flows from financing activities:		
Proceeds from common stock option exercises	330	42
Employee withholding taxes related to stock-based awards	(1,276)	(198)
Proceeds from existing revolving credit facility	110,000	—
Payment of debt	(1,000)	(2,500)
Repurchases of common stock	(999)	—
Net cash provided by (used in) financing activities	<u>107,055</u>	<u>(2,656)</u>
Net increase in cash and cash equivalents	92,241	23,348
Cash and cash equivalents at beginning of period	109,775	78,791
Cash and cash equivalents at end of period	<u>\$ 202,016</u>	<u>\$ 102,139</u>
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes, net	\$ 24	\$ (6,490)
Interest	576	625
Right-of-use asset obtained in exchange for lease obligation - lease amendment	842	2,871

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Interim Condensed Consolidated Financial Statements

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, 2019 was derived from audited financial statements, but certain information and footnote disclosures normally included in the Company's 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 months ended March 31, 2020 are not necessarily indicative of the results for the year ending December 31, 2020 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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 2, 2020.

2. Organization and Business Activities

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

Our science-based business model has a proven track record with U.S. Food and Drug Administration ("FDA") approval and commercial launches of three products: RYANODEX® (dantrolene sodium) ("RYANODEX"), bendamustine ready-to-dilute ("RTD") 500ml solution ("BELRAPZO"), and rapidly infused bendamustine RTD ("BENDEKA"). We market our products through marketing partners and/or our internal direct sales force. Eagle markets RYANODEX and BELRAPZO, and Teva Pharmaceutical Industries Ltd. ("Teva") markets BENDEKA through its subsidiary Cephalon, Inc. Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for PEMFEXY®, our novel pemetrexed product ("PEMFEXY"), a branded alternative to ALIMTA® for metastatic nonsquamous nonsmall cell lung cancer and malignant pleural mesothelioma. We expect to launch PEMFEXY in early 2022.

With 11 pipeline projects underway and the potential for up to five or more product launches over the next several years, we believe we have growth opportunities ahead. We believe that each of our pipeline projects currently has the potential to enter the market as a first-in-class, first-to-file or best-in-class product. In particular, we are applying our expertise to conduct novel research regarding the potential for RYANODEX to address conditions including exertional heat stroke, Alzheimer's disease, traumatic brain injury/concussion, nerve agent exposure and acute radiation syndrome. In addition, our clinical development program includes a strategic partnership with Tyme Technologies ("Tyme") for SM-88, a product candidate for the treatment of patients with pancreatic or other advanced cancers, as well as investigations of compounds such as EA-114, our fulvestrant product candidate, for patients with hormone receptor ("HR")-positive advanced breast cancer. Other products in development include Vasopressin, our first-to-file Abbreviated New Drug Application ("ANDA") that references Endo International plc's Vasostrict® indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; and EA-111, a new chemical entity and next-generation ryanodine receptor antagonist, in an intramuscular formulation that that would allow for easier and more rapid administration in emergency situations (military and civilian).

3. Summary of Significant Accounting Policies

Significant Accounting Policies

The Company's significant accounting policies are described in the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and the notes thereto filed with the SEC on March

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

2, 2020. Since the date of those consolidated financial statements, there have been no material changes to the Company's significant accounting policies other than as listed below.

Significant Risks and Uncertainties

With the global spread of the ongoing COVID-19 pandemic in the first quarter of 2020, the Company has taken active measures designed to address and mitigate the impact of the COVID-19 pandemic on its business, such as facilitating management's daily communication to address employee and business concerns and frequent provision of updates to the Company's Board of Directors ("Board"). The Company anticipates that the COVID-19 pandemic may have an impact on the clinical development timelines for certain of its clinical programs, such as EA-114, in addition to the clinical programs of its collaborators, such as Tyme's clinical development of SM-88. The Company also anticipates that the COVID-19 pandemic may have an impact on the Company's supply chain and sales for certain of its products, including BENDEKA. The extent to which the COVID-19 pandemic impacts the Company's business, its clinical development and regulatory efforts, its supply chain and sales efforts, its corporate development objectives and the value of, and market for, its common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States, and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

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

Use of Estimates

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

Reclassifications

Certain reclassifications have been made to prior year amounts to conform with the current year presentation. None of the reclassifications were significant.

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

Cash and Cash Equivalents

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

The Company, at times, maintains 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.

Our investment in restricted shares of Tyme's common stock are classified as Level 1. Refer to Note 13, Collaboration with Tyme for further details.

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

The fair value of the contingent consideration/accrued royalty is classified as Level 3 for the periods presented.

Intangible Assets

Other Intangible Assets, Net

The Company capitalizes and includes in intangible assets the costs of acquired product licenses and developed technology purchased individually or identified in a business combination. Intangible assets are recorded at fair value at the time of their acquisition and stated net of accumulated amortization. The Company amortizes its definite-lived intangible assets using either the straight-line or accelerated method, based on the useful life of the asset over which it is expected to be consumed utilizing expected undiscounted future cash flows. The Company will evaluate the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the condensed consolidated statements of operations.

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

With respect to determining an asset's fair value and useful life, because this process involves management making certain estimates and these estimates form the basis of the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates.

Goodwill

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

Acquisition-Related Contingent Consideration

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

Concentration of Major Customers and Vendors

The Company is dependent on commercial partners to market and sell BENDEKA. The Company's customers for BENDEKA are its commercial and licensing partners; therefore, the Company's future revenues are highly dependent on these collaboration and distribution arrangements.

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

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

	Three Months Ended March 31,	
	2020	2019
Net revenues		
Cephalon, Inc. (Teva) - See Revenue Recognition	65%	84%
Other	35%	16%
	<u>100%</u>	<u>100%</u>

	March 31,	December 31,
	2020	2019
Accounts receivable		
Cephalon, Inc. (Teva) - See Revenue Recognition	63%	80%
Other	37%	20%
	<u>100%</u>	<u>100%</u>

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Inventories

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

Property and Equipment

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

Research and Development Expense

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

Costs for certain development activities, such as clinical studies, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the patterns of costs incurred, and are reflected in the 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 \$1,113 and \$626 for the three months ended March 31, 2020 and 2019, respectively.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 740 - Income Taxes (“ASC 740”). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income (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 the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct.

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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. Receivables from our product sales have payment terms ranging from 30 to 75 days with select extended terms to wholesalers on initial purchases of product launch quantities. Our receivables from royalty revenue are due 45 days from the end of the quarter.

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

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

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

Royalty Revenue — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 25 days for BENDEKA and 60 days for Argatroban 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.

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.

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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 March 31, 2020.

Collaborative licensing and development revenue — The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties when its contractual services are performed, provided collectability is reasonably assured. Its principal costs under these agreements include its personnel conducting research and development, its allocated overhead, as well as the research and development performed by outside contractors or consultants.

Upon termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in its condensed consolidated statements of operations. The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of its performance obligations under the collaboration agreement.

Stock-Based Compensation

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

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

Earnings Per Share

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

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The anti-dilutive common shares equivalents outstanding for the three months ended March 31, 2020 and 2019 were as follows:

	Three Months Ended March 31,	
	2020	2019
Stock Options	2,927,306	2,194,399
Restricted stock units	253,777	44,383
Total	3,181,083	2,238,782

The following table sets forth the computation for basic and diluted net income (loss) per share for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Numerator		
Numerator for basic and diluted earnings per share-net (loss) income	\$ (2,871)	\$ 8,973
Denominator		
Basic weighted average common shares outstanding	13,667,606	13,925,227
Dilutive effect of stock awards	—	492,984
Diluted weighted average common shares outstanding	13,667,606	14,418,211
Basic net income (loss) per share		
Basic net income (loss) per share	\$ (0.21)	\$ 0.64
Diluted net income (loss) per share		
Diluted net income (loss) per share	\$ (0.21)	\$ 0.62

All potentially dilutive items were excluded from the diluted share calculation for the three months ended March 31, 2020 because their effect would have been anti-dilutive, as the Company was in a loss position.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

In March 2020, the FASB issued Update 2020-04 Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting to provide temporary optional guidance to ease the potential burden in accounting for reference rate reform. The amendments in Update 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR, formerly known as the London Interbank Offered Rate,

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

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Recently Adopted Accounting Pronouncements

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

CARES Act

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into U.S. federal law, which is aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, includes provisions related to refundable payroll tax credits, deferment of the employer portion of social security payments, net operating loss carryback periods, modifications to the net interest deduction limitations, and technical corrections to tax depreciation methods for qualified improvement property. Assessing the impact of this legislation, the Company does not expect there to be a material impact to our financial statements at this time.

4. Property and equipment, net

Property and equipment consisted of the following:

	March 31, 2020	December 31, 2019	Estimated Useful Life (years)
Furniture and fixtures	\$ 1,514	\$ 1,188	7
Office equipment	1,105	1,094	3
Equipment	3,203	3,095	7
Leasehold improvements	1,171	1,144	2
	<u>6,993</u>	<u>6,521</u>	
Less accumulated depreciation	(4,570)	(4,319)	
Property and equipment, net	<u>\$ 2,423</u>	<u>\$ 2,202</u>	

Depreciation expense related to property and equipment amounted to \$251 and \$242 for the quarter ended March 31, 2020 and 2019, respectively.

5. Inventories

Inventories consist of the following:

	March 31, 2020	December 31, 2019
Raw material	\$ 5,195	\$ 2,460
Work in process	2,486	3,243
Finished products	753	863
	<u>\$ 8,434</u>	<u>\$ 6,566</u>

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6. Balance Sheet Accounts

Prepaid and Other Current Assets

Prepaid and other current assets consist of the following:

	March 31, 2020	December 31, 2019
Prepaid income taxes	\$ 4,778	\$ 2,462
Prepaid FDA user fee and Advances to clinical research organization	2,080	6,345
Prepaid insurance	876	191
Advances to commercial manufacturers	2,206	4,661
All other	691	1,445
Total Prepaid expenses and other current assets	<u>\$ 10,631</u>	<u>\$ 15,104</u>

Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2020	December 31, 2019
Accrued sales reserves	\$ 6,019	\$ 8,364
Royalties payable to commercial partners	5,459	6,004
Accrued salary and other compensation	2,704	8,083
Accrued professional fees	2,441	1,926
Accrued research & development	873	1,686
Current portion of lease liability	1,267	1,101
Accrued other	1,360	1,197
Total Accrued expenses	<u>\$ 20,123</u>	<u>\$ 28,361</u>

Adoption of FASB ASU No. 2016-02, "Leases (Topic 842)" as of January 1, 2019

The Company leases its corporate office under an amended lease agreement that expires on June 30, 2025 (the "Corporate Office Lease"). The Corporate Office Lease was amended on August 8, 2019 to extend the term through such date and to increase the amount of leased office space. The Company also leases lab space under a lease agreement that expires on October 31, 2023 (the "Lab Space Lease"). The Company estimated the right of use asset and the corresponding lease liability, on a discounted basis, as of the adoption date of January 1, 2019. The future minimum lease payments under this Corporate Office Lease are approximately \$6.6 million.

For the Company's two operating leases (the Corporate Office Lease and Lab Space Lease), the depreciation and interest expense components are combined and recognized ratably over the remaining term of the lease as research and development and selling, general and administrative in the Company's condensed consolidated statements of operations, respectively.

The Company used its estimated incremental borrowing rate to calculate the present value of the right of use ("ROU") assets and lease liabilities as of the date of adoption date. The implicit interest rate related to the Company's two lease agreements was not known as of the date of adoption. Therefore, the Company calculated an incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment.

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Lease related disclosures consist of the following:

	March 31, 2020	December 31, 2019	March 31, 2019
ROU asset, net included in Other assets	\$ 4,337	\$ 3,716	\$ 2,871
Lease liability included with Other long-term liabilities	\$ 3,454	\$ 3,000	\$ 2,871
Lease liability included with Accrued expenses and other liabilities	\$ 1,267	\$ 1,101	\$ —
Quarter to date ("QTD") depreciation of ROU asset	\$ 221	n/a	\$ 261
QTD related rent expense	\$ 286	n/a	\$ 287
QTD operating cash flows from operating leases	\$ 286	n/a	\$ 287
QTD operating lease costs	\$ 286	n/a	\$ 287
Weighted-average remaining lease term - operating leases	4.7 years	5.0 years	2.8 years
Weighted-average discount rate - operating leases	6.5%	6%	6.4%

As of March 31, 2020, the future minimum lease commitments for the Company's two leases were as follows:

Total	2020	2021	2022	2023	2024	2025	Beyond
\$ 6,576	\$ 1,314	\$ 1,362	\$ 1,376	\$ 1,291	\$ 820	\$ 413	\$ —

As of December 31, 2019, the future minimum lease commitments for the Company's two leases were as follows:

Total	2020	2021	2022	2023	2024	2025
\$ 6,607	\$ 1,345	\$ 1,362	\$ 1,376	\$ 1,291	\$ 820	\$ 413

7. Intangible Assets, Net

The gross carrying amounts and net book value of the Company's intangible assets are as follows:

	Useful Life (In Years)	March 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Net Book Value
RYANODEX intangible (i)	20	\$ 15,000	\$ (2,715)	\$ 12,285
Developed technology	5	8,100	(5,468)	2,632
Total		\$ 23,100	\$ (8,183)	\$ 14,917

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

(i) Represent payments made to reduce the royalties payable to a third party on RYANODEX net sales.

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Amortization expense was \$666 and \$630 for the three months ended March 31, 2020 and 2019, respectively.

Estimated Amortization Expense for Intangible Assets

Based on definite-lived intangible assets recorded as of March 31, 2020, and assuming that the underlying assets will not be impaired and that the Company will not change the expected lives of the assets, future amortization expenses are estimated as follows:

Year Ending December 31,	Estimated Amortization Expense
2020 (remainder)	1,999
2021	2,623
2022	1,369
2023	1,570
2024	1,898
Thereafter	5,458
Total estimated amortization expense	<u>\$ 14,917</u>

8. Common Stock and Stock-Based Compensation

Common Stock

Share Repurchase Program

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

Under the Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The repurchases have no time limit and may be suspended or discontinued completely at any time. The specific timing and amount of repurchases will vary based on available capital resources and other financial and operational performance, market conditions, securities law limitations, and other factors. The repurchases will be made using the Company's cash resources.

On October 30, 2018, the Company announced the Previous Share Repurchase Program was approved by the Board of Directors pursuant to which the Company may have repurchased of up to \$150 million of its outstanding common stock, that consisted of (i) up to \$50 million in repurchases pursuant to an accelerated share repurchase agreement (the "ASR"), with JPMorgan Chase Bank, N.A. ("JPMorgan"), and (ii) up to \$100 million in additional repurchases.

As of March 31, 2020, the Company had repurchased an aggregate of 2,933,320 shares of common stock for an aggregate of \$172.9 million pursuant to its share repurchase programs.

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Stock-Based Compensation

In November 2013, the Company's Board of Directors approved the 2014 Equity Incentive Plan (the "2014 Plan") which became effective on February 11, 2014. The 2014 Plan provides for the awards of incentive stock options, non-qualified stock options, restricted stock, restricted stock units and other stock-based awards. Awards generally vest equally over a period of four years from grant date. Vesting may be accelerated under a change in control of the Company or in the event of death or disability to the recipient. In the event of termination, any unvested shares or options are forfeited.

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

A summary of stock option, RSU and PSU activity under the 2014 Plan during the three months ended March 31, 2020 and 2019 is presented below:

	Stock Options	RSUs	PSUs
Outstanding at December 31, 2018	2,556,365	54,219	117,219
Granted	550,433	211,829	—
Options Exercised/RSUs Vested/PSUs Vested	(4,914)	(13,555)	—
Forfeited or expired	(9,588)	(531)	(709)
Outstanding at March 31, 2019	<u>3,092,296</u>	<u>251,962</u>	<u>116,510</u>
Outstanding at December 31, 2019	3,096,161	251,215	116,181
Granted	600,200	231,450	—
Options Exercised/RSUs Vested/PSUs Vested	(15,971)	(66,142)	—
Forfeited or expired	(60,294)	(10,824)	(2,431)
Outstanding at March 31, 2020	<u>3,620,096</u>	<u>405,699</u>	<u>113,750</u>

Stock Options

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

	Three Months Ended	
	March 31,	
	2020	2019
Risk-free interest rate	0.47% - 1.65%	2.57% - 2.61%
Volatility	54.94%	50.47%
Expected term (in years)	6.03 years	5.98 years
Expected dividend yield	0.0%	0.0%

RSUs

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

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PSUs

The fair value of PSUs granted to employees was estimated using a Monte Carlo simulation model. Inputs used in the calculation include a risk-free interest rate of 2.06%, an expected volatility of 47%, contractual term of 3 years, and no expected dividend yield.

The Company recognized stock-based compensation in its condensed consolidated statements of operations for the three months ended March 31, 2020 and 2019 as follows:

	Three Months Ended March 31,	
	2020	2019
Stock options	\$ 4,993	\$ 4,428
RSUs	1,852	608
PSUs	627	746
Stock-based compensation expense	<u>\$ 7,472</u>	<u>\$ 5,782</u>
Selling, general and administrative	\$ 5,922	\$ 4,639
Research and development	1,550	1,143
Stock-based compensation expense	<u>\$ 7,472</u>	<u>\$ 5,782</u>

9. Commitments

Our future material contractual obligations as of March 31, 2020, include the following:

Obligations	Total	2020	2021	2022	2023	2024	2025	Beyond
Operating leases (1)	\$ 6,576	\$ 1,314	\$ 1,362	\$ 1,376	\$ 1,291	\$ 820	\$ 413	\$ —
Credit facility (2)	148,000	114,000	8,000	26,000	—	—	—	—
Purchase obligations (3)	21,033	21,033	—	—	—	—	—	—
Total obligations	<u>\$ 175,609</u>	<u>\$ 136,347</u>	<u>\$ 9,362</u>	<u>\$ 27,376</u>	<u>\$ 1,291</u>	<u>\$ 820</u>	<u>\$ 413</u>	<u>\$ —</u>

(1) We lease our corporate office location. On August 8, 2019, we amended the lease for our corporate office location in order to rent additional office space and extend the term of our existing lease to June 30, 2025. The Company also leases its lab space under a lease agreement that expires on October 31, 2023. Rental expense for the operating leases was \$286 and \$287, for the three months ended March 31, 2020 and 2019. The remaining future lease payments under the operating leases are \$6,576 as of March 31, 2020.

(2) Refer to Note 10 Debt for details of the Revised Credit Agreement entered into as of November 8, 2019.

(3) As of March 31, 2020, the Company has purchase obligations in the amount of \$21,033 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.

10. Debt

On November 8, 2019, the Company entered into the Second Amended and Restated Credit Agreement (the "Revised Credit Agreement"), with JPMorgan Chase Bank, N.A., as administrative agent (the "Agent") and the lenders party thereto, which replaced the Company's existing credit agreement, dated as of August 8, 2017 (the "Amended Credit Agreement"). The terms and amounts borrowed under the Revised Credit Agreement includes a drawn term loan of \$40.0 million and a undrawn

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revolving credit facility of \$110.0 million. The schedule of principal payments for the new term loan facility has been extended until November 8, 2022. As of March 31, 2020, the terms and amounts borrowed under the Revised Credit Agreement includes a drawn term loan of \$40.0 million and a drawn revolving credit facility of \$110.0 million. The Company classified the current portion of long-term debt of \$116.0 million on the consolidated balance sheet as of March 31, 2020. Per the terms of the Revised Credit Agreement, the Company is limited in its ability to pay dividends. As of March 31, 2020, the Company was in compliance with each of the senior secured net leverage ratio; total net leverage ratio; and fixed charge coverage ratio covenants. The Company has repaid the full \$110.0 million drawn under its revolving credit facility as of the date of this Quarterly Report.

The new term loan facility shall bear interest at the Adjusted LIBOR (equal to (a) the LIBOR for such Interest Period multiplied by (b) the Statutory Reserve Rate as established by Board of Governors of the Federal Reserve System of the United States of America) for the Interest Period in effect for such Borrowing plus the Applicable Rate as described below. The Agent and the Company may amend the Revised Credit Agreement to replace the LIBOR with a Benchmark Replacement, described below.

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

The Company is required to pay a commitment fee on the unused portion of the new revolving credit facility in the Revised Credit Agreement at a rate ranging from 0.35% to 0.45% per annum based upon the total net leverage ratio. The Company is obligated to repay a contractually agreed portion of the term loan on the last day of each March, June, September and December in accordance with the Revised Credit Agreement.

As of March 31, 2020, the Company has \$1.2 million of unamortized deferred debt issuance costs as part of long-term debt in its condensed consolidated balance sheets.

Debt Maturities	As of March 31, 2020	
2020 (remainder)	\$	114,000
2021		8,000
2022		26,000
Total	\$	148,000

11. Income Taxes

	Three Months Ended March 31,	
	2020	2019
Income tax benefit (provision)	\$ 137	\$ (3,004)
Effective tax rate	5%	25%

For interim periods, we recognize an income tax (provision) benefit 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 temporary and estimated permanent differences, and certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur.

The provision for income taxes was based on the applicable federal and state tax rates for those periods. The effective tax rate for the three months ended March 31, 2020 reflects the impact of a valuation allowance established for the fair value adjustment on the Company's investment in Tyme, certain non-deductible executive compensation partially offset by credits for research and

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development activity. The effective tax rate for the three months ended March 31, 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity.

Deferred income tax assets as of March 31, 2020 consist of temporary differences primarily related to stock-based compensation and research and development tax credit carryforwards, partially offset by temporary differences related to intangible assets.

The Company files income tax returns in the U.S. federal jurisdiction and several states. Given that the Company has incurred tax losses since its inception, all of the Company's tax years are effectively open to examination. The Company is currently under audit by one State tax jurisdiction. The Company has no amount recorded for any unrecognized tax benefits as of March 31, 2020. The Company regularly evaluates its tax positions for additional unrecognized tax benefits and associated interest and penalties, if applicable. There are many factors that are considered when evaluating these tax positions including: interpretation of tax laws, recent tax litigation on a position, past audit or examination history, and subjective estimates and assumptions. The Company reflects interest and penalties attributable to income taxes, to the extent they arise, as a component of income tax provision or benefit.

12. Legal Proceedings

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

Commercial Litigation

In Re: Taxotere (Docetaxel)

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

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

Eagle v. Burwell

On April 27, 2016, the Company filed an action in the U.S. District Court for the District of Columbia (the "District Court") against the FDA and other federal defendants seeking an order requiring the FDA to recognize orphan drug exclusivity for Bendeka for the treatment of CLL and indolent B-cell NHL. On June 8, 2018, the District Court issued a decision requiring the FDA to recognize seven years of orphan drug exclusivity in the U.S. for Bendeka, and on July 6, 2018 the FDA recognized such ODE until December 7, 2022. In addition, on July 6, 2018, the FDA submitted a Motion to Alter or Amend the Judgement Pursuant to Rule 59(e), pursuant to which the FDA requested that the District Court amend its decision to make clear that the decision does not affect any applications referencing TREANDA. The FDA's motion was denied by the District Court on August 1, 2018 on the grounds that the FDA had not satisfied the standard for altering or amending the judgment. The FDA and two intervenors appealed the District Court's final judgment to the U.S. Court of Appeals for the District of Columbia Circuit (the "Court of Appeals"). Oral arguments occurred on October 17, 2019, and on March 13, 2020 a panel of the Court of Appeals affirmed the District Court's decision. FDA has until May 27, 2020 to file a petition for rehearing *en banc*. Previously, on February 20, 2019, the FDA issued a decision in favor of the Company, regarding the scope of orphan drug exclusivity for

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Bendeka. Pursuant to the FDA's decision, no bendamustine product used to treat the same indications (including generic versions of TREANDA) may launch in the United States until December 7, 2022 unless it is clinically superior to Bendeka.

Eagle v. Eli Lilly

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

Chiesi v. Eagle

On October 3, 2018, Chiesi USA, Inc. ("Chiesi") filed a complaint against Eagle in the Superior Court of Wake County, North Carolina. The complaint alleges that Eagle has failed to provide adequate information regarding the sales of Argatroban pursuant to a License and Development Agreement between the parties. On July 17, 2019, Chiesi dismissed the actions without prejudice.

Patent Litigation

Eli Lilly and Company. v. Eagle Pharmaceuticals, Inc. (PEMFEXYTM (Pemetrexed))

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

On September 8, 2017, Eagle moved to dismiss the Indiana Suit for improper venue. On September 11, 2017, Lilly voluntarily dismissed the Indiana Suit. It then filed a complaint in the United States District Court for the District of Delaware, alleging similar patent infringement claims (the "Delaware Suit"). Eagle answered and filed various counterclaims in the Delaware Suit on October 3, 2017. Lilly answered Eagle's counterclaims on October 24, 2017. The Court held a scheduling conference on December 11, 2017 and set trial in the Delaware Suit to begin on September 9, 2019, but later rescheduled trial to begin October 28, 2019. On May 31, 2018, Eagle filed a Motion for Judgment on the Pleadings, which the Court denied on October 26, 2018. On January 23, 2019, the Court held a Markman hearing. Trial took place from October 28, 2019 to October 31, 2019 and is scheduled to continue on December 12, 2019 through December 13, 2019. On December 13, 2019, the Company and Lilly settled this litigation. The agreement provides for a release of all claims by the parties and allows for an initial entry of PEMFEXYTM into the market (equivalent to approximately a three week supply of current ALIMTA® utilization) on February 1, 2022 and a subsequent uncapped entry on April 1, 2022. On December 16, 2019, the District Court entered the Company and Lilly's stipulation dismissing this case with prejudice.

Eagle Pharmaceuticals, Inc., 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.; Eagle Pharmaceuticals, Inc. et al v. Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd - (Bendeka®)

Bendeka, which contains bendamustine hydrochloride, is an alkylating drug that is indicated for the treatment of patients with chronic lymphocytic leukemia, as well as for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Slayback Pharma Limited Liability Company ("Slayback"), Apotex Inc. and Apotex Corp. ("Apotex"), Fresenius Kabi USA, LLC ("Fresenius"),

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Mylan Laboratories Limited (“Mylan”), Lupin, Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”), and Aurobindo Pharma, Ltd, Aurobindo Pharma USA, Inc., and Eugia Pharma Specialities Ltd (“Aurobindo”) have filed Abbreviated New Drug Applications (“ANDA’s”) referencing Bendeka® that include challenges to one or more of the Bendeka® Orange Book-listed patents. Hospira, Inc. (“Hospira”) filed a 505(b)(2) NDA.

The Company, Cephalon, Inc. and/or Teva Pharmaceuticals International GMBH (together the “Patentees”), filed separate suits against Slayback, Apotex, Fresenius, Mylan, Hospira, Lupin, and Aurobindo in the United States District Court for the District of Delaware on August 16, 2017 (Slayback (“Slayback I”)), August 18, 2017 (Apotex), August 24, 2017 (Fresenius), December 12, 2017 (Mylan), January 19, 2018 (Slayback (“Slayback II”)), July 19, 2018 (Hospira), and July 2, 2019 (Lupin) 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. Patentees expect to file suit against Aurobindo the week of May 11, 2020. 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. Under this decision, the FDA cannot approve Slayback, Apotex, Fresenius and Mylan before 2031. 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. Trial is set for November 15, 2021. The case remains pending.

The FDA is stayed from approving Hospira’s 505(b)(2) application until the earlier of (1) December 20, 2020 (the “30-month stay date”); and (2) a court decision that the ‘887 patent is not infringed, invalid, or unenforceable. The 30-month stay dates may be shortened or lengthened if either party to the action fails to reasonably cooperate in expediting the action.

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

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

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

Slayback filed a 505(b)(2) NDA referencing Eagle’s BELRAPZO NDA. Slayback’s NDA includes challenges to one or more of the BELRAPZO Orange Book-listed patents. On December 11, 2018, the Company filed a suit against Slayback in the United States District Court for the District of Delaware, alleging patent infringement of U.S. Patent Nos. 9,265,831, 9,572,796, 9,572,797, and 10,010,533. On January 4, 2019, Slayback filed a motion for judgment on the pleadings. On May 9, 2019, the United States District Court for the District of Delaware granted Slayback’s motion for judgment on the pleadings. On July 23, 2019, the Company filed an appeal of this decision with the United States Court of Appeals for the Federal Circuit. On May 8, 2020, the Federal Circuit upheld the district court’s decision.

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Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals, Inc. (Vasopressin)

On May 31, 2018, Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (together “Par”) filed suit against the Company in the United States District Court for the District of Delaware. Par alleged patent infringement based on the filing of the Company’s ANDA seeking approval to manufacture and sell the Company’s vasopressin product. The Company’s vasopressin product, if approved by FDA, will be an alternative to Vasostrict, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. The Company answered the complaint on August 6, 2018, and filed an amended answer and counterclaims on October 30, 2019. The court issued a Markman ruling on July 1, 2019. On December 20, 2019, Par dismissed with prejudice claims of three of the patents asserted against Eagle, and the Court entered an Order reflecting that dismissal on December 27, 2019. Mediation took place on March 3, 2020. On April 17, 2020, the Company submitted a letter requesting leave to file a motion for summary judgment of non-infringement. Par’s responsive letter was submitted on May 8, 2020. Due to the COVID-19 pandemic, trial, which was scheduled to begin May 18, 2020, has been adjourned to a future date. The court scheduled a status conference on May 18, 2020. This suit is pending.

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

On March 27, 2019, the Company and Chiesi filed suit against Accord Healthcare, Inc. (“Accord”) in the United States District Court for the District of New Jersey (the “New Jersey suit”) and in the United States District Court for the Middle District of North Carolina (the “North Carolina suit”) (together “the suits”). The suits alleged patent infringement based on Accord’s 505(b)(2) NDA seeking approval to manufacture and sell Accord’s proposed argatroban product. On May 21, 2019, the Company and Chiesi voluntarily dismissed the North Carolina suit. On July 10, 2019, Accord moved for judgment on the pleadings in the New Jersey suit. The New Jersey suit is currently pending.

13. Collaboration with Tyme

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

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

- (a) an initial \$20.0 million upfront payment. In return, we received 10 million restricted shares of Tyme’s common stock at \$2.00 per share. The Company is contractually restricted from selling its investment in Tyme for up to three years; and
- (b) a second potential \$20.0 million milestone payment upon the earlier of (i) the successful completion of a pivotal trial in pancreatic cancer or (ii) FDA approval of SM-88 in any cancer indication within the United States. Upon occurrence of such milestone event, this payment would be split into a \$10.0 million one-time milestone cash payment and a \$10.0 million additional investment in Tyme’s preferred stock. The preferred shares will be convertible into common stock with a conversion price at a 15% premium to the then-prevailing common stock market price per share.

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

Under the terms of the agreement, the initial \$20.0 million paid to Tyme, was accounted for as a \$17.5 million readily determinable fair value equity investment based on the closing price per share of Tyme’s common stock on January 7, 2020. The remainder was treated as an upfront collaboration payment of \$2.5 million that was recorded as selling, general and administrative expense in the first quarter of 2020. The investment in Tyme represents approximately 9% of the total shares outstanding of Tyme’s common stock.

As of March 31, 2020, the Company included its investment in Tyme in Other Assets (non-current) on its condensed consolidated balance sheet. For the three months ended March 31, 2020, the fair value adjustments for the equity investment was \$6.5 million which was recorded in Other expense of our condensed consolidated statements of operations.

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 2, 2020, or the 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 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 FDA approval and commercial launches of three products: RYANODEX, BELRAPZO and BENDEKA. We market our products through marketing partners and/or our internal direct sales force. We market RYANODEX and BELRAPZO, and Teva markets BENDEKA through its subsidiary, Cephalon, Inc. Reflecting further expansion of our oncology portfolio, in February 2020, we received final FDA approval for PEMFEXY, a branded alternative to ALIMTA for metastatic nonsquamous nonsmall cell lung cancer and malignant pleural mesothelioma. We expect to launch PEMFEXY in early 2022.

With 11 pipeline projects underway and the potential for up to five or more product launches over the next several years, we believe we have many growth opportunities ahead. We believe that each of our pipeline projects currently has the potential to enter the market as a first-in-class, first-to-file or best-in-class product. In particular, we are applying our expertise to conduct novel research regarding the potential for RYANODEX to address conditions including exertional heat stroke, Alzheimer’s disease, traumatic brain injury/concussion, nerve agent exposure and acute radiation syndrome. In addition, our clinical development program includes a strategic partnership with Tyme for SM-88, a product candidate for the treatment of patients with pancreatic or other advanced cancers, as well as investigations of compounds such as EA-114 and our Fulvestrant product candidate for patients with HR-positive advanced breast cancer. Other products in development include Vasopressin, our first-to-file ANDA that references Endo International plc’s Vasostrict indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; and EA-111, a new chemical entity and next-generation ryanodine receptor antagonist, in an intramuscular formulation that that would allow for easier and more rapid administration in emergency situations (military and civilian).

Recent Developments

Clinical Trial of RYANODEX

On April 16, 2020, we announced that our product RYANODEX (dantrolene sodium) for injectable suspension was demonstrated to inhibit the growth of SARS-CoV-2, the virus causing the COVID-19 pandemic, in a controlled *in vitro* laboratory test. On April 14, 2020, we submitted Investigational New Drug (“IND”) application to U.S. Food and Drug Administration (“FDA”) for a Phase 2 clinical trial in partnership with Hackensack University Medical Center to evaluate the efficacy of RYANODEX (dantrolene sodium) in patients infected with SARS-CoV-2, the virus causing the COVID-19 pandemic. We have been in contact with the FDA’s Coronavirus Treatment Acceleration Program, or CTAP, to request potential expedited review of the IND application with the aim of beginning the clinical trial as soon as possible. We are partnering with Hackensack University Medical Center to conduct the controlled Phase 2 clinical trial in patients with COVID-19 to evaluate the effectiveness and safety of RYANODEX for the treatment of COVID-19 as adjunctive treatment to current standard of care. The World Health Organization Ordinal Scale of Severity, the Sequential Organ Failure Assessment and other relevant clinical

measurements will be used as efficacy endpoints. If we receive FDA authorization of our IND application, we expect the trial to begin enrolling approximately 60 adult patients hospitalized with COVID-19 and with confirmed SARS-CoV-2 infection in May 2020.

New Share Repurchase Program

On March 17, 2020, we announced that our Board approved a new share repurchase program, or the Share Repurchase Program, providing for the repurchase of up to an aggregate of \$160.0 million of our outstanding common stock. The Share Repurchase Program replaces our existing share repurchase program, or the Previous Share Repurchase Program, which was announced on October 30, 2018 and was terminated in connection with the Board's approval of the Share Repurchase Program. At termination, we had repurchased approximately \$68.0 million of our outstanding common stock under the Previous Share Repurchase Program. On October 30, 2018, we announced that our Board had approved a share repurchase program providing for the repurchase of up to \$150.0 million of our outstanding common stock, that consisted of (i) up to \$50.0 million in repurchases pursuant to an accelerated share repurchase agreement, or the ASR, with JPMorgan Chase Bank, N.A., or JPMorgan, and (ii) up to \$100.0 million in additional repurchases, or, collectively, the 2018 Share Repurchase Program. In connection with its approval of the 2018 Share Repurchase Program, the Board terminated our 2016 Share Repurchase Program and 2017 Share Repurchase Program in October 2018. As of March 31, 2020, we have repurchased an aggregate of 2,933,320 shares of common stock for \$172.9 million.

COVID-19 Business Update

With the global spread of the ongoing COVID-19 pandemic in the first quarter of 2020, we have taken precautions to help ensure the safety and well-being of our team members and the patients and healthcare providers who rely on our products, and have implemented processes and technologies to minimize disruption to our business and mitigate the impact of the COVID-19 pandemic on our stakeholders. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global healthcare systems and other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected. We continue to closely monitor the COVID-19 situation as we evolve our business plans and response strategy. The impact of COVID-19 pandemic on our business and financial condition is more fully described below in *Trends and Uncertainties*.

Financial Operations Overview

Revenue

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

Product Sales. Through March 31, 2020, we have recognized revenues from product sales of BENDEKA, Argatroban, RYANODEX and BELRAPZO. Sales of BENDEKA were made to our commercial partner Teva, while Argatroban was sold directly to our commercial partners Chiesi and Sandoz AG, or Sandoz. Sales to our commercial partners are typically made at little or no profit for resale. RYANODEX and BELRAPZO were sold directly to wholesalers, hospitals and surgery centers through a third-party logistics partner.

We typically enter into agreements with group purchasing organizations acting on behalf of their hospital members, in connection with the hospitals' purchases of our direct commercial products. Based on these agreements, most of our hospital customers have contracted prices for products and volume-based rebates on product purchases. These amounts are estimated and recorded at the time of sale. In the case of discounted pricing, we typically pay a chargeback, representing the difference between the price invoiced to the wholesaler and the customer contract price.

Royalty Revenue. We recognize revenue from royalties based on a percentage of Teva's net sales of BENDEKA and Sandoz's and Chiesi's gross profit of Argatroban, both net of discounts, returns and allowances incurred by our commercial partners. Royalty revenue is recognized as earned in accordance with contract terms when it can be reasonably estimated and collectability is reasonably assured.

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

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

- the level of orders submitted by our commercial partner, Teva;
- the rate at which Teva can convert the current market to BENDEKA;
- the level of institutional demand for BENDEKA;

- unit sales prices charged by Teva, net of any sales reserves; and
- the level of orders submitted by wholesalers, hospitals and surgery centers.

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

- the level of orders submitted by our commercial partners, Sandoz and Chiesi;
- the level of institutional demand for Argatroban; and
- unit sales prices charged by Sandoz and Chiesi, net of any sales reserves.

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

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

Cost of Revenues

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

Research and Development

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

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

Selling, General and Administrative

Selling, general and administrative costs consist primarily of salaries, benefits and other related costs, including 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.

Results of Operations

Comparison of Three Months Ended March 31, 2020 and 2019

Revenues

	Three Months Ended March 31,		Increase / (Decrease)
	2020	2019	
	(in thousands)		
Product sales	\$ 17,694	\$ 14,472	\$ 3,222
Royalty revenue	28,326	26,313	2,013
License and other revenue	—	9,000	(9,000)
Total revenue	<u>\$ 46,020</u>	<u>\$ 49,785</u>	<u>\$ (3,765)</u>

Product sales increased \$3.2 million in the three months ended March 31, 2020 as compared to the three months ended March 31, 2019. The contributing factors to the increase primarily included an increase of \$7.4 million in product sales of RYANODEX®(dantrolene sodium) and a \$1.3 million increase in BELRAPZO. These increased sales were partially offset by a decrease of \$5.0 million in product sales of BENDEKA primarily due to volume decrease.

Royalty revenue increased \$2.0 million in the three months ended March 31, 2020 as compared to the three months ended March 31, 2019 as a result of a \$2.0 million increase in royalty revenue from our share of Teva's BENDEKA sales.

The decrease in License and other revenue for the quarter ended March 31, 2020 was due to the non-recurrence of an upfront cash payment of \$9.0 million upon execution of an amendment to the Cephalon License to terminate Teva's obligation to pay future milestones and royalties on Bendeka sales outside of the U.S that was executed in the three months ended March 31, 2019.

Cost of Revenue

	Three Months Ended March 31,		Decrease
	2020	2019	
	(in thousands)		
Cost of product sales	\$ 4,765	\$ 9,554	\$ (4,789)
Cost of royalty revenue	3,038	3,546	(508)
Total cost of revenue	<u>\$ 7,803</u>	<u>\$ 13,100</u>	<u>\$ (5,297)</u>

Cost of product sales decreased \$4.8 million in the three months ended March 31, 2020 to \$4.8 million as compared to \$9.6 million in the three months ended March 31, 2019, primarily as a result of the decrease in product sales for BENDEKA of \$5.0 million.

Cost of royalty revenue decreased \$0.5 million in the three months ended March 31, 2020 to \$3.0 million as compared to \$3.5 million in the three months ended March 31, 2019, primarily as a result of the decrease in royalty revenue for BENDEKA.

Research and Development

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

	Three Months Ended March 31,		Increase / (Decrease)
	2020	2019	
	(in thousands)		
Fulvestrant "EGL-5385-C-1701"	\$ 2,801	\$ 187	\$ 2,614
Vasopressin	283	1,317	(1,034)
RYANODEX EHS "EP-4104"	1,287	\$ 555	732
All other projects	641	\$ 926	(285)
Salary and other personnel related	<u>\$ 4,415</u>	<u>\$ 3,390</u>	<u>1,025</u>
Research and development	<u>\$ 9,427</u>	<u>\$ 6,375</u>	<u>\$ 3,052</u>

Research and development expenses increased \$3.1 million in the three months ended March 31, 2020 to \$9.4 million as compared to \$6.4 million in the three months ended March 31, 2019. The increase primarily resulted from our increased project spending for EGL-5385-C-1701 (the Company's Fulvestrant formulation) of \$2.6 million coupled with increased project spending for RYANODEX® (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke ("EHS") of \$0.7 million and increased personnel related costs of \$1.0 million, partially offset by decreased spending for Vasopressin of \$1.0 million.

Selling, General and Administrative

	Three Months Ended March 31,		
	2020	2019	Increase
	(in thousands)		
Selling, general and administrative	\$ 24,755	\$ 18,141	\$ 6,614

Selling, general and administrative expenses increased \$6.6 million for the three months ended March 31, 2020 to \$24.8 million as compared to \$18.1 million for the three months ended March 31, 2019. This increase is primarily related to \$2.5 million of costs related to the collaboration with Tyme, coupled with an increase of \$1.4 million in external legal fees resulted from ongoing litigation matters coupled with an increase of stock compensation costs of \$1.3 million and an increase of direct marketing costs of \$0.5 million and severance costs of \$0.2 million.

Other Expense

	Three Months Ended March 31,		
	2020	2019	Decrease
	(in thousands)		
Interest income	\$ 346	\$ 494	\$ (148)
Interest expense	(889)	(686)	(203)
Other expense	(6,500)	—	(6,500)
Total other expense, net	\$ (7,043)	\$ (192)	\$ (6,851)

Interest income decreased \$148.0 thousand for the three months ended March 31, 2020 primarily due to lower interest rates associated with money market funds as compared to the three months ended March 31, 2019.

Interest expense increased for the three months ended March 31, 2020 as compared to the three months ended March 31, 2019 primarily due to higher total long-term debt outstanding primarily due to additional borrowings from the revolving credit facility.

On January 7, 2020, the Company announced a strategic collaboration with Tyme that included an initial \$20.0 million upfront payment. In return, we received 10 million restricted shares of Tyme's common stock which was accounted for as a \$17.5 million readily determinable fair value equity investment based on the closing price per share of Tyme's common stock on January 7, 2020. The remainder was treated as an upfront collaboration payment of \$2.5 million that was recorded as research and development expense in the first quarter of 2020. For the three months ended March 31, 2020, the Company marked its investment in Tyme to market based on its ending closing price per share as of March 31, 2020 and recorded a \$6.5 million loss.

Income Tax Benefit (Provision)

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Benefit (Provision) for income taxes	\$ 137	\$ (3,004)
Effective tax rate	5%	25%

The benefit (provision) for income taxes was based on the applicable federal and state tax rates. The effective tax rate for the three months ended March 31, 2020 reflects the impact of a valuation allowance established for the fair value adjustment on the Company's

investment in Tyme, certain non-deductible executive compensation partially offset by credits for research and development activity. The effective tax rate for the three months ended March 31, 2019 reflects the impact of certain non-deductible executive compensation partially offset by credits for research and development activity.

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, product development costs and operating expenses. Cash and cash equivalents were \$202.0 million and \$102.1 million as of March 31, 2020 and March 31, 2019, respectively.

For the three months ended March 31, 2020, we generated a net loss of \$2.9 million. As of March 31, 2020, our working capital surplus was \$129.7 million. For the three months ended March 31, 2019, we realized net income of \$9.0 million.

We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for the next 12 months.

The COVID-19 pandemic is disrupting the U.S. healthcare system, as well as global capital markets. There are significant uncertainties surrounding the extent and duration of the impact of the COVID-19 pandemic on our business and operations. The COVID-19 pandemic could have a material adverse impact on our financial condition and results of operations in the future, including our ability to obtain financing. The impact of COVID-19 on our business and financial condition is more fully described below in *Trends and Uncertainties*

Operating Activities:

Net cash provided by operating activities for the three months ended March 31, 2020 was \$3.2 million. Net loss for the period was \$2.9 million enhanced by the net of non-cash adjustments of approximately \$15.1 million from deferred income taxes, depreciation, amortization of intangible assets, stock-based compensation expense, fair value adjustment on an equity investment and amortization of debt issuance costs. Net changes in working capital increased cash from operating activities by approximately \$9.0 million, due to changes in working capital accounts. The total amount of accounts receivable at March 31, 2020 was approximately \$54.5 million, which included \$24.5 million related to product sales and \$30.0 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:

In the three months ended March 31, 2020, we invested \$17.5 million to purchase 10 million restricted shares of Tyme's common stock and spent \$0.5 million for purchases of property and equipment.

Financing Activities:

Net cash provided by financing activities for the three months ended March 31, 2020 was \$107.1 million, primarily as a result of drawing down from the revolving credit facility for \$110.0 million coupled with \$0.1 million of proceeds from common stock option exercises by employees partially offset by payments associated with employee withholding tax upon vesting of stock-based awards of \$1.0 million and principal payments for debt required by the Amended Credit Agreement of \$1.0 million and payments related to the repurchases of our common stock of \$1.0 million.

The Company has repaid the full \$110.0 million drawn under its revolving credit facility as of the date of this Quarterly Report.

Trends and Uncertainties

Impact of the COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared a global pandemic and recommended containment and mitigation measures worldwide. On March 13, 2020, the President of the United States declared a national emergency relating to the pandemic. Government authorities in the United States have recommended or imposed various social distancing, quarantine, and isolation measures on large portions of the population, and similar measures have also been taken in many other countries around the world. Both the COVID-19 pandemic and the containment and mitigation efforts related to the pandemic have had a serious adverse impact on the U.S. economy and the economies of other countries around the world, the severity and duration of which are uncertain.

During the three months ended March 31, 2020, we incurred an insignificant amount of incremental administrative costs related to the COVID-19 pandemic. The COVID-19 pandemic, including containment and mitigation measures, however, has impacted, and is expected to continue to impact, our business and operations in a number of ways, including:

- *Day-to-Day Operations:* Since mid-March 2020, our employees, including customer-facing employees, have been working remotely. The duration and extent of these restrictions are uncertain. We have developed plans to resume in-person work practices as we determine it to be safe to do so and pending relevant health authority guidance. We expect to incur additional expenses in 2020 related to the impact of the COVID-19 pandemic on our operations, including procurement of personal protective equipment for our employees and maintenance of our facilities to align with safety protocols.
- *Manufacturing and Supply Chain:* We are working closely with our commercial partners and third-party manufacturers to mitigate potential disruptions as a result of the COVID-19 pandemic by continuing to monitor the supply and availability of BENDEKA, RYANODEX and BELRAPZO for the patients who rely on these products. As of the date of this Quarterly Report, the COVID-19 pandemic has not caused significant disruptions to manufacturing operations or supply of our commercial products in the United States or of clinical trial material for our ongoing trials, no significant additional costs have been incurred and we currently expect to have adequate commercial product availability of BENDEKA, RYANODEX and BELRAPZO in 2020. While the supply disruptions we have experienced in 2020 have been minor, if the COVID-19 pandemic persists for an extended period of time and begins to impact essential distribution systems such as FedEx and postal delivery, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and our clinical supply, which would adversely impact our development activities.
- *Marketing and Sale of Products:* Although we did not see a material impact on our product revenues in the three months ended March 31, 2020, we are expecting an impact on our near-term financial results as a result of the COVID-19 pandemic. In the three months ended March 31, 2020, we have 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 and desire to avoid contact with infected individuals. In addition, our sales and marketing teams have been working remotely, and we cannot predict how effective our virtual initiatives will be with respect to marketing and supporting the sale and administration of our products, or when we will be able to resume in-person sales and marketing activities.
- *Liquidity and Capital Resources:* We believe that future cash flows from operations will be sufficient to fund our currently anticipated working capital requirements for the next 12 months. While we do not expect the COVID-19 pandemic to have a material adverse effect on our liquidity, the situation continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital when and if needed. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate distribution of our commercialized products, product portfolio expansion or some or all of our research and development programs, which would adversely affect our business prospects. We expect to use future loans, if any, under the 2019 Credit Agreement, for general corporate purposes and any strategic acquisitions.
- *Regulatory Activities:* With respect to regulatory activities, to date, FDA has not notified us of any delays impacting our Prescription Drug User Fee Act, or PDUFA, action date for our NDA for RYANODEX (dantrolene sodium for injectable suspension) for the treatment of exertional heat stroke. However, it is possible that we could experience delays in the timing of NDA review and/or our interactions with FDA due to, for example, absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of FDA's efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay approval decisions with respect to the NDA for RYANODEX for exertional heat stroke and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals.

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. Although the COVID-19 pandemic did not materially impact our results of operations during the three months ended March 31, 2020, it could have a material adverse impact on our financial condition and results of operations in the future.

Contractual Obligations

Other than as set forth below, there have been no material changes to our contractual and commercial obligations during the three months ended March 31, 2020, as compared to the obligations disclosed in our Annual Report.

Our future material contractual obligations included the following as of March 31, 2020, (in thousands):

Obligations	Total	2020	2021	2022	2023	2024	2025	Beyond
Operating leases (1)	\$ 6,576	\$ 1,314	\$ 1,362	\$ 1,376	\$ 1,291	\$ 820	\$ 413	\$ —
Credit facility (2)	148,000	114,000	8,000	26,000	—	—	—	—
Purchase obligations (3)	21,033	21,033	—	—	—	—	—	—
Total obligations	\$ 175,609	\$ 136,347	\$ 9,362	\$ 27,376	\$ 1,291	\$ 820	\$ 413	\$ —

(1) We lease our corporate office location. On August 8, 2019, we amended the lease for our corporate office location in order to rent additional office space and extend the term of our existing lease to June 30, 2025. The Company also leases its lab space under a lease agreement that expires on October 31, 2023.

(2) Refer to Note 10 Debt for details of the Revised Credit Agreement entered into as of November 8, 2019.

(3) As of March 31, 2020, the Company has purchase obligations in the amount of \$21.0 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.

Recent Accounting Pronouncements

Recent Accounting Pronouncements - Not Yet Adopted

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

Recently Adopted Accounting Pronouncements

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

Off-Balance Sheet Arrangements

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

Impact of Inflation

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

During the three months ended March 31, 2020, 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 potential impacts of the COVID-19 pandemic on our business. While the potential 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 March 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2020 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 12. Legal Proceedings in the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report are incorporated into this Part II, Item 1 by reference.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except for the updated risk factors set forth immediately below, our risk factors have not changed materially from those described in “Part I, Item 1A. Risk Factors” of our Annual Report.

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

On March 11, 2020, the World Health Organization made the assessment that a novel strain of coronavirus, which causes the COVID-19 disease, can be characterized as a pandemic. The President of the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the United States have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing “shelter-in-place” orders which direct individuals to shelter at their places of residence (subject to limited exceptions). In addition, in mid-March 2020, we implemented work-from-home policies for the majority of our employees. Our work-from-home policies may negatively impact productivity or disrupt our business, the magnitude of which will depend, in part, on the length of this remote working arrangement and other limitations on our ability to conduct our business in the ordinary course. We expect to work from home in the near future and will closely follow the guidance from federal and state authorities, including the Centers for Disease Control and Prevention and the New Jersey Department of Health, in deciding when to transition back to working in our offices. The effects of government actions and our policies and those of third parties to reduce the spread 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 may be adversely impacted by COVID-19 and actions taken to slow its spread. Although we did not see a material impact on our product revenues in the first quarter of 2020, we are expecting an impact on our near-term financial results, and other parts of our business have been, and continue to be, impacted by the outbreak. For example, patients may 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 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 and desire to avoid contact with infected individuals. We also cannot predict how effective our virtual initiatives will be with respect to marketing and supporting the sale and administration of our products, or when we will be able to resume in-person sales and marketing activities.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could 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 have been 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 COVID-19, 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 may be affected by COVID-19. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward COVID-19. Current or potential patients in our ongoing or planned clinical trials may also choose 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 impede patient

movement or interrupt healthcare services. Some clinical sites in the United States have started to slow or stop further enrollment of new patients in clinical trials, denied access to site monitors or otherwise curtailed certain operations. For example, our timeline for EA-114, Tyme's timeline for SM-88 or the development timelines for any of our other clinical or preclinical programs may experience delays because of these factors. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may 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 may also materially affect us economically. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently 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 continue to 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, COVID-19 may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future 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 may impact the marketing, sale and commercialization of our products, our supply chain, our clinical trials, our access to capital and our business development activities, will depend 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 and the impact on the economy and capital markets.

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

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

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

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

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

Issuer Purchases of Equity Securities

Share Repurchase Program

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

Under the Share Repurchase Program, the Company is authorized to repurchase shares through open market purchases, privately-negotiated transactions, accelerated share repurchases or otherwise in accordance with applicable federal securities laws, including through Rule 10b5-1 trading plans and under Rule 10b-18 of the 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 the Company's cash resources.

The Company made the following purchases of our equity securities during the period covered by this Quarterly Report.

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)
January 1, 2020 to January 31, 2020	—	N/A	—	82,039
February 1, 2020 to February 29, 2020	—	N/A	—	82,039
March 1, 2020 to March 31, 2020	25,633	\$ 39.03	25,633	158,999
Total	<u>25,633</u>		<u>25,633</u>	

(1) All shares repurchased by the Company during the first quarter of 2020 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	<u>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)</u>
3.2	<u>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)</u>
10.1	<u>Securities Purchase Agreement, dated January 7, 2020, between the Registrant and Tyme Technologies Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-36306, filed January 8, 2020)</u>
10.2	(1) <u>Co-Promotion Agreement, dated January 7, 2020, between the Registrant and Tyme Technologies Inc.</u>
31.1	(1) <u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	(1) <u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	** <u>Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
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.

**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 of such Form 10-Q), 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: May 11, 2020

By: /s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

DATED: May 11, 2020

By: /s/ Pete A. Meyers

Pete A. Meyers
Chief Financial Officer
(Principal Accounting and Financial Officer)

CO-PROMOTION AGREEMENT

by and between

TYME TECHNOLOGIES, INC.
And

EAGLE PHARMACEUTICALS, INC.

January 7, 2020

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CO-PROMOTION AGREEMENT

This Co-Promotion Agreement (this “**Agreement**”) is entered into and dated as of January 7, 2020 (the “**Effective Date**”) by and between Tyme Technologies, Inc., a Delaware corporation (“**TYME**”), and Eagle Pharmaceuticals, Inc., a Delaware corporation (“**Eagle**”). TYME and Eagle are each referred to individually as a “**Party**” and together as the “**Parties**”.

RECITALS

WHEREAS, TYME is an emerging biotechnology company developing cancer metabolism-based therapies and owns or otherwise controls certain intellectual property rights, clinical data and regulatory filings related to the compound SM-88 (racemetyrosine) (defined below), which is the subject of clinical development;

WHEREAS, Eagle is in the business of developing and commercializing drugs, primarily in the critical care and oncology areas, including through collaboration agreements;

WHEREAS, the Parties believe that it would be mutually beneficial to collaborate on promotional activities for the Product (defined below) and, accordingly, TYME desires that Eagle conduct certain promotional activities, and Eagle desires to conduct such activities, for the Product in the Territory;

WHEREAS, simultaneously with the execution and delivery of this Agreement, the Parties have entered into that certain Securities Purchase Agreement, providing for, among other things, the issuance and sale by TYME of shares of TYME common stock to Eagle in return for Eagle’s upfront payment of \$20 million in cash and TYME’s right to receive additional milestone payments upon the achievement of certain milestones as provided therein;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise defined in this Agreement, the following terms shall have the meanings provided hereunder:

1.1 “**Act**” shall mean the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as it may be amended from time to time, and the regulations promulgated thereunder.

1.2 “**Adverse Event**” shall mean any untoward medical occurrence in a patient or clinical investigation subject who is administered the Product, but which does not necessarily have a causal relationship with the treatment for which the Product is used. An “Adverse Event” can include any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the Product, whether or not related to the Product. A pre-existing condition that worsened in severity after administration of the Product would be considered an “Adverse Event”.

1.3 **“Affiliate”** shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of fifty percent (50%) or more (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting securities of such Person, by contract or otherwise.

1.4 **“Agreement”** shall have the meaning set forth in the preamble to this Agreement.

1.5 **“Alliance Managers”** shall have the meaning set forth in Section 4.1.5.

1.6 **“Applicable Laws”** shall mean all applicable statutes, ordinances, regulations, codes, rules, or orders of any kind whatsoever of any Governmental Authority in the Territory pertaining to any of the activities and obligations contemplated by this Agreement, including, as applicable, the Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), the Health Insurance Portability and Accountability Act of 1996, the Federal False Claims Act (31 U.S.C. §§ 3729-3733) (and applicable state false claims acts), the Physician Payments Sunshine

Act, the Code, the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, released April 2003, the Antifraud and Abuse Amendment to the Social Security Act, the American Medical Association guidelines on gifts to physicians, generally accepted standards of good clinical practices adopted by current FDA regulations, as well as any state laws and regulations (i) impacting the promotion of pharmaceutical products,

(ii) governing the provision of meals and other gifts to medical professionals, including pharmacists, or (iii) governing consumer protection and deceptive trade practices, including any state anti-kickback/fraud and abuse related laws, all as amended from time to time.

1.7 **“Business Day”** means each day of the week, excluding Saturday, Sunday or a day on which banking institutions in New York, New York, USA are closed.

1.8 **“Buyout Amount”** means \$200 million.

1.9 **“Claims”** shall mean all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions, in each case of a Third Party (including any Governmental Authority).

1.10 **“Code”** shall mean the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA)/BIO, as it may be amended.

1.11 **“Commercialize,” “Commercializing,”** and **“Commercialization”** means activities directed to manufacturing, obtaining pricing and reimbursement approvals for, marketing, promoting, distributing, importing, and/or selling the Product.

1.12 **“Commercially Reasonable Efforts”** means, with respect to a Party’s obligations under this Agreement, a measure of effort and resources consistent with the exercise of prudent scientific and business judgment and the reasonable practices that would typically be exerted by a similarly situated pharmaceutical or biotechnology company of comparable size and capabilities as such company for the Development or Commercialization of a pharmaceutical product with similar characteristics owned by such company at a similar stage of development or commercialization as the Product, taking into account efficacy and safety considerations, and other relevant scientific, technical, and commercial factors, including product profile, the regulatory environment, competitiveness of the marketplace and market potential, and price and reimbursement status.

1.13 **“Compensation Report”** shall have the meaning set forth in Section 4.2.2(b).

1.14 **“Compliance Manager”** shall have the meaning set forth in Section 4.3.10.

1.15 **“Compliance Report”** shall have the meaning set forth in Section 4.2.2(c).

1.16 **“Confidential Information”** shall mean all secret, confidential, non-public or proprietary Know-How, whether provided in written, oral, graphic, video, computer or other form, provided by or on behalf of one Party to the other Party pursuant to this Agreement, including information relating to the disclosing Party’s existing or proposed research, development efforts, promotional efforts, regulatory matters, patent applications or business and any other materials that have not been made available by the disclosing Party to the general public. All such information related to this Agreement disclosed by or on behalf of a Party (or its Affiliate) to the other Party (or its Affiliate) pursuant to the Confidentiality Agreement shall be deemed to be such Party’s Confidential Information disclosed hereunder. For purposes of clarity, (i) TYME’s Confidential Information shall include all Product Materials unless and until made available by TYME to the general public (including through Eagle) and (ii) the terms of this Agreement shall be considered Confidential Information of both Parties.

1.17 **“Confidentiality Agreement”** shall have the meaning set forth in Section 8.1.1.

1.18 **“Detail(s)”** shall mean the Product presentation during a face-to-face sales call between a Target Professional and a Sales Representative, during which a presentation of the Product’s attributes, benefits, prescribing information and safety information are orally presented, for use in the Field in the Territory. Neither e-details, nor presentations made at conventions, exhibit booths, a sample drop, educational programs or speaker meetings, or similar gatherings, shall constitute a Detail.

1.19 **“Detail Report”** shall have the meaning set forth in Section 4.2.2.

1.20 **“Development”** shall mean non-clinical, pre-clinical and clinical drug discovery, research, and/or development activities, including without limitation quality assurance and quality control development, and any other activities reasonably related to or leading to the development and submission of information to a Regulatory Authority. When used as a verb, **“Develop”** means to engage in Development.

1.21 **“Dispute”** shall have the meaning set forth in Section 12.6.

1.22 **“Dollar”** or **“\$”** shall mean United States dollar.

1.23 “**Eagle Activities**” shall mean any and all promotional activities (including Detailing) conducted by Eagle with respect to the Product in the Territory, as set forth in the Sales Plan or otherwise mutually agreed upon by the Parties in writing, in each case, in accordance with the terms of this Agreement.

1.24 “**Eagle Property**” shall have the meaning set forth in Section 7.1.1.

1.25 “**Eagle Quarterly Minimum Details**” for an applicable Fiscal Quarter shall mean the number established by the Operating Parameters Schedule as in effect from time to time.

1.26 “**Effective Date**” shall have the meaning set forth in the preamble to this Agreement.

1.27 “**Exclusive Detail**” shall mean a Detail for which the Product is the sole product detailed on the call.

1.28 “**Exhibit**” shall mean an exhibit attached to this Agreement.

1.29 “**FDA**” shall mean the United States Food and Drug Administration or any successor agency performing comparable functions.

1.30 “**Field**” shall mean the treatment of any and all indications for which the Product is approved in humans in the Territory.

1.31 “**Field Force Personnel**” shall mean collectively, the Sales Representatives, and any other employees of Eagle engaged in the Eagle Activities.

1.32 “**First Commercial Sale**” shall mean the first commercial sale of the Product for monetary value by TYME, one or more of its Affiliates or one or more of its licensees in an arm’s length transaction to a Third Party that is not a licensee, including without limitation any final sale to a distributor or wholesaler under any non-conditional sale arrangement, of the Product in the Field in the Territory after Regulatory Approval of the Product has been granted in the Field in the Territory. For the avoidance of doubt, sales or transfers of the Product for clinical and non-clinical research and trials (including studies reasonably necessary to comply with Applicable Law or requests by a Regulatory Authority), early access programs or for compassionate or similar use, shall not be considered a First Commercial Sale.

1.33 “**Fiscal Quarter**” shall mean each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1.

1.34 “**Fiscal Year**” shall mean each successive period of (12) twelve months commencing on April 1 and ending on March 31st.

1.35 “**GAAP**” shall mean United States generally accepted accounting principles.

1.36 “**Governmental Authority**” shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member, which has competent and binding authority to decide, mandate, regulate, enforce, or otherwise control the activities of the Parties contemplated by this Agreement.

1.37 “**Indemnified Party**” shall have the meaning set forth in Section 10.3.

1.38 “**Indemnifying Party**” shall have the meaning set forth in Section 10.3.

1.39 “**Intellectual Property**” shall have the meaning set forth in Section 7.1.2.

1.40 “**Inventions**” shall have the meaning set forth in Section 7.1.2.

1.41 “**Know-How**” shall mean information, whether or not in written form, including biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, or sales and marketing information, including processes, methods, procedures, techniques, plans, programs and data.

1.42 “**License**” shall mean any agreement pursuant to which TYME grants to a Third Party (a “**Licensee**”) a license, sublicense, or other right to any TYME Patent Rights or Regulatory Filings or Regulatory Approvals relating to the Product; *provided, however*, that a License shall not include (a) any agreement with any distributor or wholesaler that obtains solely the right to distribute the Product after purchase from TYME and (i) serves as a logistics services provider or (ii) otherwise distributes the Product to pharmacies, group purchasing organizations or similar entities, but in each case of (i) and (ii), without the right to co-market or co-promote the Product, or (b) any agreement pursuant to which TYME or any of its Affiliates grants a license or sublicense of any of its intellectual property rights (i) solely to conduct research, (ii) solely to manufacture the Product, or (iii) otherwise to service providers solely on a non-exclusive basis in the ordinary course of Development or Commercialization of the Product (e.g., material transfer agreements, distribution agreements, and consulting agreements).

1.43 “**Licensee**” has the meaning set forth in the definition of License.

1.44 “**Losses**” shall mean any and all amounts paid or payable to Third Parties with respect to a Claim (including any and all losses, damages, obligations, liabilities, fines, fees, penalties, awards, judgments, interest), together with all documented out-of-pocket costs and expenses, including attorney’s fees, reasonably incurred.

1.45 “**Minimum Sales Representatives Requirement**” has the meaning set forth in the definition of Operating Parameters Schedule.

1.46 “**Multidisciplinary Detail**” shall mean a Detail call to a sales account with a multidisciplinary oncology practice, as determined by TYME.

1.47 **“Net Sales”** shall mean, for an applicable period, with respect to the Product, commencing with the First Commercial Sale, net sales as determined in accordance with GAAP, which, for the avoidance of doubt, shall comprise the gross amounts received by TYME, its Affiliates and Licensees for arm’s length sales of the Product in the Field in the Territory to a Third Party (excluding any sales among TYME, its Affiliates and any Licensee), less the following deductions solely to the extent incurred or allowed with respect to such sales, and solely to the extent such deductions are in accordance with GAAP, and which are not already reflected as a deduction from the invoiced price: (a) discounts (to the extent not previously applied to such amounts received), charge-back payments, and rebates; (b) credits or allowances for damaged goods, rejections, recalls or returns of the Product; (c) freight, insurance, postage, and shipping charges for delivery of the Product, to the extent separately billed on the invoice as well as any bona fide service fee specifically incurred for the distribution of the Product; (d) taxes, customs, or duties levied on, absorbed, or otherwise imposed on the sale of the Product, as adjusted for rebates and refunds, to the extent not paid by the Third Party and only to the extent such taxes, customs, or duties are not reimbursed to the paying party, but excluding all income taxes; (e) allowances for doubtful or uncollectible amounts (provided that, such amounts shall be included in the computation of “Net Sales” to the extent subsequently collected or earned) and (f) that portion of the annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and any other fees imposed by Applicable Law. If the Product is sold by TYME, its Affiliates or Licensees through intermediaries such as agents, consignees or co-promoters who do not purchase and take title to the Product, the promotion fee will be due only on sales to those Third Parties who actually purchase and take title to the Product through such intermediaries.

If the Product is transferred to Third Parties in connection with clinical and non-clinical research and trials (including studies reasonably necessary to comply with Applicable Law), Product samples, charitable purposes, promotional purposes, early access programs, compassionate sales or use, or an indigent program or similar *bona fide* arrangements for which TYME or

any of its Affiliates or Licensees for good faith business reasons receives consideration in respect thereof that is less than the average cost of goods for this Product, such consideration shall not be included in Net Sales.

1.48 **“NDA”** means a New Drug Application filed with the FDA that is required for approval for the Product in the United States, or its foreign equivalent in the Territory.

1.49 **“Operating Parameters Schedule”** means the requirements set forth in Schedule 4.1 to this Agreement, as such may, subject to the provisions of Section 3.4.2, be revised from time to time by TYME in consultation with the SOC. The Operating Parameters Schedule shall be updated no less than annually with the minimum required number of Sales Representatives (the **“Minimum Sales Representatives Requirement”**) and the Eagle Quarterly Minimum Details.

1.50 **“Party”** shall have the meaning set forth in the preamble to this Agreement.

1.51 **“Patent Rights”** means (a) patents and patent applications, and any foreign counterparts thereof, (b) all divisionals, continuations, continuations-in-part of any of the foregoing, and any foreign counterparts thereof, and (c) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, substitutions or extensions thereof, and any foreign counterparts thereof.

1.52 **“Person”** shall mean any individual, corporation, partnership, limited liability company, association, joint- stock company, trust, unincorporated organization or other entity, or government or political subdivision thereof.

1.53 **“Pivotal Clinical Study”** shall mean a human clinical study of the Product in any country on a sufficient number of subjects that is designed to establish that the Product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of the Product, as described in 21 C.F.R. § 312.21(c), or equivalent clinical study in a country other than the United States.

1.54 **“Primary Multidisciplinary Detail”** shall mean a Multidisciplinary Detail call where the Product (i) is the first product Detailed, (ii) is emphasized more than any other product and (iii) is the primary focus of such Detail, primary focus meaning greater than 50% of the total call time during the Detail is spent on promoting the Product.

1.55 **“Product”** shall mean any product that contains SM-88 (racemetyrosine).

1.56 **“Product Labeling”** shall mean the labels and other written, printed or graphic matter upon (a) any container or wrapper utilized with the Product or (b) any written material accompanying the Product, including Product package inserts, in each case as approved by the FDA.

1.57 **“Product Materials”** shall have the meaning set forth in Section 4.4.1(a).

1.58 **“Product Training Materials”** shall have the meaning set forth in Section 4.4.1(a).

1.59 **“Professionals”** shall mean health care practitioners, consisting of physicians, nurse practitioners, physician assistants, pharmacists and any other medical professionals in the Territory with prescribing, formulary or dispensing authority (as authorized under Applicable Law) in the Territory for the Product.

1.60 **“Promotional Materials”** shall have the meaning set forth in Section 4.4.1(a).

1.61 **“Promotional Program”** shall mean an educational program regarding the Product conducted by a Third Party healthcare provider within TYME’s approved speakers bureau for SM-88 (racemetyrosine), located in a healthcare provider office or an outside venue, all in accordance with TYME speakers bureau guidelines.

1.62 **“Quarterly Average Sales Force Size”** shall have the meaning set forth in Section 4.2.2.

1.63 **“Regulatory Approval”** shall mean any and all necessary approvals, licenses, registrations or authorizations from any Governmental Authority, in each case, necessary to Commercialize the Product in the Territory.

1.64 **“Regulatory Authority”** means any national or supranational Governmental Authority, including without limitation the FDA, that has responsibility for granting any licenses or approvals or granting pricing and/or reimbursement approvals necessary for the development, marketing, and sale of the Product in any country.

1.65 **“Regulatory Exclusivity”** means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority under Applicable Law with respect to the Product in a country or jurisdiction in the Territory to prevent Third Parties from Commercializing the Product in such country or jurisdiction, other than a Patent Right, including without limitation orphan drug exclusivity, pediatric exclusivity and rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997.

1.66 **“Regulatory Filings”** means any and all regulatory applications, filings, modifications, amendments, supplements, revisions, reports, submissions, authorizations, and Regulatory Approvals, and associated correspondence required to Develop and Commercialize the Product in the Territory, including without limitation any reports or amendments necessary to maintain Regulatory Approvals.

1.67 **“Restricted Period”** shall have the meaning set forth in Section 2.3.1.

1.68 **“Schedule”** shall mean a schedule attached to this Agreement.

1.69 **“Sales Forecast”** shall have the meaning set forth in Section 4.1.3.

1.70 **“Sales Plan”** shall mean the written sales plan relating to promotion and Detailing of the Product in the Field in the Territory by the Sales Representatives, which shall include, without limitation, the Eagle Quarterly Minimum Details and other commercial activities geared towards achieving the Sales Forecast, that is prepared by the SOC and approved by TYME as provided in Section 3.

1.71 **“Sales Representative”** shall mean an individual employed and compensated by Eagle as a full-time employee as part of its sales forces and who engages in Detailing of the Product in the Territory, and who is also trained with respect to the Product in accordance with this Agreement (including the Product Labeling and the use of the Promotional Materials) to deliver Details for the Product in the Field in the Territory.

1.72 **“Senior Officer”** shall mean, with respect to TYME, its Chief Executive Officer and Chief Operating Officer (or such officer’s designee), and with respect to Eagle, its President and Chief Operating Officer (or such officer’s designee). From time to time, each Party may change its Senior Officer by giving written notice to the other Party.

1.73 **“SM-88 (racemetyrosine)”** means TYME’s SM-88 (racemetyrosine) novel oral therapy. SM-88 (D,L-alpha- metyrosine; racemetyrosine [USAN]) is a proprietary modified dysfunctional tyrosine derivative.

1.74 **“Specialty”** means a sales account’s primary oncology specialty designation, as reasonably determined by TYME.

1.75 **“SOC”** shall have the meaning set forth in Section 3.1.

1.76 **“Target Launch Date”** shall mean the date selected by TYME, in its sole discretion, and of which TYME has provided notice to Eagle in writing at least nine (9) months in advance thereof, for the initial Commercialization of the Product in the Territory.

1.77 **“Target Professionals”** shall mean, with respect to the Product, one of the specifically identified community and/or hospital-based Professionals to be called upon by a Sales Representative based upon the Sales Plan. “Target Professionals” shall exclude key thought leaders as identified on Schedule 1.77 to this Agreement, which Schedule shall be prepared and provided by TYME prior to the Target Launch Date.

1.78 **“Term”** shall have the meaning set forth in Section 11.1.

1.79 **“Territory”** shall mean the United States of America and its territories and possessions.

1.80 **“Third Party(ies)”** shall mean any person or entity other than TYME and Eagle and their respective Affiliates.

1.81 **“TYME Trademarks and Copyrights”** shall mean the logos, trade dress, slogans, domain names and housemarks of TYME or any of its Affiliates as may appear on any Product Materials or Product Labeling, in each case, as may be updated from time to time by TYME.

ARTICLE 2 RIGHTS AND OBLIGATIONS

2.1 **Engagement; Grant of Rights.** During the Term, subject to the terms and conditions of this Agreement, TYME hereby grants to Eagle the non-exclusive right to Detail and promote the Product in the Territory in the Field, and to conduct the Eagle Activities in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing, TYME retains and reserves the right for TYME and its Affiliates to promote the Product in the Territory and to grant the non- exclusive right to Detail and/or promote the Product in the Territory to any other Third Party in its sole discretion. Eagle shall have no other rights relating to the Product, except as specifically set forth in this Agreement. Eagle’s rights and obligations under this Section 2.1 are non-transferable, non-assignable, and non-delegable. Eagle shall not subcontract the Eagle Activities with any Third Party (including any contract sales force). For clarity, Eagle shall not have any other license rights hereunder except as expressly set forth in this Section 2.1, nor any rights to sublicense any rights hereunder.

2.2 **Retention of Rights.** Except with respect to the limited rights granted to Eagle to conduct the Eagle Activities for the Product in the Territory in the Field pursuant to Section 2.1, TYME retains all rights in and to the Product. TYME shall have the sole right, as between the Parties, to Develop and Commercialize the Product, including without limitation, determining the marketing and regulatory strategies for seeking (if and when appropriate) Regulatory Approvals and Regulatory Exclusivity in the Territory for Product in the Field, filing for such Regulatory Approvals and Regulatory Exclusivity for Product in the Territory, preparing, submitting, and maintaining any and all Regulatory Filings and Regulatory Approvals for Product in the Field in the Territory, and seeking any necessary Regulatory Approvals of Regulatory Authorities for Product Labeling and Promotional Materials to be used in connection with Commercializing Product in the Field in the Territory. TYME shall solely own and control any and all Regulatory Approvals and any and all other Regulatory Filings submitted in connection with seeking and maintaining Regulatory Approvals for the Product in the

Field in the Territory. As between the Parties, TYME shall be responsible for all costs and expenses incurred by TYME in connection with the foregoing activities. Without limiting the generality of the foregoing (and without limiting TYME's retained rights set forth in Section 2.1), TYME specifically retains the following rights (and Eagle and its Affiliates shall have no rights to the following, except as set forth below in this Section 2.2):

2.2.1 responsibility for all decisions regarding regulatory submissions and for all communications that relate to any Regulatory Approvals or other Regulatory Filings prior to and after any Regulatory Approval with respect to the Product in the Field in the Territory;

2.2.2 responsibility for the manufacture and distribution of the Product, and any future development of the Product;

2.2.3 responsibility, except as expressly set forth herein, for interactions with any Governmental Authority, including but not limited to FDA, with respect to the Product (provided that, Eagle shall retain the right to respond to communications or inquiries from Governmental Authorities in connection with the conduct of any Eagle Activities);

2.2.4 responsibility for creation and final approval of all Product Materials content (including submission of Promotional Materials to FDA's Office of Prescription Drug Promotion) with respect to the conduct of the Eagle Activities for the Product, except as expressly set forth herein;

2.2.5 selling and booking all sales of the Product;

2.2.6 responsibility for the Product's overall commercial strategy, including marketing, payer strategy, pricing, regulatory and other government affairs; and

2.2.7 responsibility for handling all safety related activities related to the Product as set forth in ARTICLE 5 (including submitting all safety reports and interacting with Governmental Authorities with respect thereto) and initiating and managing any Product recalls.

For clarity, except as provided in Sections 2.1 or 2.4, Eagle shall not acquire any license or other intellectual property interest, by implication or otherwise, in any technology, Know-How or other Intellectual Property owned or controlled by TYME or any of its Affiliates, and TYME is not providing any such technology, Know-How or other Intellectual Property, or any assistance related thereto, to Eagle for any use other than for the mutual benefit of the Parties as expressly contemplated hereby.

2.3 Non-Competition; Non-Solicitation.

2.3.1 **Non-Competition.** During the Term of this Agreement and through and including the first anniversary of the date of Termination of this Agreement (the "**Restricted Period**"), neither Eagle nor its Affiliates shall, directly or indirectly, market, detail, offer for sale, sell, or promote any oncology product in the Territory that is targeting an indication for which SM-88 (racemetyrosine) is approved other than the sales of the Product in accordance with the terms and conditions of this Agreement without TYME's prior written consent, which shall be given or withheld within its sole discretion.

2.3.2 **Non-Solicitation.** During Restricted Period, neither Eagle nor TYME (nor any of their respective Affiliates) shall directly or indirectly solicit for hire or employ as an employee, consultant or otherwise, any employee, consultant or other professional personnel of the other Party who has had direct involvement with the SOC, Eagle Activities under this Agreement or TYME's Commercialization activities for the Product, without the other Party's prior written consent, which shall not be unreasonably withheld; provided, however, that this restriction shall not apply to: (a) conducting any general solicitation not specifically targeted at any such employee; or (b) hiring any employee who responds to such general advertising or who approaches such Party or its Affiliates without any solicitation or inducement to leave the employ of such other Party or its Affiliates.

2.4 TYME Trademarks and Copyrights.

2.4.1 Eagle shall have the non-exclusive right to use the TYME Trademarks and Copyrights solely on Product Materials in order to perform the Eagle Activities and solely in accordance with the terms and conditions of this Agreement. TYME shall promptly notify Eagle of any updates or changes to the TYME Trademarks and Copyrights on the Product Materials, and Eagle shall thereafter solely use such updated Product Materials in performing its obligations under this Agreement. Eagle shall promptly notify TYME upon becoming aware of any violation of this Section 2.4.1.

2.4.2 Eagle shall follow all instructions and guidelines of TYME (of which TYME shall provide Eagle copies) in connection with the use of any TYME Trademarks and Copyrights, and, if TYME reasonably objects to the manner in which any such TYME Trademarks and Copyrights are being used, Eagle shall immediately cease the use of any such TYME Trademarks and Copyrights in such manner upon written notice from TYME thereof. Without limiting the foregoing, Eagle shall also adhere to at least the same quality control provisions as companies in the pharmaceutical industry adhere to for their own trademarks and copyrights. In all cases, Eagle shall use the TYME Trademarks and Copyrights with the necessary trademark (and copyright, as applicable) designations, and shall use the TYME Trademarks and Copyrights in a manner that does not derogate from TYME's rights in the TYME Trademarks and Copyrights. Eagle shall not at any time during the Term knowingly do or allow to be done any act or thing which will in any way impair or diminish the rights of TYME in or to the TYME Trademarks and Copyrights. All goodwill and improved reputation generated by Eagle's use of the TYME Trademarks and Copyrights shall inure to the benefit of TYME, and any use of the TYME Trademarks and Copyrights by Eagle shall cease at the end of the Term. Eagle shall have no rights under this Agreement in or to the TYME Trademarks and Copyrights except as specifically provided herein. During the Term, Eagle shall not contest the ownership of the TYME Trademarks and Copyrights, their validity, or the validity of any registration therefor. During the Term, Eagle shall not knowingly register and/or use any marks (including in connection with any domain names) that are confusingly similar to the TYME Trademarks and Copyrights.

ARTICLE 3 JOINT SALES OPERATIONS COMMITTEE

3.1 **Formation of the Joint Sales Operations Committee.** As soon as practicable, but no later than nine (9) months prior to the Target Launch Date, the Parties shall form a joint sales operations committee ("**SOC**") whose responsibilities during the Term shall be to oversee the activities set forth in Section 3.3. The SOC shall consist of no more

than seven (7) members, with four (4) members designated by TYME and three (3) members designated by Eagle, each with suitable seniority and relevant experience and expertise to enable such person to address matters falling within the purview of the SOC; provided, that each Party may also have up to three (3) observers present at any SOC meeting. All meetings of the SOC shall be chaired by one of the four representatives from TYME. From time

to time, each Party may change any of its representatives on the SOC by giving written notice to the other Party. The SOC shall determine a meeting schedule; provided that in any event, meetings shall be conducted no less frequently than quarterly by teleconference or in person, or as otherwise agreed by the Parties. In person meetings shall occur at such places as mutually agreed by the Parties. Employees or consultants of either Party that are not representatives of the Parties on the SOC may attend meetings of the SOC as one of a Party's designated observers; provided that, such attendees (i) shall not participate in the decision-making process of the SOC, and (ii) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in ARTICLE 8.

3.2 **Meetings and Minutes.** Meetings of the SOC may be called by either Party on no less than thirty (30) days' prior notice during the Term. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least ten (10) days in advance to the applicable meeting; provided that under exigent circumstances requiring input by the SOC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for that particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting, such consent not to be unreasonably withheld. Members may participate in a meeting of the SOC by means of a conference telephone or other communications equipment allowing all persons participating in the meeting to hear each other. Participation by such means shall constitute presence in person at the meeting. The chairperson shall prepare and circulate for review and approval of the Parties minutes of each meeting within thirty (30) days after the meeting. Each Party shall bear its own costs for its members to attend such meetings.

3.3 **Purpose of the SOC.** The purposes of the SOC shall be to, subject to Section 3.4:

3.3.1 provide a forum to discuss and coordinate the Parties' activities under this Agreement, in particular sales performance and metrics, and, subject to Section 3.4.2, develop, update, amend and approve the Sales Plan, including the identification of sales accounts;

3.3.2 provide a forum to discuss and coordinate the promotion of the Product in the Territory;

3.3.3 provide a forum to discuss Product Materials (it being understood that the SOC shall not have the right to approve such Product Materials);

3.3.4 provide a forum for discussing the annual Sales Forecast and revisions thereto (it being understood that TYME retains the right to update the Sales Forecast as described in Section 4.1.3);

3.3.5 provide a forum for reviewing, updating and agreeing on revisions to the Operating Parameters Schedule, including without limitation, to update the Eagle Quarterly Minimum Details and the Minimum Sales Representatives Requirement;

3.3.6 facilitate the flow of information and otherwise promote the communications and collaboration within and among the Parties relating to this Agreement and the promotion of the Product;

3.3.7 discuss planning and implementation of all Eagle Activities, including but not limited to training of Sales Representatives and development and implementation of policies and procedures for conduct of Promotional Programs and Details and Sales Representatives' interactions with sales accounts;

3.3.8 decide on the acceptable form of and review and discuss the Detail Reports and reports of Net Sales;

3.3.9 review and discuss the Compensation Reports and the incentive compensation matters described in Section 4.1.4, including any applicable adjustments to Product-related sales goals and targets of the Sales Representatives proposed by TYME (it being understood that Eagle shall retain final decision-making authority with respect to such matters but shall give good faith consideration to TYME's feedback with respect thereto);

3.3.10 review and discuss any matters brought to its attention by either Party's Alliance Manager;

3.3.11 discuss the Promotional Materials matters described in Section 4.4.1(a);

3.3.12 discuss supply or distribution issues relating to the Product;

3.3.13 act as a first level escalation to address disagreements or disputes between the Parties;

3.3.14 form and oversee any sub-committee or working group in furtherance of the activities contemplated by this Agreement;

3.3.15 decide on the acceptable form of and review and discuss the Compliance Reports; and

3.3.16 perform such other responsibilities as may be mutually agreed upon by the Parties in writing from time to time; provided, however, for clarity the SOC shall have no authority to amend or modify any provisions of this Agreement and no authority to waive or definitively interpret the provisions of this Agreement.

In connection with the SOC meetings contemplated under Section 3.2 (but in any event, no less frequently than each Fiscal Quarter), Tyme shall provide Eagle with a written summary of its material Development and Commercialization strategies and activities with respect to the Product in the Territory since the last SOC meeting or Fiscal Quarter, as applicable, including the results of such activities, and a description of its then-current marketing plans, marketing campaigns and Product-related messaging with key opinion leaders, except and to the extent such information is subject to confidentiality or similar restrictions on disclosure imposed by contractual, regulatory or similar requirements.

3.4 **Decision Making.**

3.4.1 **Quorum; Voting.** Meetings of the SOC shall occur only if at least one (1) representative of each Party is present at the meeting. Each Party shall have one (1) vote. The SOC shall use good faith efforts to reach consensus on all matters properly brought before it. If the SOC does not reach unanimous consensus on an issue at a meeting, or within a period of 30 days thereafter, then the SOC shall submit in writing the respective positions of the Parties to the Senior Officers of the Parties. Such Senior Officers shall use good faith efforts to resolve promptly such matter, which good faith efforts shall include at least one (1) teleconference between such Senior Officers within 30 days after the SOC's submission of such matter to them.

Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within 30 days after such issue was first referred to them, then, except with respect to those disputes that are expressly subject to arbitration pursuant to Section 12.6: (i) Eagle shall have the right to conclusively determine all matters related to the incentive compensation of the Sales Representatives and (ii) subject to Section 3.4.2, TYME shall have the right to conclusively determine all other matters; provided, however, for clarity, that such determination and any related activities comply with the terms and conditions of this Agreement. Notwithstanding anything to the contrary in the foregoing, for the avoidance of doubt, any such determination shall not amend, modify or waive any provisions of this Agreement or definitively interpret the provisions of this Agreement.

3.4.2 **Eagle Approvals.** Any proposed change or amendment to the (a) Operating Parameters Schedule or (b) Sales Plan that would (i) increase Eagle's percentage of the sales force requirements above the percentage provided in the Operating Parameters Schedule (as may be subsequently amended by mutual agreement of the Parties), (ii) increase the number of Eagle Quarterly Minimum Requirements (as such requirements may be updated by mutual agreement of the Parties), (iii) increase the number of Sales Representatives from the number agreed to prior to the Target Launch Date (or as otherwise agreed by mutual agreement of the Parties) or (iv) without duplication of items (i) – (iii) hereof, materially increase Eagle's costs associated with conducting any Eagle Activities other than Detailing shall, in each case of (a) and (b), require the written approval of Eagle (which approval shall not be unreasonably withheld). The initial Sales Plan developed by the SOC to be in effect at the Target Launch Date, which shall set forth the commercial activities geared towards achieving the Sales Forecast, including, without limitation the Eagle Quarterly Minimum Details and the target number of Promotional Programs, shall be developed by the SOC, approved by TYME and require the written approval of Eagle (which Eagle approval shall not be unreasonably withheld).

ARTICLE 4 EAGLE ACTIVITIES FOR THE PRODUCT

4.1 **Eagle Activities.**

4.1.1 **General.** Eagle shall conduct the Eagle Activities for the Product in the Field in the Territory in accordance with this Agreement, including, without limitation, in accordance with the then-current Sales Plan.

4.1.2 **Sales Representatives.** Without limiting the generality of the foregoing, Eagle shall hire, and continuing throughout the remainder of the Term, shall maintain, a sales force with responsibility to Detail the Product in the Territory in accordance with the terms of the Operating Parameters Schedule. Eagle shall have such sales force in place by such time specified in the Operating Parameters Schedule in order to appropriately train on the Product prior to Target Launch Date. The Sales Representatives and their managers shall have the qualifications and meet the criteria set forth in Schedule

4.1.2 hereto, which schedule shall be jointly developed and mutually agreed by TYME and Eagle within 180 days of the execution and delivery of this Agreement.

4.1.3 **Sales Forecast.**

(a) No later than three (3) months prior to the Target Launch Date, TYME shall develop a forecast of reasonably expected Net Sales of the Product in the Territory in the Field for a one (1) year period, including projected quarterly Net Sales (the "**Sales Forecast**"). Thereafter, each Fiscal Year of the Term, TYME shall prepare an annual Sales Forecast for such period. The Sales Forecast shall be updated by TYME from time to time as appropriate, discussed at the SOC, and comprise part of the Sales Plan.

(b) On a quarterly basis, the SOC shall review actual Fiscal Year-to-date Net Sales performance compared to the Sales Forecast.

4.1.4 **Target Incentive Compensation.** Prior to the Target Launch Date, Eagle shall develop an incentive compensation package for each Sales Representative that derives an appropriate portion of target incentive compensation from achieving target sales of the Product, subject to TYME's review and comment prior to implementation of the incentive plan. On at least a quarterly basis, the Parties shall meet, through the SOC, to review the target incentive compensation and the actual incentive compensation paid out to the Sales Representatives to discuss, in good faith, any appropriate adjustments to the sales targets and goals related to the Product.

4.1.5 **Alliance Managers.** Each Party shall appoint a person who shall oversee interactions between the Parties for all matters related to this Agreement, and any related agreements between the Parties (each an "**Alliance Manager**"). The Alliance Managers shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information, and shall serve as a single point of contact for all matters arising under this Agreement. The Alliance Managers shall have the right to attend all SOC meetings and, if applicable, subcommittee meetings as non-voting participants and may bring to the attention of the SOC or, if applicable, the subcommittee, any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.

4.2 **Detailing.**

4.2.1 **Detail Requirements.** Commencing promptly upon completion of training of the Field Force Personnel that are engaged in Detailing the Product as described in Section 4.4.1 (but on the condition that Promotional Materials have been approved and delivered), Eagle shall deploy its Field Force Personnel that are engaged in Detailing to Detail the Product in accordance with the terms of this Agreement, including without limitation, the requirements for reach, frequency and position of the Product in the Detail provided in the Operating Parameters Schedule and the requirements of the then-current Sales Plan as updated from time to time. From time to time, Field Force Personnel shall organize and coordinate on the presentation of Promotional Programs as developed by the SOC and included in the then-current Sales Plan; however, except as set forth in this Agreement, without the prior written consent of TYME (not to be unreasonably withheld, delayed or conditioned), Eagle shall not conduct any Eagle Activities, other than Detailing, with respect to any Product. The Promotional Program requirements, guidelines and TYME approved speaker bureau will be provided to Eagle prior to initiation of the Promotional Programs.

4.2.2 **Records and Reports.**

(a) Eagle shall keep accurate and complete records, consistent with pharmaceutical industry standards, of each Detail and its obligations hereunder in connection therewith. Such records shall be kept for the longer of (i) five (5) years after the end of the Fiscal Year to which they relate and (ii) such period of time as required by Applicable Laws. Within 15 days following the end of each Fiscal Quarter during the Term, Eagle shall

provide TYME with a written report (each a “**Detail Report**”), setting out (1) the quarterly average number of Sales Representatives during such Fiscal Quarter (calculated by taking the sum of the number of Sales Representatives employed by Eagle (or its affiliates) that have incentive compensation packages that comply with the terms of Section 4.1.4 on each Business Day of the Fiscal Quarter divided by the number of Business Days in such Fiscal Quarter) (the “**Quarterly Average Sales Force Size**”), (2) the aggregate actual number of Details for the Product made by its Sales Representatives during such Fiscal Quarter, (3) the aggregate number of Exclusive Details, (4) the aggregate number of Multidisciplinary Details, (5) the number of Primary Multidisciplinary Details, and (6) the number of Details broken down by the name of the Target Professionals and such professional’s Specialty. Through the SOC, the Parties shall agree on a mutually acceptable form of Detail Report.

(b) Within 30 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a “**Compensation Report**”), which describes (i) the details of the incentive compensation package of each Sales Representative as it relates to the Product and (ii) the actual incentive compensation payouts for each Sales Representatives as described in Section 4.1.4. Through the SOC, the Parties shall agree on a mutually acceptable form of Compensation Report.

(c) Within 30 days following the end of each Fiscal Quarter during the Term, Eagle shall provide TYME with a written report (each a “**Compliance Report**”), which sets out a summary of any compliance-related disciplinary actions relating to any Field Force Personnel that are engaged in Detailing and any associated remedial actions. Through the SOC, the Parties shall agree on a mutually acceptable form of Compliance Report.

(d) TYME shall have the right, at its own expense, during normal business hours and upon reasonable prior notice, through an independent third party, reasonably acceptable to Eagle, and upon execution of a confidentiality agreement reasonably satisfactory to Eagle in form and substance, to inspect the applicable records and books maintained by Eagle relating to the Eagle Activities solely for purposes of verifying Eagle’s compliance with the terms of this Agreement. For purposes of clarity, any such inspection right described in this Section 4.2.2(d) shall be limited to only those books and records of Eagle that are applicable to Eagle’s performance of its obligations under this Agreement and may be conducted no more than once per calendar year. Where necessary, on reasonable request, TYME’s inspection rights shall include interviewing Sales Representatives and other employees of Eagle. Eagle shall reasonably cooperate in any such inspection conducted by TYME. TYME shall treat all information subject to review under this Section 4.2.2(d) in accordance with the confidentiality provisions of this Agreement.

4.3 Compliance with Applicable Law.

4.3.1 In conducting the Eagle Activities hereunder, Eagle shall, and shall require all Field Force Personnel to, comply in all respects with Applicable Laws. In addition, TYME shall, and shall require all of its sales representatives to, comply in all respects with Applicable Laws in connection with its Development or Commercialization (including promotion and Detailing) of the Product in the Territory.

4.3.2 Neither Eagle or Field Force Personnel, nor TYME, its Affiliates or their respective licensees, shall offer, pay, solicit or receive any remuneration to or from any Professionals (including Target Professionals), in order to induce referrals of or purchase of the Product.

4.3.3 In performing the activities contemplated by this Agreement, neither Eagle or Field Force Personnel, nor TYME, its Affiliates or their respective licensees, shall make any payment, either directly or indirectly, of money or other assets to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing where such payment would constitute violation of any Applicable Law. In addition, neither Eagle nor TYME shall make any payment, either directly or indirectly, to officials if such payment is for the purpose of unlawfully influencing decisions or actions with respect to the subject matter of this Agreement.

4.3.4 No employee of Eagle or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by TYME or its agents to any Third Party in violation of terms of this or any other provision of this Agreement

4.3.5 Neither Eagle nor TYME shall undertake any activity under or in connection with this Agreement which violates any Applicable Law.

4.3.6 TYME shall ensure that any patient assistance program used in connection with the Product (and the services performed thereby in connection with the Product) shall be operated in accordance with Applicable Law. Notwithstanding the immediately preceding sentence, TYME shall have no liability with respect to any breach or non-compliance with Applicable Law relating to any patient assistance program used in connection with the Product to the extent caused by the act or omission of any Field Force Personnel, which act or omission is not in compliance with the terms of this Agreement, Applicable Law or instructions of TYME.

4.3.7 TYME shall ensure that government-insured patients do not receive co-pay support from TYME with respect to the Product.

4.3.8 TYME shall ensure that its donations to, and interactions with, any 501(c)(3) charitable foundation that provides co-pay assistance to government-insured patients with respect to the Product are in full compliance with all Applicable Laws.

4.3.9 If, during the Term, Eagle becomes aware of a material violation or failure to comply with Applicable Law or the terms of this Agreement by a member of the Field Force Personnel that are engaged in Detailing, it shall promptly, but no later than two (2) Business Days after it becomes aware, notify TYME of such violation and, as promptly as possible thereafter, shall notify the steps it has taken or intends to take to remediate such violation.

4.3.10 As soon as practicable, but no later than six (6) months prior to the Target Launch Date, each Party shall appoint a representative to act as its compliance manager under this Agreement, each of which shall be routinely responsible for advising such Party on compliance matters and has suitable seniority and other relevant experience and expertise (each, a “**Compliance Manager**”). From time to time, each Party may change its Compliance Manager by giving written notice to the other Party. The Compliance Managers shall serve as a key point of contact between the Parties for compliance-related matters. Each Compliance Manager shall facilitate the resolution of any compliance issue with the Compliance Manager of the other Party. The Compliance Managers shall use good faith efforts to reach consensus on all compliance matters. If the Compliance Managers do not reach consensus on an issue promptly, then such issue shall be submitted to dispute resolution process described in Section 12.6. Upon the reasonable request of TYME from time to time, Eagle shall deliver to TYME copies of Eagle’s compliance program policies and compliance training materials which are applicable to the Field Force Personnel’s promotion of the Product. Other than as expressly stated herein, Eagle shall not be required to modify its compliance policies or practices in connection with the compliance-related provisions herein.

4.4 Field Force Personnel Training; Product Materials.

4.4.1 Training, Training Materials and Promotional Materials.

(a) Subject to the terms of this Section 4.4.1, TYME shall prepare and control the content of

(i) all Product training materials for Field Force Personnel (the “**Product Training Materials**”) and (ii) all Product marketing and educational materials (the “**Promotional Materials**”) (the Product Training Materials and the Promotional Materials, collectively, the “**Product Materials**”). TYME shall be solely responsible for ensuring that the Product Materials prepared and approved by it are in compliance with the Regulatory Approval for the Product, the Product Labeling and Applicable Law. Once approved by TYME, the content of the Product Materials shall be provided by TYME to Eagle in advance of the Eagle Activities to allow for Eagle to review such content and provide verbal feedback to TYME in advance of use of the Product Materials. Within 15 days of receipt of such Product Materials, Eagle shall verbally provide to TYME any comments and/or proposed revisions to such Product Materials, which comments and revisions TYME shall reasonably consider so long as TYME deems such suggestions are acceptable in the promotion of the Product; provided that in any event, to the extent that TYME reasonably believes that such changes are not in compliance with Applicable Law, the Regulatory Approval for the Product or the applicable Product Labeling, then TYME shall not be required to incorporate any such suggestions from Eagle in the Product Materials. In the event of any disagreement between the Parties regarding any feedback received from Eagle

with respect to the Product Materials, TYME shall have the right to conclusively determine such matter; provided that, Eagle shall not be required to use any Product Materials that it reasonably believes violate Applicable Law. If Eagle has provided comments to TYME on the Product Materials and TYME accepts some or all of such comments, then, once revised, TYME shall provide to Eagle the revised versions of such Product Materials for further review by Eagle, in accordance with the terms and timelines of this Section 4.4.1(a) above. Eagle shall use only Product Materials approved by TYME in the performance of Eagle Activities under this Agreement. The content of Product Materials shall not be modified or changed by Eagle or Field Force Personnel at any time without the prior written approval of TYME in each instance. TYME shall be responsible for the costs and expenses of creation and development of the Product Materials and Eagle shall be responsible for the costs and expense of reproduction, printing and delivery of the Product Materials to and for Eagle. The information regarding the Product that is provided by Eagle or Field Force Personnel as part of the Eagle Activities shall not deviate from the Product Materials. The Parties shall coordinate the production and delivery of Product Materials to allow sufficient internal and field force review time to accommodate scheduled training meetings and distribution to Field Force Personnel that are engaged in Detailing. In the event that TYME incurs costs and expenses for which Eagle is responsible under this Section 4.4.1, TYME may deduct such amounts from the payments due under Section 6.1 and shall include a description thereof in the applicable report under Section 6.2. The Parties shall collaborate to finalize the Product Materials in accordance with this Section 4.4.1(a) in advance of the Target Launch Date.

(b) By no later than six (6) months prior to the Target Launch Date, the Parties shall collaborate to plan and schedule training for the Sales Representatives at a mutually acceptable time(s) and date(s), including a launch meeting for the Sales Representatives at a mutually acceptable location. TYME shall lead such initial training and Eagle shall cooperate with any reasonable requests of TYME in order to support such training. The costs and expenses of such launch meeting shall be the responsibility of Eagle. All other training costs and expenses shall be the responsibility of Eagle. After the initial training, the Parties shall collaborate to provide additional training at such frequency, times and places as the circumstances warrant and the Parties mutually agree, but no less frequently than quarterly with at least three (3) live, in-person training sessions annually. Eagle shall have the right, but not the obligation, to conduct such additional training itself, provided that the Eagle trainers have been trained by TYME, and provided further that TYME shall have the right to attend such training upon reasonable notice by TYME to Eagle. Eagle shall certify in writing to TYME that all Field Force Personnel have completed the training described in this Section 4.4.1(b).

(c) Eagle and all Field Force Personnel that are engaged in Eagle Activities shall comply with the applicable provisions of the Code, and shall be trained on Eagle’s compliance policies, including those that are consistent with the applicable provisions of Sec. 1128B(b) of the Social Security Act and the American Medical Association Ethical Guidelines for Gifts to Physicians from Industry (which such training may have been accomplished prior to the Term), prior to commencing any Eagle Activities. Eagle agrees that it shall train any employee or agent of Eagle who is involved in performing the activities contemplated by this Agreement on anti-corruption and anti-bribery at its own expense.

(d) Field Force Personnel that are engaged in Detailing shall conduct the Eagle Activities only after having undergone the training described in this Section 4.4 and, without limiting the foregoing, no Field Force Personnel member shall Detail the Product without having undergone such training. Subject to the foregoing, Eagle shall have the responsibility for on-going training of its Field Force Personnel that are engaged in Detailing in accordance with customary practice in the pharmaceutical industry, provided that TYME shall be entitled to approve all such training objectives and content.

4.4.2 Ownership of Product Materials. As between the Parties, TYME shall own all right, title and interest in and to any Product Materials (and all content contained therein) and any Product Labeling (and all content contained therein), including applicable copyrights and trademarks (other than any name, trademark, trade name or logo of Eagle or its Affiliates that may appear on such Product materials or Product Labeling), and to the extent Eagle (or any of its Affiliates) obtains or otherwise has a claim to any of the foregoing, Eagle hereby assigns (and shall cause any applicable Affiliate to assign) all of its right, title and interest in and to such Product Materials (and content) and Product Labeling (and content) (other than any name, trademark, trade name or logo of Eagle or its Affiliates that may appear on such Product materials or Product Labeling) to TYME and Eagle agrees to (and shall cause its applicable Affiliate to) execute all documents and take all actions as are reasonably requested by TYME to vest title to such Product Materials (and content) and Product Labeling (and content) in TYME (or its designated Affiliate).

4.5 Provisions Related to Field Force Personnel.

4.5.1 Activities of Field Force Personnel. Eagle hereby agrees and acknowledges that the following shall apply with respect to itself and the Field Force Personnel that are engaged in Detailing:

(a) Eagle shall instruct and cause the Field Force Personnel that are engaged in Detailing to use only the Product Labeling and, subject to the terms of Section 4.4, Product Materials approved by TYME for the conduct of the Eagle Activities for the Product and consistent with Applicable Laws. Eagle shall instruct the Field Force Personnel that are engaged in Detailing to, and shall monitor (in accordance with Eagle’s standard practice) the Field Force Personnel that are engaged in Detailing, in order to ensure that such Field Force Personnel limit their claims of efficacy and safety for such Product to those claims which are consistent with and do not exceed the Product Labeling and any Promotional Materials.

(b) Eagle shall instruct the Field Force Personnel that are engaged in Detailing to conduct the Eagle Activities for the Product, and shall monitor and audit (in accordance with Eagle’s standard practice) the Field Force Personnel that are engaged in Detailing so that such personnel conduct the Eagle Activities for such Product in adherence in all respects with Applicable Laws.

(c) Eagle shall instruct the Field Force Personnel that are engaged in Detailing regarding provisions of this Agreement applicable to Details of the Product, including Section 4.2 and this Section 4.5.1.

(d) Eagle acknowledges and agrees that TYME will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of the Field Force Personnel, all of which shall be Eagle's sole responsibility.

(e) Eagle acknowledges and agrees that all Field Force Personnel are employees of Eagle and are not, and are not intended to be treated as, employees of TYME or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plans" (as such term is defined in section 3(3) of the Employee Retirement Income Security Act of 1974, as amended) that are sponsored by TYME or any of its Affiliates or that are offered from time to time by TYME or its Affiliates to their own employees. All matters of compensation, benefits and other terms of employment for any such Field Force Personnel shall be solely a matter between Eagle and such individual. TYME shall not be responsible to Eagle, or to the Field Force Personnel, for any compensation, expense reimbursements or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, severance or termination of employment benefits, pension or profit-sharing benefits and disability benefits), payroll-related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen's compensation contributions or benefits) that may be imposed upon or be related to the performance by Eagle or such individuals of this Agreement, all of which shall be the sole responsibility of Eagle, even if it is subsequently determined by any Governmental Authority that any such individual may be an employee or a common law employee of TYME or any of its Affiliates or is otherwise entitled to such payments and benefits.

(f) Eagle shall be solely responsible for the acts or omissions of the Field Force Personnel that are not in compliance with Applicable Law and the terms of this Agreement while performing any of the activities under this Agreement. Eagle shall be solely responsible and liable for all probationary and termination actions taken by it, as well as for the formulation, content and dissemination (including content) of all employment policies and rules (including written probationary and termination policies) applicable to its employees.

4.5.2 **Termination of Employment; Cessation of Eagle Activities.** If any Field Force Personnel leaves the employ of Eagle (or any of its Affiliates), or otherwise ceases to conduct the Eagle Activities for the Product, Eagle shall, to the extent consistent with, and in a manner similar to, its practices with respect to departures of the sales representatives or other field force personnel, as applicable, promoting, marketing or detailing other products for Eagle, account for, and shall cause such departing Field Force Personnel to return to Eagle and delete from his/her computer files (to the extent such materials or information have been provided in, or converted into, electronic form) all materials relating to the Product that have been provided to such individual, including the Product Materials and account level information, including all copies of the foregoing.

4.5.3 **Discipline.** If TYME has a reasonable basis for believing any member of the Field Force Personnel that are engaged in Detailing has violated any Applicable Laws, or failed to comply with this Agreement, then TYME shall

notify Eagle of the alleged violation and Eagle shall promptly investigate the matter and, if the allegation turns out to be true, shall take the appropriate remedial action. Subject to the foregoing, Eagle shall be solely responsible for taking any disciplinary actions in connection with its Field Force Personnel that are engaged in Detailing. If, at any time, TYME has any other compliance-related concerns regarding any Field Force Personnel Detailing, TYME's Compliance Manager shall notify Eagle's Compliance Manager of such concerns in writing and the Compliance Managers shall discuss and resolve such matters pursuant to Section 4.3.10.

4.6 **Responsibility for Eagle Activity Costs and Expenses.** Other than as expressly set out herein, Eagle shall be solely responsible for any and all costs and expenses incurred by Eagle or any of its Affiliates in connection with the conduct of the Eagle Activities for the Product hereunder, including all costs and expenses in connection with Sales Representatives, including salaries, bonuses, employment benefits, travel expenses and other expenses, credentialing, licensing, providing benefits, deducting federal, state and local payroll taxes, and paying workers' compensation premiums, unemployment insurance contributions and any other payments required by Applicable Laws to be made on behalf of employees.

4.7 **Data Sharing.** Without limiting the information that Eagle shall provide to TYME hereunder, including, without limitation, the reports deliverable under Section 4.2 hereof, TYME shall provide to Eagle certain information relating to the sale, Commercialization, marketing and promotion of the Product, as may be mutually agreed by the Parties from time to time, for use by Eagle and the Field Force Personnel in connection with the Eagle Activities. The timing of the delivery of such information shall be mutually agreed upon by the Parties, acting reasonably.

4.8 **Material Changes.** Eagle acknowledges no Product is available for Commercialization as of the date hereof and that the service levels and requirements of Eagle and its personnel under this Article IV and the accompanying Schedules are based on the Parties' current expectations regarding SM-88 (racemetyrosine)'s approval pathway in pancreatic cancer. Should SM-88 (racemetyrosine) be approved in additional or different indications, a new Product or class of Product becomes available for Commercialization, or there is otherwise a material change in TYME's requirements hereunder, the Parties agree to amend the Operating Parameters Schedule in good faith to address such development. For the avoidance of doubt, the Parties agree that any such amendment will be made in good faith to preserve the spirit and service levels established hereunder for such new indications or changes. Any disputes arising from this Section 4.8 or amendments to the Operating Parameters Schedule incident thereto that are not resolved by the Senior Officers pursuant to Section 3.4.1 shall be governed by Section 12.6.

ARTICLE 5 REGULATORY, SAFETY AND SURVEILLANCE, COMMERCIAL MATTERS

5.1 **TYME Responsibility.** As between the Parties, except as expressly set out herein, all regulatory matters regarding the Product shall be the responsibility of TYME, including responsibility for all communications with Governmental Authorities, including but not limited to the FDA, related to the Product, and TYME shall have sole responsibility to seek and/or obtain any necessary approvals of any Product Labeling and the Promotional Materials used in connection with the Product, and for determining whether the same requires approval. As between the Parties, TYME shall be responsible for any reporting of matters regarding the manufacture, sale or promotion of the Product (including Adverse Events) to or with the FDA and other relevant Regulatory Authorities, in accordance with Applicable Laws. TYME shall maintain, at its cost, the Regulatory Approvals for the Product and shall comply with all Applicable Law relevant to the conduct of TYME's business with respect to the Product or pursuant to this Agreement, including, without limitation, all applicable requirements under the Act.

5.2 **Eagle Involvement.** Except as expressly permitted herein, Eagle shall not, without TYME's prior written consent, correspond or communicate with the FDA or with any other Governmental Authority concerning the Product, or otherwise take any action concerning any Regulatory Approval or other authorization under which the Product is marketed or sold. If not prohibited by any Government Authority or Applicable Law, Eagle

shall provide to TYME, promptly upon receipt, copies of any communication from the FDA or other Governmental Authority related to the Product. If not prohibited by any Government Authority or Applicable Law, TYME has the right to review and comment on Eagle's draft responses to any Governmental Authorities relevant to Detail of the Product prior to Eagle's issuance of such response; and Eagle agrees to consider any comments or suggestions from TYME in good faith.

5.3 **Inspections.**

5.3.1 If not prohibited by any Government Authority or Applicable Law, Eagle shall notify TYME immediately upon receipt of any notice of inspection or investigation by any Governmental Authority related to or that Eagle

reasonably believes may impact any aspect of the Eagle Activities. If not prohibited by any Government Authority or Applicable Law, TYME shall have the right to have a representative present at any such portion of the inspection involving any Eagle Activities. In such cases, Eagle shall (i) keep TYME fully informed of the progress and status of any such inspection or investigation, (ii) prior to undertaking any action pursuant to this Section 5.3.1, notify TYME of the inspection or investigation, and disclose to TYME in writing the Governmental Authorities' assertions, findings and related results of such inspection or investigation pertaining to the Eagle Activities, and (iii) provide full disclosure to TYME with respect to any action undertaken or proposed to be undertaken pursuant to this Section 5.3.1 prior to acting as it pertains to the Eagle Activities. In addition, if such findings or the Governmental Authority requests or suggests that Eagle should change any aspect of the Eagle Activities, the Parties shall work together to make any such modification; provided, however, that notwithstanding anything to the contrary herein, Eagle shall not be required to engage in any Eagle Activities to the extent any finding or Government Authority has requested or suggested that Eagle may not engage in such activity.

5.3.2 If not prohibited by any Government Authority or Applicable Law, TYME shall notify Eagle immediately upon receipt of any notice of inspection or investigation by any Governmental Authority related to or that TYME reasonably believes may impact any aspect of the Eagle Activities. In such cases, TYME shall (i) keep Eagle fully informed of the progress and status of any such inspection or investigation, (ii) disclose to Eagle in writing the Governmental Authorities' assertions, findings and related results of such inspection or investigation pertaining to the Product or its promotion, and (iii) provide full disclosure to Eagle with respect to any action undertaken or proposed to be undertaken pursuant to this Section 5.3.2 prior to acting as it pertains to the Eagle Activities. In addition, if such findings or the Governmental Authority requests or suggests that Eagle should change any aspect of the Eagle Activities, the Parties shall work together to make any such modification; provided, however, that notwithstanding anything to the contrary herein, Eagle shall not be required to engage in any Eagle Activities to the extent any finding or Government Authority has requested or suggested that Eagle may not engage in such activity.

5.4 **Pharmacovigilance.** Subject to the terms of this Agreement, no later than six (6) months prior to the Target Launch Date, TYME and Eagle (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) shall identify and finalize the responsibilities the Parties shall employ to protect patients and promote their well-being in a separate safety data exchange agreement ("**Pharmacovigilance Agreement**"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication and exchange (as between the Parties) of safety information, such as Adverse Events, lack of efficacy, misuse/abuse, and any other information concerning the safety of the Product. Such guidelines and procedures will be in accordance with, and enable the Parties and their Affiliates to fulfill, regulatory reporting obligations to Governmental Authorities. For the avoidance of doubt, such guidelines and procedures shall provide that any Eagle Sales Representative, Field Force Personnel or Eagle Affiliate that becomes aware of an Adverse Event shall follow all TYME policies and procedures regarding Adverse Event reporting, including TYME's Adverse Event Reporting standard operating procedure, which shall be provided to Eagle for training prior to the Target Launch Date. The Pharmacovigilance Agreement shall provide that: (i) TYME shall be responsible for all pharmacovigilance activities regarding the Product, including signal detection, medical surveillance, risk management, medical literature review and monitoring, Adverse Event reporting and responses to Governmental Authority requests or enquiries, and shall provide information related thereto to Eagle, and (ii) in the event Eagle receives safety information regarding the Product, or information regarding any safety-related regulatory request or inquiry, Eagle shall notify TYME as soon as practicable, but, in any event, within the timelines set forth in the Pharmacovigilance Agreement.

5.5 **Unsolicited Requests for Medical Information.** Eagle shall direct to TYME any unsolicited requests for off-label medical information from health care professionals with respect to the Product promptly following receipt by Eagle (but in no event later than two (2) days after receipt). TYME shall, within two (2) days following receipt of any such request from Eagle, address any such requests directly.

5.6 **Recalls and Market Withdrawals.** As between the Parties, TYME shall have the sole right to determine whether to implement, and to implement, a recall, field alert, withdrawal or other corrective action related to the Product. TYME shall bear the cost and expense of any such recall, field alert, withdrawal or other corrective action. Each Party shall promptly (but in any case, not later than one (1) day after) notify the other Party in writing of any order, request or directive of a court or other Governmental Authority to recall or withdraw the Product.

5.7 **Certain Reporting Responsibilities.** Notwithstanding the foregoing provisions of this ARTICLE 5, each Party shall be responsible for its own federal, state and local government pricing reporting and payment transparency reporting in the Territory arising from its Product promotional activities and related expenditures pursuant to Applicable Law. It is the intention of the Parties that any payments or transfer of value by a Party as it relates to the Product shall constitute transfers of

value by that Party and such Party shall be responsible for the reporting described in the immediately preceding sentence. However, if a Party is deemed to have provided any payments or transfers of value to a Third Party on behalf of the other Party as it relates to the Product, then such Party shall provide to the other Party, in a format reasonably acceptable to such other Party, the data and other information on a timely basis (i.e., in the case of manual reporting of such data and other information, within 30 days following the end of each Fiscal Quarter, and, in the case of automated reporting of such data and other information, on a periodic basis during each Fiscal Quarter as reasonably requested by such other Party) for such other Party's reporting under the Physician Payments Sunshine Act and other Applicable Laws.

5.8 **Booking of Sales Revenues.** TYME shall retain ownership of the rights to the Product and record on its books all revenues from sales of the Product. TYME shall be exclusively responsible for accepting and filling purchase orders, billing, and returns with respect to the Product. If Eagle receives an order for the Product, it shall promptly transmit such order to TYME (or its designee) for acceptance or rejection. TYME shall have sole responsibility for shipping, distribution and warehousing of the Product, and for the invoicing and billing of purchasers of the Product and for the collection of receivables resulting from the sales of the Product in the Territory.

5.9 **Returns.** Eagle is not authorized to accept any Product returns. Eagle shall advise any customer who attempts to return any Product to Eagle (or its Affiliates) that such Product must be shipped by the customer to the facility designated by TYME from time to time (and in accordance with

other instructions provided by TYME). TYME shall provide to Eagle written instructions as to how Eagle should handle any Product that is actually physically returned to Eagle. Eagle shall take no other actions with respect to such return without the prior written consent of TYME.

5.10 **Development; Manufacturing; Distribution; Marketing.** TYME shall have the sole authority to Develop, Commercialize, manufacture, package, label, warehouse, sell and distribute the Product in the Territory. TYME shall use Commercially Reasonable Efforts to Develop and Commercialize at least one (1) Product in the Field in the Territory. Following the acceptance of the NDA for SM-88 (racemetyrosine) by the FDA and no later than 90 days prior to the Target Launch Date, TYME shall use Commercially Reasonable Efforts to cause sufficient quantities of Product to be available in inventory to promptly fill orders throughout the Territory and otherwise meet the forecasted demand for Product in the Territory. If, despite such efforts, there is insufficient supply of Product to meet demand, then TYME shall use Commercially Reasonable Efforts to promptly address such insufficiency. TYME shall contractually require (and shall use commercially reasonable efforts to enforce such contractual provisions) that all Product is manufactured, shipped, sold and distributed in accordance with all Product specifications and all Applicable Law and that its contract manufacturers and/or suppliers of Product operate their facilities in accordance with Applicable Law. TYME shall ensure that all Product Labeling complies with the applicable Regulatory Approval for the Product and Applicable Law. Other than as set forth in this Agreement, TYME shall be responsible for all marketing of the Product in the Territory.

ARTICLE 6 FINANCIAL PROVISIONS

6.1 **Promotion Fee.**

6.1.1 **Calculation of Promotion Fee.**

(a) Subject to Section 6.1.2, commencing with the Fiscal Quarter following the First Commercial Sale, as consideration for the Eagle Activities performed by Eagle, TYME shall pay Eagle a promotion fee based on Net Sales during the Term, calculated by multiplying fifteen percent (15%) by Net Sales of all Product in the Territory in each Fiscal Quarter.

(b) At any time after the date hereof, TYME shall have the right to terminate Eagle's right to Detail and Promote the Product in the Territory in the Field upon a payment to Eagle of all accrued, earned but unpaid promotion fee amounts plus the Buyout Amount.

6.1.2 **Adjustment of Promotion Fee.** In the event that Eagle fails to satisfy the Eagle Quarterly Minimum Details for the Product or fails to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for a period of two (2) consecutive Fiscal Quarters, the promotion fee payable by TYME pursuant to Section 6.1.1(a) shall be reduced to twelve percent (12%) for subsequent Fiscal Quarters and Eagle shall continue to receive such reduced promotion fee until such Fiscal Quarter in which Eagle satisfies the Eagle Quarterly Minimum Details for the Product or demonstrates Commercially Reasonable Efforts to execute on other aspects of the Sales Plan, as the case may be.

Eagle's failure to meet the Eagle Quarterly Minimum Details or to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for the Product for a period of four (4) consecutive Fiscal Quarters shall be deemed a material breach of this Agreement (it being understood that a failure to meet the Eagle Quarterly Minimum Details or to demonstrate Commercially Reasonable Efforts to execute on other aspects of the Sales Plan then in effect for the Product for any period less than four consecutive Fiscal Quarters shall not alone be deemed a material breach of this Agreement). For the avoidance of doubt, notwithstanding anything to the contrary herein, such material breach of this Agreement shall give rise to TYME's immediate ability to terminate the Agreement pursuant to Section 11.2.2 and shall not be subject to any cure period.

6.2 **Reports; Payments.**

6.2.1 **Quarterly Reports and Payments.** Within fifteen (15) Business Days after the end of each Fiscal Quarter during the Term, TYME shall provide to Eagle a written report setting forth in reasonable detail the calculation of the Net Sales for such Fiscal Quarter and the promotion fee payable in respect of such Net Sales in accordance with Section 6.1, including the number of units of the Product shipped to patients in the Territory during such Fiscal Quarter, together with an itemized list of such units by Target Professional writing the applicable prescription. Within sixty (60) days after the end of each Fiscal Quarter during the Term, TYME shall pay to Eagle the undisputed portion of the promotion fee payable in respect of such Net Sales in accordance with Section 6.1. If this Agreement terminates or expires during a Fiscal Quarter, the promotion fee payable to Eagle under Section 6.1 shall be calculated only on the Net Sales that occurred during prior to the effective date of such termination or expiration in such Fiscal Quarter.

6.2.2 **Monthly Estimate Reports.** Within fifteen (15) Business Days of the end of each month within each Fiscal Quarter, TYME shall provide to Eagle a written report setting forth TYME's good faith estimate of the Net Sales and the estimated promotion fee payable in respect of such Net Sales for each of such calendar month and the Fiscal Quarter- to-date period, together with its good faith estimates of each of the items described in Section 6.2.1 above. The Parties acknowledge and agree that the monthly reports shall only set forth TYME's good faith estimates of the items contained therein and are being provided to Eagle for information purposes only and shall not be determinative of the any amounts due hereunder.

6.2.3 **Payment Adjustments.** If new information becomes available after the close of a Fiscal Quarter under the process described in Section 6.2.1 that would adjust the amount of recognized Net Sales or payments under this Agreement, such adjustments shall be made in the Fiscal Quarter they become available. Additions or deductions in payments resulting from any adjustments shall be applied to the next regularly scheduled quarterly payment.

6.2.4 **Disputes.** Promptly upon receipt of the quarterly or monthly reports described in this Section 6.2, Eagle shall review such reports and, in the event that Eagle disputes any of the items described in such report, Eagle shall promptly notify TYME of any such disputes. The Parties shall meet promptly thereafter to attempt to resolve such disputes.

6.2.5 **Manner of Payment.** All payments under this Agreement shall be made in US Dollars by wire transfer or Automated Clearing House to a bank account designated in writing by Eagle or TYME, as applicable, which shall be designated at least five (5) Business Days before such payment is due.

6.2.6 **Late Payments.** If Eagle does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Eagle from the due date until the date of payment at the prime rate published in the Wall Street Journal on the due date plus two percent (2.0%) per annum or the maximum rate allowable by Applicable Law, whichever is less. Notwithstanding the foregoing, if the reason for any late payment is resulting from or arising out of any act or omission on the part of Eagle, including, but not limited to, any delay providing the payment

instructions pursuant to Section 6.2.5, such interest shall not accrue. For clarity, any payments due from adjustments under Section 6.2.3 shall not be considered late payments.

6.3 **Taxes.** To the extent TYME is required to deduct and withhold taxes from any payment to Eagle, TYME shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Eagle an official tax receipt or other evidence of timely payment sufficient to enable Eagle to claim the payment of such taxes as a deduction or tax credit. Eagle may provide to TYME any tax forms that may be reasonably necessary in order for TYME to not withhold tax and TYME shall dispense with withholding, as applicable. TYME shall provide Eagle with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding taxes.

6.4 **Recordkeeping.** Each Party shall maintain complete and accurate books and records in sufficient detail, in accordance with GAAP (to the extent applicable and in accordance with the Agreement) and all Applicable Law, to enable verification of the performance of such Party's obligations under this Agreement and any payments due to a Party under this Agreement. Unless otherwise specified herein, the books and records for a given Fiscal Year of the Term shall be maintained for a period of three (3) years after the end of such Fiscal Year or longer if required by Applicable Law.

6.5 **Eagle Rights.** Eagle shall have the right, at its own expense, during normal business hours and upon reasonable prior notice, through an independent certified public accountant reasonably acceptable to Tyme, and upon execution of a confidentiality agreement reasonably satisfactory to TYME in form and substance, to inspect the applicable records and books maintained by TYME solely for purposes of verifying the accuracy of Net Sales amounts reported by TYME pursuant to Section 6.2.1 hereof and the fees payable by TYME to Eagle under this Agreement in respect of such amounts. For clarity, such inspection right described in this Section 6.5 shall be limited to only those books and records of payment reports and amounts owed to Eagle as a result of Tyme's achievement of Net Sales of the Product in the Territory under this Agreement and (i) may be conducted no more than once per calendar year, (ii) may only cover the most recently completed Fiscal Year and the two (2) years prior to such Fiscal Year, and (iii) may not be conducted in March through June of any given Fiscal Year. Disputes, if any, must be submitted to TYME within sixty (60) days after the completion of such inspection. TYME shall reasonably cooperate in any such inspection or audit conducted by Eagle. Eagle shall treat all information subject to review under this Section 6.5 in accordance with the confidentiality provisions of this Agreement.

ARTICLE 7 INTELLECTUAL PROPERTY

7.1 **Ownership of Intellectual Property.**

7.1.1 **Eagle Property.** TYME acknowledges that Eagle owns or is licensed to use certain Know-How relating to proprietary sales and marketing information, methods and plans that has been independently developed or licensed by Eagle (such Know-How, the "**Eagle Property**"). The Parties agree that any improvement, enhancement or modification made, discovered, conceived, or reduced to practice by Eagle to any Eagle Property in performing its activities pursuant to this Agreement which is not primarily related to the Product, or which is not otherwise derived from the Confidential Information of TYME, shall be deemed Eagle Property. Eagle hereby grants to TYME a fully paid-up, royalty free, non-transferable, non-exclusive perpetual license (with a limited right to sub-license to its Affiliates) to any Eagle Property that appears on, embodied on or contained in Product Materials or Product Labeling solely for use in connection with TYME's promotion or other Commercialization of the Product in the Territory.

7.1.2 **TYME Property.** Subject to the terms of Section 7.1.1, TYME shall have and retain sole and exclusive right, title and interest in and to all inventions, developments, discoveries, writings, trade secrets, Know-How, methods, practices, procedures, designs, improvements and other technology, whether or not patentable or copyrightable, and any patent applications, patents, or copyrights based thereon (collectively, "**Intellectual Property**") relating to the Product that are (i) owned or controlled by TYME as of the Effective Date, (ii) made, discovered, conceived, reduced to practice or generated by TYME (or its employees or representatives) during the Term, or (iii) made, discovered, conceived, reduced to practice or generated by Eagle (or its employees or representatives) in performing its activities pursuant to this Agreement to the extent primarily related to the Product or which is otherwise derived from the Confidential Information of TYME ("**Inventions**"). Eagle agrees to assign, and hereby does assign, to TYME (and shall cause its Affiliates and its and their respective employees and other representatives to assign to TYME) any and all right, title and interest that Eagle (or any such Affiliates, employees or other representatives) may have in or to any Invention. For clarity, any and all Inventions and any information contained therein or related thereto shall constitute Confidential Information of TYME.

7.2 **Title to Trademarks and Copyrights.** The ownership, and all goodwill from the use, of any TYME Trademarks and Copyrights shall at all times vest in and inure to the benefit of TYME, and Eagle shall assign, and hereby does assign, any rights it may have in the foregoing to TYME. Eagle shall not, directly or indirectly, adopt, apply for or acquire any trademarks, trade names, or domain names that include or are confusingly similar to any of the TYME Trademarks and Copyrights.

7.3 **Protection of Trademarks and Copyrights.** As between the Parties, TYME shall have the sole right (but not the obligation), as determined by TYME in its sole discretion, to (i) maintain the TYME Trademarks and Copyrights and/or (ii) protect, enforce and defend the TYME Trademarks and Copyrights. Eagle shall give notice to TYME of any infringement of, or challenge to, the validity or enforceability of the TYME Trademarks and Copyrights promptly after learning of such

infringement or challenge. If TYME institutes an action against Third Party infringers or takes action to defend the TYME Trademarks and Copyrights, Eagle shall reasonably cooperate with TYME, at TYME's cost and expense. Any recovery obtained by TYME as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by TYME. Eagle shall not have any right to institute any action to defend or enforce the TYME Trademarks and Copyrights.

7.4 **Protection of Patent Rights.** As between the Parties, TYME shall have the sole right (but not the obligation), as determined by TYME in its sole discretion, to (i) prosecute and maintain the TYME Patent Rights and/or (ii) protect, enforce and defend the TYME Patent Rights. Eagle shall give notice to TYME of any misappropriation or infringement of, or challenge to, the validity or enforceability of the TYME Patent Rights promptly after learning of such misappropriation or infringement or challenge. If TYME institutes an action against Third Party infringers or takes action to stop the misappropriation or infringement of the TYME Patent Rights, Eagle shall reasonably cooperate with TYME, at TYME's cost and expense. Any recovery obtained by TYME as a result of such proceeding or other actions, whether obtained by settlement or otherwise, shall be retained by TYME. Eagle shall not have any right to institute any action to defend or enforce the TYME Patent Rights.

7.5 **Disclosure of Know-How.** For clarity, the Parties hereby agree and acknowledge that to the extent that either Party hereto has disclosed, or in the future discloses, to the other Party any Know-How or other Intellectual Property of such Party or its Affiliates pursuant to this Agreement, the other

Party shall not acquire any ownership rights in such Know-How or other Intellectual Property by virtue of this Agreement or otherwise, and as between the Parties, all ownership rights therein shall remain with the disclosing Party (or its Affiliate).

ARTICLE 8 CONFIDENTIALITY

8.1 Confidential Information.

8.1.1 **Confidentiality and Non-Use.** Each Party agrees that, during the Term and for a period of five (5) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of its rights or performance of any obligations hereunder) any Confidential Information furnished to it by or on behalf of the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. Without limiting the foregoing, each Party shall use at least the same standard of care as it uses to protect its own Confidential Information to ensure that its employees, agents, consultants and contractors do not disclose or make any unauthorized use of such Confidential Information. Each Party shall promptly notify the other upon discovery of any unauthorized use or disclosure of the other's Confidential Information. Any and all information and materials disclosed by a Party pursuant to the Confidentiality Agreement between the Parties dated June 25, 2019 (the "**Confidentiality Agreement**") shall be deemed Confidential Information disclosed pursuant to this Agreement. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent tangible evidence:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure to the receiving Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party (or its Affiliate); or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application, use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

8.1.2 **Authorized Disclosure.** Notwithstanding the obligations set forth in Section 8.1.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (x) to comply with the requirements of Governmental Authorities; or (y) for the prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its Affiliates, employees, agents, consultants and contractors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by obligations of confidentiality and non-use consistent with those contained in this Agreement and the disclosing Party shall be liable for any failures of such disclosees to abide by such obligations of confidentiality and non-use; or

(c) such disclosure is reasonably necessary to comply with Applicable Laws, including regulations promulgated by applicable securities exchanges, court order, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 8.1.2(a) or 8.1.2(c), such Party shall, if permitted, promptly notify the other Party of such required disclosure and shall use reasonable efforts to assist the other Party (at the other Party's cost) in obtaining, a protective order preventing or limiting the required disclosure.

8.2 **Public Announcements.** No public announcement or statements (including presentations to investor meetings and customer updates) concerning the existence of or terms of this Agreement or incorporating the marks of the other Party or their respective Affiliates shall be made, either directly or indirectly, by either Party or a Party's Affiliates, without first obtaining the written approval of the other Party and agreement upon the nature, text and timing of such announcement or disclosure. Either Party shall have the right to make any such public announcement or other disclosure required by Applicable Law after such Party has provided to the other Party a copy of such announcement or disclosure and an opportunity to comment thereon and the disclosing Party shall reasonably consider the other Party's comments. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other Governmental Authorities, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with this Section 8.2, either Party may make a subsequent public disclosure of the same contents of such statement in the same context as such statement without further approval of the other Party. Notwithstanding anything to the contrary contained herein, in no event shall either Party disclose any financial information of the other without the prior written consent of such other Party, unless such financial information already has been publicly disclosed by the Party owning the financial information or otherwise has been made part of the public domain by no breach of a Party of its obligations under this ARTICLE 8.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES; ADDITIONAL COVENANTS

9.1 **Representations and Warranties of TYME.** TYME represents and warrants to Eagle as of the Effective Date that:

9.1.1 it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

9.1.2 the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

9.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.1.4 this Agreement constitutes a legal, valid and binding obligation enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

9.1.5 the execution, delivery and performance of this Agreement by TYME does not require the consent of any Person (including under any agreement with a Third Party) or the authorization of (by notice or otherwise) any Governmental Authority including the FDA;

9.1.6 there is no action, suit or proceeding pending or, to the knowledge of TYME, threatened, against TYME or any of its Affiliates, or to the knowledge of TYME, any Third Party acting on their behalf, which would be reasonably expected to impair, restrict or prohibit the ability of TYME or Eagle to perform its obligations and enjoy the benefits of this Agreement;

9.1.7 it has no knowledge of any information relating to the safety or efficacy of the Product or any communications with any Governmental Authority, which would reasonably be expected to materially impair, restrict, prohibit or affect TYME's ability to perform its obligations and enjoy the benefits of this Agreement;

9.1.8 it is in compliance in all material respects with all Applicable Laws applicable to the subject matter of this Agreement;

9.1.9 it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to execute and deliver this Agreement and to fulfill any of its obligations under this Agreement;

9.1.10 it is currently conducting a Pivotal Clinical Study for SM-88 (racemetyrosine) though its TYME- 88-Panc trial and SM-88 (racemetyrosine) is also being studied in the Pancreatic Cancer Action Network adaptive Phase II/III trial known as Precision PromiseSM, which TYME believes can serve as a Pivotal Clinical Study; however, TYME does not currently have an NDA for SM-88 (racemetyrosine) accepted by the FDA;

9.1.11 neither TYME nor any of its personnel (i) have been debarred under the 21 U.S.C. § 335a, (ii) are excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in federal procurement or nonprocurement programs, (iii) are convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, (iv) are listed on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) or (v) are listed on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>). If, during the Term, TYME or any of its personnel becomes or is the subject of a proceeding that could lead to, as applicable, (i) debarment under 21 U.S.C. § 335a, (ii) exclusion, debarment, suspension or ineligibility to participate in the federal health care programs or in federal procurement or nonprocurement programs, (iii) convicted (or conviction) of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal healthcare programs, (iv) listed (or listing) on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) or (v) listed (or listing) on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>), TYME shall immediately notify Eagle, and Eagle shall have the option to prohibit such Person from performing work relating to this Agreement or the Product; and

9.1.12 the Product Materials provided by TYME to Eagle for the conduct of Eagle Activities are, and shall be, compliant with the Regulatory Approval for the Product, the Product Labeling and Applicable Law.

9.2 **Representations and Warranties of Eagle**. Eagle represents and warrants to TYME as of the Effective Date that:

9.2.1 it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation;

9.2.2 the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

9.2.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

9.2.4 this Agreement constitutes a legal, valid and binding obligation enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement

of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);

9.2.5 the execution, delivery and performance of this Agreement by Eagle does not require the consent of any Person or the authorization of (by notice or otherwise) any Governmental Authority or the FDA;

9.2.6 there is no action, suit or proceeding pending or, to the knowledge of Eagle, threatened, against Eagle or any of its Affiliates, or to the knowledge of Eagle, any Third Party acting on their behalf, which would be reasonably expected to impair, restrict or prohibit the ability of TYME or Eagle to perform its obligations and enjoy the benefits of this Agreement;

9.2.7 it is in compliance in all material respects with all Applicable Laws applicable to the subject matter of this Agreement;

9.2.8 it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction agreement (including any outstanding order, judgment or decree of any court or administrative agency) which in any way limits or conflicts with its ability to execute and deliver this Agreement and to fulfill any of its obligations under this Agreement;

9.2.9 it has no knowledge of any information relating to any communications with any Governmental Authority, which would reasonably be expected to materially impair, restrict, prohibit or affect Eagle's ability to perform its obligations and enjoy the benefits of this Agreement;

9.2.10 neither Eagle nor any of its personnel (i) have been debarred under the 21 U.S.C. § 335a, (ii) are excluded, debarred, suspended, or otherwise ineligible to participate in the federal health care programs or in Federal procurement or nonprocurement programs, (iii) are convicted of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal health care programs but has not yet been excluded, debarred, suspended, or otherwise declared ineligible to participate in those programs, (iv) are listed on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) or (v) are listed on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>). If, during the Term, Eagle or any of its personnel become or are the subject of a proceeding that could lead to, as applicable, (i) debarment under 21 U.S.C. § 335a, (ii) exclusion, debarment, suspension or ineligibility to participate in the federal health care programs or in Federal procurement or nonprocurement programs, (iii) convicted (or conviction) of a criminal offense that falls within the ambit of the federal statute providing for mandatory exclusion from participation in federal healthcare programs, (iv) listed (or listing) on the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) or (v) listed (or listing) on the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>), Eagle shall immediately notify TYME, and TYME shall have the option to prohibit such Person from performing work under this Agreement; and

9.2.11 all Field Force Personnel that are engaged in Detailing are, and shall be, licensed to the extent required and in accordance with all Applicable Laws.

9.3 **Disclaimer of Warranty.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, TYME (AND ITS AFFILIATES) AND EAGLE (AND ITS AFFILIATES) MAKE NO REPRESENTATIONS AND NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND TYME (AND ITS AFFILIATES) AND EAGLE (AND ITS AFFILIATES) EACH SPECIFICALLY DISCLAIM ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS, STATUTORY OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY INTELLECTUAL PROPERTY OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 10 INDEMNIFICATION; LIMITATIONS ON LIABILITY

10.1 **Indemnification by TYME.** TYME shall defend, indemnify and hold harmless Eagle and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all

Claims, and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, agreements or covenants of TYME under this Agreement, (b) the negligence, willful misconduct or violation of Applicable Laws by TYME (or any of its Affiliates or its or their respective officers, directors, employees, agents or representatives), (c) the misappropriation or infringement of the intellectual property rights of any Third Party in connection with the Product, including from the use of the TYME Trademarks and Copyrights on Product Labeling or Product Materials in accordance with this Agreement, or (d) the Development and Commercialization of the Product by or on behalf of TYME, its Affiliates and any of their respective licensees, including the death or personal injury to any person related to use of the Product; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which Eagle is obligated to indemnify TYME pursuant to Section 10.2.

10.2 **Indemnification by Eagle.** Eagle shall defend, indemnify and hold harmless TYME and its Affiliates and its and their respective officers, directors, employees, agents, representatives, successors and assigns from and against all Claims and all associated Losses, to the extent incurred or suffered by any of them to the extent resulting from or arising out of (a) any misrepresentation or breach of any representations, warranties, agreements or covenants of Eagle under this Agreement, (b) the negligence, willful misconduct, or violation of Applicable Laws by Eagle (or any of its Affiliates or its and their respective officers, directors, employees, agents or representatives) or (c) labor disputes, Equal Employment Opportunity Commission charges or employment-related claims arising from or related to Eagle's employees; except in each case to the extent any such Claims, and all associated Losses, are caused by an item for which TYME is obligated to indemnify Eagle pursuant to Section 10.1.

10.3 **Indemnification Procedures.** The Party seeking indemnification under Section 10.1 or 10.2, as applicable (the "**Indemnified Party**") shall give prompt notice to the Party against whom indemnity is sought (the "**Indemnifying Party**") of the assertion or commencement of any Claim in respect of which indemnity may be sought under Section 10.1 or 10.2, as applicable, and shall provide the Indemnifying Party such information with respect thereto that the Indemnifying Party may reasonably request. The failure to give such notice shall relieve the Indemnifying Party of any liability hereunder only to the extent that the Indemnifying Party has suffered actual prejudice thereby. The Indemnifying Party shall assume and control the defense and settlement of any such action, suit or proceeding at its own expense; provided, however, if the Indemnified Party is TYME, it shall assume and control the defense and settlement of any such action, suit or proceeding. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in such defense, at the Indemnifying Party's expense. The Indemnified Party shall be entitled at its own expense to participate in such defense and to employ separate counsel for such purpose. For so long as the Indemnifying Party is diligently defending any proceeding pursuant to this Section 10.3, the Indemnifying Party shall not be liable under Section 10.1 or 10.2, as applicable, for any settlement effected without its consent. No Party shall enter into any compromise or settlement which commits the other Party to take, or to forbear to take, any action without the other Party's prior written consent (unless such compromise or settlement includes no payments by the Indemnified Party, an unconditional release of, and no admission of liability by, the Indemnified Party from all liability in respect of such Claim).

10.4 **Limitation of Liability.** NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN (OTHER THAN AS SET FORTH IN THE SECOND SENTENCE OF THIS SECTION 10.4), IN NO EVENT SHALL TYME (OR ITS AFFILIATES) OR EAGLE (OR ITS AFFILIATES) BE LIABLE TO THE OTHER OR ANY OF THE OTHER PARTY'S AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING SENTENCE SHALL NOT LIMIT (1) THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 10.1 OR 10.2, AS APPLICABLE, OR (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF THE NON-COMPETE AND NON-SOLICIT OBLIGATIONS IN SECTION 2.3 AND THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 8.

10.5 **Insurance.** Each Party acknowledges and agrees that during the Term, it shall maintain, through purchase or self-insurance, adequate insurance, including products liability coverage and comprehensive general liability insurance, adequate to cover its obligations under this Agreement and which are consistent with normal business practices of prudent companies similarly situated. Each Party shall provide reasonable written proof of the existence of such insurance to the other Party upon request. TYME does not and will not maintain or procure any worker's compensation, healthcare, or other insurance for or on behalf of any Field Force Personnel, all of which shall be Eagle's sole responsibility. For clarity, the insurance

requirements of this Section 10.5 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this ARTICLE 10.

ARTICLE 11 TERM AND TERMINATION

11.1 **Term.** This Agreement shall become effective as of the Effective Date and, unless earlier terminated as provided in this ARTICLE 11, will continue for ten (10) years (the "**Term**").

11.2 **Early Termination.** A Party shall have the right to terminate this Agreement before the end of the Term as follows:

11.2.1 by Eagle at its sole discretion and for any reason or no reason, upon twelve (12) months written notice to TYME given any time after the second (2nd) anniversary of the First Commercial Sale of the Product in the Territory;

11.2.2 by a Party upon written notice to the other Party in the event of a material breach of this Agreement by such other Party where such breach is not cured (if able to be cured) within 60 days following such other Party's receipt of written notice of such breach (and any such termination shall become effective at the end of such 60-day period unless the breaching Party has cured such breach prior to the expiration of such 60-day period), provided, however, for the avoidance of doubt such 60-day period shall not apply for termination relating to a material breach arising under Section 6.1.2 of this Agreement;

11.2.3 by either Party upon 90 days' written notice to the other Party following the withdrawal of the Product from the market by TYME (or the decision by TYME to withdraw the Product from the market) due to (i) any decision, judgment, ruling or other requirement of the FDA, or (ii) material safety concern;

11.2.4 by TYME pursuant to Section 6.1.1(b); and

11.2.5 by a Party immediately upon written notice to the other Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings with respect to such other Party, or upon an assignment of a substantial portion of the assets for the benefit of creditors by such other Party, or in the event a receiver or custodian is appointed for such other Party's business or a substantial portion of such other Party's business is subject to attachment or similar process; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

11.3 **Effects of Termination.** Upon the expiration or effective date of termination of this Agreement, (i) all rights and obligations of both Parties hereunder shall immediately terminate, subject to any survival as set forth in Section 11.4, (ii) Eagle, at TYME's direction, shall immediately return to TYME or destroy in accordance with all Applicable Laws all Product Materials, reports and other tangible items provided by or on behalf of TYME to Eagle or otherwise developed or obtained by Eagle pursuant to the terms of this Agreement (other than Eagle Property) (and at the request of TYME, Eagle shall certify destruction of such materials if Eagle does not to return such materials to TYME), (iii) Eagle shall immediately cease all Eagle Activities with respect to the Product, and (iv) each of TYME and Eagle shall, at the other Party's direction, either return to such other Party or destroy all Confidential Information of such other Party. Notwithstanding the foregoing, each Party may retain archival copies of any Confidential Information to the extent required by law, regulation or professional standards or copies of Confidential Information created pursuant to the automatic backing-up of electronic files where the delivery or destruction of such files would cause undue hardship to the receiving Party, so long as any such archival or electronic file back-up copies are accessible only to its legal or IT personnel, provided that such Confidential Information shall continue to be subject to the terms of this Agreement.

11.4 **Survival.** Termination or expiration of this Agreement shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Notwithstanding any expiration or termination of this Agreement, such expiration or termination shall not relieve any Party from obligations which are expressly or by implication intended to survive expiration or termination, including Sections 2.3, 4.4.2, 5.7, 5.9, 6.2.4, 6.2.5, 10.1, 10.2, 10.3, 10.4, 11.3 and 11.4, Articles 7, 8 and 12 (to the extent applicable to implementation of the survival of the preceding Sections and Articles) and, solely as it relates to the last Fiscal Quarter, Sections 6.1, 6.2 and 6.3, which shall survive and be in full force and effect.

ARTICLE 12 MISCELLANEOUS

12.1 **Force Majeure.** Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement (other than any failure to make payments owed under this Agreement) to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances and re-commence its performance hereunder as soon as practicable.

12.2 **Assignment.** Except as provided in this Section 12.2, this Agreement may not be assigned or otherwise transferred, nor may any rights or obligations hereunder be assigned or transferred, by either Party, without the written consent of the other Party (such consent not to be unreasonably withheld); provided that a merger, sale of stock or comparable transaction shall not constitute an assignment. In the event either Party desires to make such an assignment or other transfer of this Agreement or any rights or obligations hereunder, such Party shall deliver a written notice to the other Party requesting the other Party's written consent in accordance with this Section 12.2, and the other Party shall provide such Party written notice of its determination whether to provide such written consent within 30 days following its receipt of such written notice from such Party. Notwithstanding the foregoing, (a) either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate; and (b) either Party may assign this Agreement to a successor in interest in connection with the sale or other transfer of all or substantially all of

such Party's assets or rights relating to the Product; provided that such assignee shall remain subject to all of the terms and conditions hereof in all respects and shall assume all obligations of such Party hereunder whether accruing before or after such assignment. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Any attempted assignment not in accordance with this Section 12.2 shall be void. This Agreement shall be binding on, and inure to the benefit of, each Party, and its permitted successors and assigns.

12.3 **Severability.** If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

12.4 **Notices.** All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by e-mail (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier, or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to TYME, to: Tyme Technologies, Inc. 17 State Street – 7th Floor New York, NY 10004
Attention: Chief Executive Officer
E-Mail: steve.hoffman@tymeinc.com

With a copy to:
Tyme Technologies, Inc. 17 State Street – 7th Floor New York, NY 10004
Attention: Chief Legal Officer
E-Mail: jim.biehl@tymeinc.com

if to Eagle, to: Eagle Pharmaceuticals, Inc.
50 Tice Boulevard Woodcliff Lake, NJ 07677

Attention: Executive Vice President & General Counsel E-Mail: mcordera@eagleus.com

With a copy to:
Eagle Pharmaceuticals, Inc. 50 Tice Boulevard Woodcliff Lake, NJ 07677
Attention: Chief Operating Officer & President E-Mail: dpernock@eagleus.com

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the Business Day after dispatch if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) Business Day following the date of mailing, if sent by mail.

12.5 **Governing Law.** This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware applicable to agreements made and to be performed entirely in such state, including its statutes of limitation but without giving effect to the conflict of law principles thereof.

12.6 **Dispute Resolution.** If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith that (a) is expressly reserved for resolution pursuant to this Section 12.6 or (b) is outside of the decision-making authority of the SOC pursuant to Section 3.4 (a “Dispute”), then the Dispute shall be submitted to and finally settled by binding arbitration by JAMS under its Comprehensive Arbitration Rules and Procedures. A Dispute settled by an arbitrator shall be conducted by three arbitrators, each having ten years of experience in the pharmaceutical industry and also shall have served as an arbitrator at least three times prior to their service as an arbitrator in this arbitration. Within ten (10) days of commencement of an arbitration each Party shall select one (1) arbitrator and together select a third arbitrator who shall serve as a neutral arbitrator. The two designated arbitrators shall select a third neutral arbitrator within ten (10) days of their selection if the Parties cannot agree on the third arbitrator. If the two arbitrators cannot agree on selection of a third arbitrator within ten (10) days of their appointment, JAMS shall do so in accordance with its rules. The fees of the arbitrator(s) and JAMS shall be paid by the losing Party, which shall be designated by the arbitrator(s). If the arbitrator(s) is unable to designate a losing Party, it shall so state and the fees shall be split equally by the Parties. The arbitrator(s) is hereby empowered to award any remedy allowed by Law, including money damages, prejudgment interest and attorneys’ fees, and to grant final, complete, interim or interlocutor relief, including injunctive relief. The Parties hereby submit to the exclusive jurisdiction of the federal and state courts located in Wilmington, Delaware for the purposes of an order to compel arbitration, for preliminary relief in aid of arbitration and for a preliminary injunction to maintain the status quo or prevent irreparable harm prior to the appointment of the arbitrators and to the non-exclusive jurisdiction of such courts for the enforcement of any award issued hereunder.

12.7 **Waiver of Jury Trial.** EACH OF THE PARTIES HERETO IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

12.8 **Entire Agreement; Amendments.** This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof (including the Confidentiality Agreement, but solely with respect to information which is deemed Confidential Information hereunder) are superseded by the terms of this Agreement. The Exhibits and Schedules to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

12.9 **Headings.** The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

12.10 **Independent Contractors.** It is expressly agreed that Eagle and TYME shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Eagle nor TYME shall have the authority to make any

statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

12.11 **Third Party Beneficiaries.** Except as set forth in ARTICLE 10, no Person other than TYME or Eagle (and their respective Affiliates and permitted successors and assignees hereunder) shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

12.12 **Waiver.** The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

12.13 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

12.14 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

12.15 **Use of Names.** Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

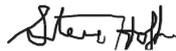
12.16 **Further Actions and Documents.** Each Party agrees to execute, acknowledge and deliver all such further instruments, and to do all such further acts, as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

12.17 **Certain Conventions.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) whenever any provision of this Agreement uses the term "including" (or "includes"), such term shall be deemed to mean "including without limitation" (or "includes without limitations"), and (e) references to any Articles or Sections include Sections and subsections that are part of the references' Article or Section (e.g., a section numbered "Section 2.2.1" would be part of "Section 2.2", and references to "ARTICLE 2" or "Section 2.2" would refer to material contained in the subsection described as "Section 2.2.1").

12.18 **Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile or electronic mail (including pdf) and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes and shall have the same force and effect as original signatures.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.



TYME TECHNOLOGIES, INC.

By: __
Name: Steve Hoffman
Title: Chief Executive Officer

EAGLE PHARMACEUTICALS, INC.



By: __

Name: Pete A. Meyers
Title: Chief Financial Officer

[Signature Page to Co-Promotion Agreement]

Schedule 1.77
Exclusions from “Target Professionals”

Key Thought Leaders:

[TO BE PROVIDED BY TYME PRIOR TO THE TARGET LAUNCH DATE]

Schedule 4.1 Operating Parameters Schedule

(As in effect January 7, 2020)

Sales Force:

- Eagle shall provide an adequate sales force, as defined below under Sales Force Requirements, to call on community and hospital based health care providers. TYME will continue to be the exclusive contact with key opinion leaders and key academic researchers, who will be defined prior to the SM-88 launch.
- Sales Force Requirements:
 - o Eagle will be responsible for having sufficient SM-88 representatives to cover 25% of the Sales Force Requirements
 - § Eagle will have the sales representatives in place in time for appropriate training at least 90 days prior to the Target Launch Date
 - § The Eagle SM-88 sales representatives will have separate accounts from the TYME representatives as identified in the Sales Plan (as such term is defined in the Agreement)
 - § The Eagle SM-88 accounts will be identified prior to the acceptance of the NDA by the FDA
 - § The percentage of the Sales Force Requirement covered by the Eagle SM-88 representatives will be reviewed with the Sales Operations Committee, as defined below, after the initial 6 months following launch and may be increased upon committee agreement, however coverage over 25% of the Sales Force Requirements shall require the consent of Eagle
 - o The total sales force for SM-88 will be sized based on the following Sales Force Requirements:
 - § Reach: The key assumption is that the sales representatives will be detailing SM-88 to at least 20 Target Professionals (as defined in the Agreement) per week per representative, with the accounts to be identified prior to acceptance of the NDA by the FDA
 - § Frequency: The accounts will be tiered based on Pancreatic Cancer patient volume. Accounts and the tiering will be defined prior to the acceptance of the NDA by the FDA. The Sales Call frequency based on tiering will be:
 - Tier 1: Sales Call Frequency of at least 2 – 3 times/month
 - Tier 2: Sales Call Frequency of at least 1 time/month
 - Tier 3: Sales Call Frequency of at least 1 time/6 weeks
 - § The Sales Force Size requirement may be modified if there is a shift in reach and/or account tiering, which will be reviewed by the Sales Operations Committee, as defined in the Agreement
 - o TYME maintains the right to, on a reasonable basis, have its personnel accompany an Eagle sales representative during a detail, following appropriate advance notice
 - o Position of SM-88 in the Eagle detail: SM-88 must be considered the first call position for at least 70% of the calls for a multi-disciplinary oncologist account. SM-88 will be the sole detail for all calls that are focused on a gastrointestinal oncologist
 - o Minimum Sales Representatives Requirement: initial requirement and time period to which it will be applicable will be determined

- by TYME by reference to the Sales Force Requirements no later than three months prior to NDA filing
- o Eagle Quarterly Minimum Details: initial requirement and time period to which it will be applicable will be determined by TYME by reference to the Sales Force Requirements no later than three months prior to NDA filing

Training:

- TYME will be responsible for training the Eagle sales force and for the creation of all sales training materials used by the Eagle team. As this material will be regulatory compliant, no changes can be made by Eagle without the written consent of TYME.
- Eagle sales representatives and their sales management will be required to complete mandatory training before detailing SM-88 to an account. This training will need to be completed prior to launch date of SM-88 with follow up quarterly training. Prior to the launch of SM-88, the training will be a live training. Subsequently,

there will be at least 3 live trainings per year and the other training can be fulfilled via webcast. The training will include but is not limited to:

- o Disease state education
- o Current treatment education
- o SM-88 clinical data education
- o SM-88 prescribing information training
- o SM-88 approved promotional materials
- o Adverse Event Reporting
- o Sales skills training
- o Compliance training

Promotional Programs:

- In compliance with the PhRMA code and other guidelines (i.e. State guidelines), Eagle sales representatives will execute on promotional programs, utilizing the TYME approved presentation
- Eagle will be responsible for the delivery of the promotional programs to its SM-88 accounts and the cost associated with delivering the programs
- The target number of promotional programs will be defined prior to launch and will be discussed at the Sales Operations Committee; Promotional Programs will be addressed in the Sales Plan (as updated from time to time)

Operating Principles:

- TYME also retains the right to have sales representatives promoting SM-88 and/or engaging in other co- promotion agreements, the co-promotion arrangement with Eagle shall not be exclusive
- Eagle is responsible for all costs associated with its sales force. This includes, but is not limited to:
 - o Cash compensation (salary and incentives)
 - o Benefits
 - o Travel and related expenses
 - o Training expenses, including but not limited to meeting facility, travel and lodging, meals, print materials, contests, awards
 - o Sales detail print materials
 - o Delivery of promotional programs

Schedule 4.1.2

Qualifications and Criteria for Sales Representatives and their managers

[TO BE JOINTLY DEVELOPED AND MUTUALLY AGREED BY TYME AND EAGLE]

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: May 11, 2020

/s/ Scott Tarriff

Scott Tarriff
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Pete A. Meyers, 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: May 11, 2020

/s/ Pete A. Meyers

Pete A. Meyers

Chief Financial Officer

(Principal Accounting and Financial Officer)

**Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), **Scott Tarriff**, Chief Executive Officer of Eagle Pharmaceuticals, Inc. (the "Company"), and **Pete A. Meyers**, 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 March 31, 2020, (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 11th day of May 2020.

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

By: /s/ Pete A. Meyers
Pete A. Meyers
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.