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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

[Mark One]

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

For the Quarterly Period Ended June 30, 2024

OR

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

Commission File No. 001-33057

CATALYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**76-0837053**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
355 Alhambra Circle Suite 801 Coral Gables, Florida	**33134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

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

Title of Each Class	Ticker Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	**CPRX**	**NASDAQ Capital Market**

Indicate by checkmark 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 report(s), 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 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 definitions of "accelerated filer", "large accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☒	Accelerated Filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date 118,687,897 shares of common stock, $0.001 par value per share, were outstanding as of August 5, 2024.

CATALYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

PART II. OTHER INFORMATION

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	June 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 375,693	$ 137,636
Accounts receivable, net	57,172	53,514
Inventory	18,014	15,644
Prepaid expenses and other current assets	23,550	12,535
Total current assets	474,429	219,329
Operating lease right-of-use asset	2,371	2,508
Property and equipment, net	1,227	1,195
License and acquired intangibles, net	175,361	194,049
Deferred tax assets, net	39,889	36,544
Investment in equity securities	13,083	16,489
Total assets	$ 706,360	$ 470,114
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 7,116	$ 14,795
Accrued expenses and other liabilities	85,202	61,268
Total current liabilities	92,318	76,063
Operating lease liability, net of current portion	2,991	3,188
Other non-current liabilities	2,396	2,982
Total liabilities	97,705	82,233
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: none issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized; 118,521,366 shares and 107,121,549 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	119	107
Additional paid-in capital	423,195	266,488
Retained earnings	185,341	121,272
Accumulated other comprehensive income (Note 4)	—	14
Total stockholders' equity	608,655	387,881
Total liabilities and stockholders' equity	$ 706,360	$ 470,114

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (unaudited)
(in thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 122,653	$ 99,477	$ 221,094	$ 184,781
License and other revenue	57	105	125	167
Total revenues	122,710	99,582	221,219	184,948
Operating costs and expenses:				
Cost of sales (a)	15,405	12,045	27,925	21,991
Research and development	2,985	3,954	5,566	7,516
Selling, general and administrative (a)	40,730	28,396	87,668	58,114
Amortization of intangible assets	9,344	8,488	18,688	15,019
Total operating costs and expenses	68,464	52,883	139,847	102,640
Operating income	54,246	46,699	81,372	82,308
Other income, net	1,542	1,813	3,505	3,517
Net income before income taxes	55,788	48,512	84,877	85,825
Income tax provision	14,994	10,750	20,808	18,495
Net income	$ 40,794	$ 37,762	$ 64,069	$ 67,330
Net income per share:				
Basic	$ 0.35	$ 0.36	$ 0.55	$ 0.64
Diluted	$ 0.33	$ 0.33	$ 0.52	$ 0.59
Weighted average shares outstanding:				
Basic	118,180,396	106,258,790	117,493,257	105,911,936
Diluted	124,655,999	113,673,534	124,028,752	113,840,155
Net income	$ 40,794	$ 37,762	$ 64,069	$ 67,330
Other comprehensive income (Note 4):				
Unrealized gain (loss) on available-for-sale securities, net of tax of $0, ($3), $4 and $2, respectively	—	8	(14)	(5)
Comprehensive income	$ 40,794	$ 37,770	$ 64,055	$ 67,325

(a)exclusive of amortization of intangible assets

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (unaudited)
For the three and six months ended June 30, 2024 and 2023
(in thousands)

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2023	$ —	107,122	$ 107	$ 266,488	$ 121,272	$ 14	$ 387,881
Issuance of common stock, net	—	10,000	10	140,694	—	—	140,704
Stock-based compensation	—	—	—	8,248	—	—	8,248
Exercise of stock options for common stock	—	664	1	1,521	—	—	1,522
Issuance of common stock upon vesting of restricted stock units, net	—	244	—	(204)	—	—	(204)
Other comprehensive gain (loss)	—	—	—	—	—	(14)	(14)
Net income	—	—	—	—	23,275	—	23,275
Balance at March 31, 2024	—	118,030	118	416,747	144,547	—	561,412
Issuance of common stock, net	—	—	—	10	—	—	10
Stock-based compensation	—	—	—	4,408	—	—	4,408
Exercise of stock options for common stock	—	491	1	2,030	—	—	2,031
Other comprehensive gain (loss)	—	—	—	—	—	—	—
Net income	—	—	—	—	40,794	—	40,794
Balance at June 30, 2024	$ —	118,521	$ 119	$ 423,195	$ 185,341	$ —	$ 608,655

	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2022	$ —	105,263	$ 105	$ 250,430	$ 49,862	$ 24	$ 300,421
Stock-based compensation	—	—	—	2,892	—	—	2,892
Exercise of stock options for common stock	—	548	1	1,269	—	—	1,270
Issuance of common stock upon vesting of restricted stock units, net	—	127	—	(477)	—	—	(477)
Other comprehensive gain (loss)	—	—	—	—	—	(13)	(13)
Net income	—	—	—	—	29,568	—	29,568
Balance at March 31, 2023	—	105,938	106	254,114	79,430	11	333,661
Stock-based compensation	—	—	—	3,298	—	—	3,298
Exercise of stock options for common stock	—	557	1	616	—	—	617
Issuance of common stock upon vesting of restricted stock units, net	—	6	—	(52)	—	—	(52)
Other comprehensive gain (loss)	—	—	—	—	—	8	8
Net income	—	—	—	—	37,762	—	37,762
Balance at June 30, 2023	$ —	106,501	$ 107	$ 257,976	$ 117,192	$ 19	$ 375,294

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(in thousands)

	For the Six Months Ended June 30,	
	2024	2023
Operating Activities:		
Net income	$ 64,069	$ 67,330
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation	177	151
Stock-based compensation	12,656	6,190
Amortization of intangible assets	18,688	15,019
Deferred taxes	(3,359)	(4,758)
Accretion of discount	287	—
Reduction in the carrying amount of right-of-use asset	137	129
Acquired inventory samples expensed from asset acquisition	—	130
Change in fair value of equity securities	3,406	—
(Increase) decrease in:		
Accounts receivable, net	(3,658)	(32,357)
Inventory	(2,370)	154
Prepaid expenses and other current assets	(11,015)	(1,891)
Increase (decrease) in:		
Accounts payable	(7,679)	446
Accrued expenses and other liabilities	24,902	(7,553)
Operating lease liability	(181)	(166)
Net cash provided by (used in) operating activities	96,060	42,824
Investing Activities:		
Purchases of property and equipment	(209)	(74)
Payment in connection with asset acquisition	—	(162,293)
Net cash provided by (used in) investing activities	(209)	(162,367)
Financing Activities:		
Payment of employee withholding tax related to stock-based compensation	(204)	(529)
Proceeds from exercise of stock options	3,553	1,887
Payment of liabilities arising from asset acquisition	(1,847)	(1,423)
Proceeds from issuance of common stock	141,000	—
Payment of fees in connection with issuance of common stock	(296)	—
Net cash provided by (used in) financing activities	142,206	(65)
Net increase (decrease) in cash and cash equivalents	238,057	(119,608)
Cash and cash equivalents – beginning of period	137,636	298,395
Cash and cash equivalents – end of period	$ 375,693	$ 178,787
Supplemental disclosures of cash flow information:		
Cash paid for income taxes	$ 34,101	$ 27,821
Cash paid for interest	$ 140	$ —
Non-cash investing and financing activities:		
Liabilities arising from asset acquisition	$ —	$ 1,915

The accompanying notes are an integral part of these consolidated financial statements.

CATALYST PHARMACEUTICALS, INC.
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1.Organization and Description of Business.

Catalyst Pharmaceuticals, Inc. and subsidiary (collectively, the Company) is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare and difficult to treat diseases. The Company currently markets three drug products, FIRDAPSE® (amifampridine), FYCOMPA® (perampanel), and AGAMREE® (vamorolone). The Company is also currently seeking to further expand its product portfolio, with a focus on acquiring the rights to late-stage products to treat rare (orphan) central nervous system and adjacent rare (orphan) diseases. With an unwavering patient focus embedded in everything it does, the Company is committed to providing innovative, best-in-class medications with the hope of making a meaningful impact on those affected by these conditions.

The Company's New Drug Application (NDA) for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome (LEMS) was approved in 2018 by the U.S. Food & Drug Administration (FDA), and FIRDAPSE® is commercially available in the United States (U.S.) as a treatment for adults with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, approved the use of FIRDAPSE® for the treatment of adult patients in Canada with LEMS in 2020 and FIRDAPSE® is commercially available in Canada for the treatment of patients with LEMS through a license and supply agreement with KYE Pharmaceuticals, Inc. (KYE). In the third quarter of 2022, the FDA approved the Company's supplemental New Drug Application approving an expansion of the FIRDAPSE® label to include pediatric patients (ages six and older). In the second quarter of 2024, the FDA approved the Company's supplemental New Drug Application increasing the indicated maximum daily dose of FIRDAPSE® (amifampridine) for adults and pediatric patients weighing more than 45 kg from 80 mg to 100 mg for the treatment of LEMS.

On December 17, 2022, the Company entered into an asset purchase agreement with Eisai Co., Ltd. (Eisai) for the acquisition of the U.S. rights to FYCOMPA® (perampanel) CIII, a prescription medication used alone or in combination with other medicines to treat focal onset seizures with or without secondarily generalized seizures in people with epilepsy aged four and older and with other medicines to treat primary generalized tonic-clonic seizures in people with epilepsy aged 12 and older. The Company closed the acquisition of the U.S. rights to FYCOMPA® on January 24, 2023 and is now marketing FYCOMPA® in the U.S.

In July 2023, the Company completed its acquisition from Santhera Pharmaceuticals Holdings (Santhera) of an exclusive license for North America for AGAMREE® (vamorolone), a treatment for patients suffering with Duchenne muscular dystrophy (DMD). The license is for exclusive commercial rights in the U.S., Canada, and Mexico, as well as the right of first negotiation in Europe and Japan should Santhera pursue partnership opportunities in those jurisdictions. Additionally, the Company holds the North American rights for any future approved indications of AGAMREE®. AGAMREE® has previously received FDA Orphan Drug and Fast Track designations. On October 26, 2023, the FDA approved AGAMREE® oral suspension 40 mg/ml for the treatment of DMD in patients aged two years and older, and on March 13, 2024, the Company began marketing AGAMREE® in the U.S.

The Company has devoted substantially all its efforts to selling its products, business planning, recruiting management and technical staff, acquiring operating assets, raising capital, and research and development. The Company has been able to fund its cash needs to date through offerings of its securities and from revenues from sales of its products. See Note 15 (Stockholders' Equity).

Capital Resources

Based on forecasts of available cash, the Company believes that it has sufficient resources to support the currently anticipated operations for at least the next 12 months from the date of this report.

The Company may raise funds in the future through public or private equity offerings, debt financings, corporate collaborations, governmental research grants or other means. The Company may also seek to raise new capital to fund additional business development activities, even if it has sufficient funds for its planned operations. Any sale by the Company of additional equity or convertible debt securities could result in dilution to the Company's current stockholders. There can be no assurance that any required additional funding will be available to the Company at all or available on terms acceptable to the Company. Further, to the extent that the Company raises additional funds through collaborative arrangements, it may be necessary to relinquish some rights to the Company's drug candidates or grant sublicenses on terms that are not favorable to the Company. If the Company is not able to secure additional funding when needed, the Company may have to delay, reduce the scope of, or eliminate one or more research and development programs, which could have an adverse effect on the Company's business.

On January 9, 2024, the Company completed a public offering of 10 million shares of its common stock, raising net proceeds of approximately $140.7 million. The proceeds of the offering will be used to potentially acquire new products and for general corporate purposes.

Risks and Uncertainties

The Company is subject to risks and uncertainties that could affect its business in unforeseen ways.

2.Basis of Presentation and Significant Accounting Policies.

a.INTERIM FINANCIAL STATEMENTS. The accompanying unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP), and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted. The consolidated balance sheet as of December 31, 2023 included in this Form 10-Q was derived from the audited financial statements and does not include all disclosures required by U.S. GAAP.

In the opinion of management, the accompanying unaudited interim consolidated financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of the dates and for the periods presented. Accordingly, these consolidated statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2023 included in the 2023 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the six months ended June 30, 2024 are not necessarily indicative of the results to be expected for any future period or for the full 2024 fiscal year.

b.PRINCIPLES OF CONSOLIDATION. The consolidated financial statements include the Company's accounts and those of its wholly-owned subsidiary, Catalyst Pharmaceuticals Ireland, Ltd. (Catalyst Ireland). All intercompany accounts and transactions have been eliminated in consolidation. Catalyst Ireland was organized in 2017.

c.USE OF ESTIMATES. 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 consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

d.CASH AND CASH EQUIVALENTS. The Company primarily invests in high credit-quality instruments in order to obtain higher yields on its cash equivalents. The Company considers all highly liquid instruments, purchased with an original maturity of three months or less, to be cash equivalents. Cash equivalents consist mainly of money market funds and U.S. Treasuries. The Company has substantially all its cash and cash equivalents deposited in money market accounts with one financial institution.

e.INVESTMENTS. At June 30, 2024 investments consisted of an investment in equity securities. At December 31, 2023, investments consisted of U.S. Treasuries and an investment in equity securities. Such investments are not insured by the U.S. Federal Deposit Insurance Corporation.

There were no U.S. Treasuries held at June 30, 2024 and U.S. Treasuries held at December 31, 2023 were classified as available-for-sale securities. The Company classifies U.S. Treasuries with stated maturities of greater than three months and less than one year in short-term investments. U.S. Treasuries with stated maturities greater than one year are classified as non-current investments in its consolidated balance sheets.

The Company records available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (in stockholders' equity). Realized gains and losses are included in other income, net in the consolidated statements of operations and comprehensive income and are derived using the specific identification method for determining the cost of securities sold. Interest income is recognized when earned and is included in other income, net in the consolidated statements of operations and comprehensive income. The Company recognizes a charge when the declines in the fair value below the amortized cost basis of its available-for-sale securities are judged to be as a result of a credit loss. The Company considers various factors in determining whether to recognize an allowance for credit losses including whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the security before recovery of the amortized cost basis. If the unrealized loss of an available-for-sale debt security is determined to be a result of a credit loss the Company would recognize an allowance and the corresponding credit loss would be included in the consolidated statements of operations and comprehensive income. The Company has not recorded an allowance for credit loss on its available-for-sale securities. See Note 3 (Investments).

In July 2023, the Company made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's post reverse-split ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction). The investment is denominated in Swiss Francs. The Company has determined that it does not have significant influence over the operations of Santhera and accordingly the investment in Santhera's ordinary shares is recorded under ASC 321, Equity Securities, with changes in fair value, inclusive of changes resulting from movements in foreign exchange rates, in other income, net in the consolidated statement of operations and comprehensive income.

2.Basis of Presentation and Significant Accounting Policies (continued).

f.ACCOUNTS RECEIVABLE, NET. Accounts receivable are recorded net of customer allowance for distribution fees, trade discounts, prompt payment discounts, chargebacks and expected credit losses. Allowances for distribution fees, trade discounts, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for expected credit losses based on existing contractual payment terms, actual payment patterns of its customers, current and future economic and market conditions and individual customer circumstances. The Company has not historically experienced any significant credit losses. All customer accounts are actively managed. At June 30, 2024 and December 31, 2023, the Company determined that an allowance for expected credit losses was not required. No accounts were written off during the periods presented.

g.INVENTORY. Inventories are stated at the lower of cost or net realizable value. Inventories consist of raw materials, work-in-process and finished goods. Costs to be capitalized as inventories primarily include third-party manufacturing costs and other overhead costs. Cost is determined using a standard cost method, which approximates actual cost, and assumes a first-in, first out (FIFO) flow of goods. If information becomes available that suggests that inventories may not be realizable, the Company may be required to expense a portion or all of the previously capitalized inventories.

Products that have been approved by the FDA or other regulatory authorities, such as FIRDAPSE®, FYCOMPA® and AGAMREE® are also used in clinical programs to assess the safety and efficacy of the products for usage in treating diseases that have not been approved by the FDA or other regulatory authorities. The forms of FIRDAPSE®, FYCOMPA® and AGAMREE® utilized for both commercial and clinical programs are identical and, as a result, the inventories have an “alternative future use” as defined in authoritative guidance. Raw materials associated with clinical development programs are included in inventory and charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes and, therefore, does not have an “alternative future use”.

The Company evaluates for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance, and patient usage.

h.PREPAID EXPENSES AND OTHER CURRENT ASSETS. Prepaid expenses and other current assets consist primarily of prepaid manufacturing, prepaid tax, prepaid insurance, prepaid subscription fees, prepaid research fees, prepaid commercialization expenses, prepaid co-pay assistance program, amounts due from collaborative and license arrangements and prepaid conference and travel expenses. Prepaid research fees consist of advances for the Company’s product development activities, including contracts for pre-clinical studies, clinical trials and studies, regulatory affairs and consulting. Prepaid manufacturing costs consist of advances for the Company’s drug manufacturing activities. Such advances are recorded as expense as the related goods are received or the related services are performed.

i.PROPERTY AND EQUIPMENT, NET. Property and equipment are recorded at cost less accumulated depreciation. Depreciation is calculated to amortize the depreciable assets over their useful lives using the straight-line method and commences when the asset is placed in service. Leasehold improvements are amortized on a straight-line basis over the term of the lease or the estimated life of the improvement, whichever is shorter. Useful lives generally range from three to five years for computer equipment and software, from five to seven years for furniture and equipment, and from five to ten years for leasehold improvements. Expenditures for repairs and maintenance are charged to expenses as incurred.

j.BUSINESS COMBINATIONS AND ASSET ACQUISITIONS. The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the requirements of a business. If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. Contingent consideration payments in asset acquisitions are recognized when the contingency is resolved and the consideration is paid or becomes payable.

2.Basis of Presentation and Significant Accounting Policies (continued).

See Notes 12 (Commitments and Contingencies) and 13 (Agreements) for further discussion of the Company's exclusive license agreement with Jacobus Pharmaceutical Company, Inc. (Jacobus), for the rights to develop and commercialize RUZURGI® in the U.S. and Mexico, which the Company accounted for as an asset acquisition under ASC 805-50. See Note 13 (Agreements) for further discussion on the Company's acquisitions of the U.S. rights to FYCOMPA® from Eisai, and on the exclusive license for North America acquired from Santhera for AGAMREE®, both of which the Company accounted for as asset acquisitions under ASC 805-50.

k.INTANGIBLE ASSETS, NET. Identifiable intangible assets with a finite life are comprised of licensed rights and other acquired intangible assets and are amortized on a straight-line basis over the respective estimated useful life.

The Company reviews intangible assets with finite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If indicators of impairment exist, an impairment test is performed to assess the recoverability of the affected assets by determining whether the carrying amount of such assets exceeds the undiscounted expected future cash flows. If the affected assets are deemed not recoverable, the Company would estimate the fair value of the assets and record an impairment loss.

l.FAIR VALUE OF FINANCIAL INSTRUMENTS. The Company's financial instruments consist of cash and cash equivalents, investments, accounts receivable, accounts payable, and accrued expenses and other liabilities. At June 30, 2024 and December 31, 2023, the fair value of these instruments approximated their carrying value.

m.FAIR VALUE MEASUREMENTS. Current Financial Accounting Standards Board (FASB) fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions that it believes market participants would use in pricing assets or liabilities (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which are typically based on an entity's own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

	Fair Value Measurements at Reporting Date Using (in thousands)			
	Balances as of June 30, 2024	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents:				
Money market funds	$ 331,714	$ 331,714	$ —	$ —
Investment in equity securities:				
Equity securities	$ 13,083	$ 13,083	$ —	$ —

2.Basis of Presentation and Significant Accounting Policies (continued).

	Fair Value Measurements at Reporting Date Using (in thousands)			
	Balances as of December 31, 2023	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents:				
Money market funds	$ 18,256	$ 18,256	$ —	$ —
U.S. Treasuries	$ 94,523	$ 94,523	$ —	$ —
Investment in equity securities:				
Equity securities	$ 16,489	$ 16,489	$ —	$ —

n.OPERATING LEASES. The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (ROU) assets, other current liabilities, and operating lease liabilities on its consolidated balance sheets. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's lease does not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company's lease term includes options to extend or terminate the lease, however, these options are not considered in the lease term as the Company is not reasonably certain that it will exercise these options. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The Company has a lease agreement with lease and non-lease components, which are accounted for separately.

o.SHARE REPURCHASES. In March 2021, the Company's Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of the Company's common stock.

The Company accounts for share repurchases by charging the excess of the repurchase price over the repurchased common stock's par value entirely to retained earnings. All repurchased shares are retired and become authorized but unissued shares. The Company accrues for the shares purchased under the share repurchase plan based on the trade date. The Company may terminate or modify its share repurchase program at any time.

p.REVENUE RECOGNITION.

Product Revenues:

To determine revenue recognition for arrangements that are within the scope of Accounting Standards Codification (ASC) Topic 606 – Revenue from Contracts with Customers (Topic 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 assesses the goods or services promised within each contract and determines those that are performance obligations by assessing whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see Product Revenue, Net below.

The Company also may generate revenues from payments received under collaborative and license agreements. Collaborative and license agreement payments may include nonrefundable fees at the inception of the agreements, contingent payments for specific achievements designated in the agreements, and/or net profit-sharing payments on sales of products resulting from the collaborative and license arrangements. For a complete discussion of accounting for collaborative and licensing arrangements, see Revenues from Collaboration and Licensing Arrangements below.

The Company recognizes revenue when its customers obtain title of the promised goods, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for these goods. For FIRDAPSE® and AGAMREE®, subsequent to receiving FDA approvals, the Company entered into an arrangement with one distributor (the Customer), which is the exclusive distributor of FIRDAPSE® and AGAMREE® in the U.S. The Customer subsequently resells FIRDAPSE® and AGAMREE® to a small group of exclusive specialty pharmacies (SPs) whose dispensing activities for patients with specific payors may result in government-mandated or privately negotiated rebate obligations for the Company with respect to the purchase of FIRDAPSE® and AGAMREE®.

2.Basis of Presentation and Significant Accounting Policies (continued).

During 2023, the Company sold FYCOMPA® in the U.S. commercial market through a Transition Service Agreement with a U.S. subsidiary of Eisai to major wholesalers and specialty pharmaceutical distributors. These sales are often subject to contracts held with managed care organizations and government agencies. The distribution services under the Transition Services Agreement ended on December 31, 2023, and beginning on January 1, 2024, the Company commenced direct sales of FYCOMPA® in the U.S. commercial market.

Product Revenue, Net: The Company recognizes revenue on product sales when its customers obtain control of the Company's products, which occur at a point in time (upon delivery or upon dispense to patient). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 15 and 60 days.

Shipping and handling costs for product shipments occur prior to the customer obtaining control of the goods and are recorded in cost of sales.

If taxes should be collected from the Customer relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three and six months ended June 30, 2024 and 2023.

During the three and six months ended June 30, 2024 and 2023, substantially all of the Company's product revenues were from sales to customers in the U.S.

The following table summarizes the Company's net product revenue disaggregated by product (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
FIRDAPSE®	$ 77,372	$ 64,898	$ 144,214	$ 122,424
FYCOMPA®+	36,535	34,579	66,960	62,357
AGAMREE®*	8,746	—	9,920	—
Total product revenue, net	$ 122,653	$ 99,477	$ 221,094	$ 184,781

+FYCOMPA® net product revenue for the six months ended June 30, 2023 is for the period between January 24, 2023 (date of acquisition) and June 30, 2023.

*AGAMREE® net product revenue for the six months ended June 30, 2024 is for the period between March 13, 2024 (date of commercial launch) and June 30, 2024.

Reserves for Variable Consideration: Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, prompt payment discounts, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to its customers) or a current liability (if the amount is payable to a party other than its customers).

These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplates application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of June 30, 2024 and, therefore, the transaction price was not reduced further during the three and six months ended June 30, 2024 and 2023. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

2.Basis of Presentation and Significant Accounting Policies (continued).

Trade Discounts, Allowances and Wholesaler Fees: The Company provides its customers with a discount that is explicitly stated in its contract and is recorded as a reduction of revenue in the period the related product revenue is recognized. To the extent the services received are distinct from the sale of products to its customers, these payments are classified in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income. However, if the Company has determined such services received are not distinct from the Company's sale of products to its customers, these payments have been recorded as a reduction of revenue within the consolidated statements of operations and comprehensive income through June 30, 2024 and 2023, as well as a reduction to accounts receivable, net on the consolidated balance sheets.

Prompt Payment Discounts: The Company provides its customers with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. The prompt payment discount reserve is based on actual invoice sales and contractual discount rates. Reserves for prompt payment discounts are included in accounts receivable, net on the consolidated balance sheets.

Funded Co-pay Assistance Program: The Company contracts with a third-party to manage the co-pay assistance program intended to provide financial assistance to qualified commercially-insured patients. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with its products, that have been recognized as revenue, but remains in the distribution channel at the end of each reporting period. These payments are considered payable to the third-party vendor and the related reserve is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other liabilities in the consolidated balance sheets.

Product Returns: Consistent with industry practice, the Company offers its customers limited product return rights for damaged and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution or master agreement. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period in which the related product revenue is recognized. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. Return payments related to the sale of products are considered payable to the third-party vendor and the related reserve is recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other liabilities in the consolidated balance sheets.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to the customer, who directly purchases the product from the Company. The customer charges the Company for the difference between what they paid for the product and the ultimate selling price to the qualified healthcare providers. The Company also participates in programs with government entities and other parties, including covered entities under the 340B Drug Pricing Program, whereby pricing on FYCOMPA® is extended below wholesaler list price to participating entities (the FYCOMPA® Participants). These entities purchase FYCOMPA® through wholesalers at the lower program price and the wholesalers then charge the Company the difference between their acquisition cost and the lower program price.

These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue, net and accounts receivable, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by the customer or at the time of a resale to a FYCOMPA® Participant by a wholesaler, and the Company generally issues credits for such amounts within a few weeks of the customer or wholesalers' notification to the Company of the resale. Reserves for chargebacks consist primarily of chargebacks that the customer or wholesalers have claimed, but for which the Company has not yet issued a credit, as well as an estimate of chargeback claims that the Company expects to receive associated with its products, that have been recognized as revenue, but remains in the distribution channel at the end of each reporting period.

Government Rebates: The Company is subject to discount obligations under state Medicaid, Medicare and other government programs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue. For reserves related to the sale of its products, there is an establishment of a current liability, which is included in accrued expenses and other liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program.

2.Basis of Presentation and Significant Accounting Policies (continued).

The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates: The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses and other liabilities on the consolidated balances sheets.

Bridge and Patient Assistance Programs: The Company provides FIRDAPSE® and AGAMREE® free of charge to uninsured patients who satisfy pre-established criteria for either the Bridge Program or the Patient Assistance Program. Patients who meet the Bridge Program eligibility criteria and are transitioning from investigational product while they are waiting for a coverage determination, or later, for patients whose access is threatened by the complications arising from a change of insurer may receive a temporary supply of free FIRDAPSE® or AGAMREE® while the Company is determining the patient's third-party insurance, prescription drug benefit or other third-party coverage for FIRDAPSE® or AGAMREE®. The Patient Assistance Program provides FIRDAPSE® or AGAMREE® free of charge for longer periods of time for those who are uninsured or functionally uninsured with respect to FIRDAPSE® or AGAMREE® because they are unable to obtain coverage from their payor despite having health insurance, to the extent allowed by applicable law.

The Company provides FYCOMPA® free of charge to uninsured patients who satisfy pre-established criteria through a Patient Assistance Program. In addition, Catalyst provides programs to assist patients through the process for obtaining reimbursement approval for their FYCOMPA® prescriptions from their insurers. Catalyst also provides support for patients using FYCOMPA® through an Instant Savings Card Program.

The Company does not recognize any revenue related to these free products and the associated costs are classified in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income.

Revenues from Collaboration and Licensing Arrangements:

The Company analyzes license and collaboration arrangements pursuant to FASB ASC Topic 808, Collaborative Arrangement Guidance and Consideration (Topic 808), to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, the Company considers whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance or if they are more reflective of a vendor-customer relationship and, therefore, within the scope of Topic 606. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to guidance in Topic 606, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance.

The Company evaluates the performance obligations promised in the contract that are based on goods and services that will be transferred to the customer and determines whether those obligations are both (i) capable of being distinct and (ii) distinct in the context of the contract. Goods or services that meet these criteria are considered distinct performance obligations. The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include fixed consideration or variable consideration.

2.Basis of Presentation and Significant Accounting Policies (continued).

The agreements provide for milestone payments upon achievement of development and regulatory events. The Company accounts for milestone payments as variable consideration in accordance with Topic 606. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of potential transaction price and the likelihood that the transaction price will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method best predicts the amount expected to be received. The amount of variable consideration that is included in the transaction price may be constrained and is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and, if so, these options are considered performance obligations.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the overall transaction price is allocated to the performance obligations based on the same methodology used at contract inception.

The Company recognizes sales-based royalties or net profit-sharing when the latter of (a) the subsequent sale occurs, or (b) the performance obligation to which the sales-based royalty or net profit-sharing has been allocated has been satisfied.

Payments to and from the collaborator are presented in the statement of operations based on the nature of the Company's business operations, the nature of the arrangement, including the contractual terms, and the nature of the payments.

See Note 11 (Collaborative and Licensing Arrangements), for further discussion on the Company's collaborative and licensing arrangements.

q.RESEARCH AND DEVELOPMENT. Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform research-related services for the Company.

The Company records upfront and milestone payments made to third parties under licensing and collaboration arrangements that occur before a compound receives regulatory approval as acquired in-process research and development (IPR&D). IPR&D acquired as part of an asset acquisition with no alternative future use is expensed immediately to research and development. Milestone payments made after regulatory approval are capitalized as a developed asset and unless the asset is determined to have an indefinite life, the Company amortizes its definite-lived intangible assets using the straight-line method, which is considered the best estimate of economic benefit, over its estimated useful life.

r.ADVERTISING EXPENSE. Advertising costs are expensed as incurred. The Company incurred approximately $1.2 million and $5.1 million in advertising costs during the three and six months ended June 30, 2024, respectively, and approximately $2.0 million and $3.7 million during the three and six months ended June 30, 2023, respectively, which are included in selling, general and administrative expenses in the Company's consolidated statements of operations and comprehensive income.

s.STOCK-BASED COMPENSATION. The Company recognizes expense in the consolidated statements of operations and comprehensive income for the grant date fair value of all stock-based payments to employees, directors and consultants, including grants of stock options and other share-based awards. For stock options, the Company uses the Black-Scholes option valuation model, the single-option award approach, and the straight-line attribution method. Using this approach, compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally one to three years. Forfeitures are recognized as a reduction of stock-based compensation expense as they occur.

t.CONCENTRATION OF RISK. The financial instruments that potentially subject the Company to concentration of credit risk are cash equivalents, investments and accounts receivable, net. The Company places its cash and cash equivalents with high-credit quality financial institutions. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in these accounts.

The Company sells its products, FIRDAPSE® and AGAMREE®, in the U.S. through an exclusive distributor (its Customer) to SPs. Therefore, its distributor and SPs account for principally all of its trade receivables and net product revenues related to these products. The Company sells its product, FYCOMPA®, directly to major wholesalers and specialty pharmaceutical distributors and indirectly to managed care organizations and government agencies. The creditworthiness of its customers is continuously monitored, and the Company has internal policies regarding customer credit limits. The Company estimates an allowance for expected credit loss primarily based on the creditworthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions.

2.Basis of Presentation and Significant Accounting Policies (continued).

As of June 30, 2024, the Company had three FDA approved products, which makes it difficult to evaluate its current business, predict its future prospects, and forecast financial performance and growth. The Company had invested a significant portion of its efforts and financial resources in the development and commercialization of its lead product, FIRDAPSE®. The Company expects sales of FIRDAPSE®, FYCOMPA®, and AGAMREE® to constitute virtually all of the Company's product revenue for the foreseeable future.

The Company relies exclusively on third parties to formulate and manufacture its products and any future drug candidates. The commercialization of its products and any other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide sufficient quantities of product or fail to do so at acceptable quality levels or prices. The Company does not intend to establish its own manufacturing facilities. The Company is using the same third-party contractors to manufacture, supply, store and distribute drug supplies for clinical trials and for the commercialization of FIRDAPSE®. The Company relies on the same third-party manufacturers for FYCOMPA® as utilized by Eisai prior to the Company's acquisition of the U.S. rights to the product in January 2023. It also relies on Santhera and its supplier as its sole source of supply for AGAMREE®. If the Company is unable to continue its relationships with one or more of these third-party contractors, it could experience delays in the development or commercialization efforts as it locates and qualifies new manufacturers. The Company intends to rely on one or more third-party contractors to manufacture the commercial supply of its drugs.

The following table illustrates the approximate percentage of the Company's total net product revenue attributed to the Company's largest customers for the periods presented:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Customer A	70.2%	65.2%	69.7%	66.3%
Customer B*	—	34.8%	—	33.7%
Customer C	11.2%	—	10.4%	—
Total	81.4%	100.0%	80.1%	100.0%

*During 2023, the Company sold FYCOMPA® through a Transition Service Agreement with a U.S. subsidiary of Eisai. Effective January 1, 2024, FYCOMPA® is being sold and distributed through a third-party logistics (3PL) organization. Customers B and C both relate to sales of FYCOMPA®.

u.ROYALTIES. Royalties incurred in connection with the Company's license agreement for FIRDAPSE® and AGAMREE®, as disclosed in Note 13 (Agreements), are expensed to cost of sales as revenue from product sales is recognized.

Royalties incurred in connection with the Company's license agreement for RUZURGI®, as disclosed in Note 13 (Agreements), are expensed to cost of sales as revenue from product sales is recognized for any royalties in excess of the minimum annual royalty payment from July 11, 2022 (the Effective Date) through 2025. The minimum royalty payment that exists annually for calendar years from the Effective Date through 2025 of $3 million are included in the purchase price of the agreement.

v.INCOME TAXES. The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is not subject to U.S. federal, state and local tax examinations by tax authorities for years before 2020. If the Company were to subsequently record an unrecognized tax benefit, associated penalties and tax related interest expense would be reported as a component of income tax expense.

2.Basis of Presentation and Significant Accounting Policies (continued).

w.COMPREHENSIVE INCOME. U.S. GAAP requires that all components of comprehensive income be reported in the financial statements in the period in which they are recognized. Comprehensive income is net income, plus certain other items that are recorded directly into stockholders' equity. The Company's comprehensive income is shown on the consolidated statements of operations and comprehensive income for the three and six months ended June 30, 2024 and 2023, and is comprised of net unrealized gains (losses) on the Company's available-for-sale securities.

x.NET INCOME PER COMMON SHARE. Basic net income per share is computed by dividing net income for the period by the weighted average number of common shares outstanding during the period. With regard to common stock subject to vesting requirements, the calculation includes only the vested portion of such stock and units.

Diluted net income per common share is computed by dividing net income by the weighted average number of common shares outstanding, increased by the assumed conversion of other potentially dilutive securities during the period.

The following table reconciles basic and diluted weighted average common shares:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Basic weighted average common shares outstanding	118,180,396	106,258,790	117,493,257	105,911,936
Effect of dilutive securities	6,475,603	7,414,744	6,535,495	7,928,219
Diluted weighted average common shares outstanding	124,655,999	113,673,534	124,028,752	113,840,155

Outstanding common stock equivalents totaling approximately 5.2 million were excluded from the calculation of diluted net income per common share for both the three and six months ended June 30, 2024, as their effect would be anti-dilutive. For both the three and six months ended June 30, 2023, approximately 2.0 million shares of common stock were excluded from the calculation of diluted net income per common share as their effect would be anti-dilutive.

y.SEGMENT INFORMATION. Management has determined that the Company operates in one reportable segment, which is the development and commercialization of drug products.

z.RECLASSIFICATIONS. Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year presentation.

aa.RECENTLY ISSUED ACCOUNTING STANDARDS. The Company did not adopt any accounting standards during the three and six months ended June 30, 2024.

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures* (ASU 2023-07) which is intended to improve reportable segment disclosures primarily through enhanced disclosure of reportable segment expenses and requires that a public entity that has a single reportable segment provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280. The new guidance is required to be applied retrospectively to all prior periods presented in the financial statements and is effective for the Company for fiscal periods beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. The Company has one reportable segment and is evaluating the impact of the standard on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires significant disclosures about income taxes, primarily focused on the disclosure of income taxes paid and the rate reconciliation table. The new guidance will be applied prospectively and is effective for the Company for fiscal periods beginning after December 15, 2024. The Company is evaluating the impact of the standard on the Company's consolidated financial statements.

3.Investments.

Available-for-sale investments by security type were as follows (in thousands):

	Estimated Fair Value	Gross Unrealized Gains	Gross Unrealized Losses	Amortized Cost
At June 30, 2024:				
U.S. Treasuries - Cash equivalents	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —
At December 31, 2023:				
U.S. Treasuries - Cash equivalents	$ 94,523	$ 18	$ —	$ 94,505
Total	$ 94,523	$ 18	$ —	$ 94,505

There were no realized gains or losses from available-for-sale securities during the three and six months ended June 30, 2024 and 2023.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Equity securities:				
Net gains (losses) recognized during the period on equity securities	$ (2,262)	$ —	$ (3,406)	$ —
Unrealized net gains (losses) recognized during the period on equity securities still held at the reporting date	$ (2,262)	$ —	$ (3,406)	$ —

There were no sales of equity securities during the three and six months ended June 30, 2024 and 2023. Unrealized net gains (losses) recognized during the periods on equity securities are included in other income, net in the consolidated statements of operations.

4.Accumulated Other Comprehensive Income.

The following table summarizes the changes in accumulated other comprehensive income, net of tax from unrealized gains (losses) on available-for-sale securities (in thousands), the Company's only component of accumulated other comprehensive income for the three and six months ended June 30, 2024 and 2023.

There were no reclassifications out of accumulated other comprehensive income during the three and six months ended June 30, 2024 and 2023.

	Total Accumulated Other Comprehensive Income (Loss)
Balance at March 31, 2024	$ —
Other comprehensive loss before reclassifications	—
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	—
Balance at June 30, 2024	$ —
Balance at December 31, 2023	$ 14
Other comprehensive loss before reclassifications	(14)
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	(14)
Balance at June 30, 2024	$ —

4.Accumulated Other Comprehensive Income (continued).

	Total Accumulated Other Comprehensive Income (Loss)
Balance at March 31, 2023	$ 11
Other comprehensive loss before reclassifications	8
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	8
Balance at June 30, 2023	$ 19
Balance at December 31, 2022	$ 24
Other comprehensive loss before reclassifications	(5)
Amount reclassified from accumulated other comprehensive income	—
Net current period other comprehensive gain (loss)	(5)
Balance at June 30, 2023	$ 19

5.Inventory.

Inventory consists of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	$ 5,597	$ 1,910
Work-in-process	4,022	4,573
Finished goods	8,395	9,161
Total inventory	$ 18,014	$ 15,644

6.Prepaid Expenses and Other Current Assets.

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid manufacturing costs	$ 1,999	$ 2,005
Prepaid tax	10,476	1,238
Prepaid insurance	838	1,332
Prepaid subscriptions fees	1,822	1,299
Prepaid research fees	1,589	1,500
Prepaid commercialization expenses	3,156	3,038
Due from collaborative and licensing arrangements	107	138
Prepaid conference and travel expenses	972	771
Prepaid co-pay assistance program	1,561	863
Other	1,030	351
Total prepaid expenses and other current assets	$ 23,550	$ 12,535

7.Operating Leases.

The Company has an operating lease agreement for its corporate office. The lease includes an option to extend the lease for up to 5 years and options to terminate the lease within 6 and 7.6 years. The Company has no obligations under finance leases.

The Company entered into an agreement in May 2020 that amended its lease for its office facilities. Under the amended lease, the Company's leased space increased from approximately 7,800 square feet of space to approximately 10,700 square feet of space. The amended lease commenced in March 2021 when construction of the asset was completed and space became available for use.

7.Operating Leases (continued).

The components of lease expense were as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease cost	$ 108	$ 108	$ 215	$ 216

Supplemental cash flow information related to lease was as follows (in thousands):

	For the Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows	$ 260	$ 252
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	$ 45	$ 45

Supplemental balance sheet information related to lease was as follows (in thousands):

	June 30, 2024	December 31, 2023
Operating lease right-of-use assets	$ 2,371	$ 2,508
Other current liabilities	$ 385	$ 369
Operating lease liabilities, net of current portion	2,991	3,188
Total operating lease liabilities	$ 3,376	$ 3,557

As of June 30, 2024 and December 31, 2023, the weighted average remaining lease term was 6.8 years and 7.3 years, respectively. The weighted average discount rate used to determine the operating lease liabilities was 4.51% as of June 30, 2024 and December 31, 2023.

Remaining payments of lease liabilities as of June 30, 2024 were as follows (in thousands):

2024 (remaining six months)	$ 262
2025	537
2026	553
2027	570
2028	587
Thereafter	1,440
Total lease payments	3,949
Less: imputed interest	(573)
Total	$ 3,376

Rent expense was approximately $0.1 million and $0.2 million for both the three and six months ended June 30, 2024 and 2023, respectively.

8.Property and Equipment, Net.

Property and equipment, net consists of the following (in thousands):

	June 30, 2024	December 31, 2023
Furniture and equipment	$ 703	$ 494
Leasehold improvements	991	991
Software	433	433
Less: Accumulated depreciation	(900)	(723)
Total property and equipment, net	$ 1,227	$ 1,195

9.License and Acquired Intangibles, Net.

The following table presents the Company's intangible assets at June 30, 2024 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 4,578	$ 28,991
License and acquired intangibles for FYCOMPA®	158,143	45,487	112,656
License and acquired intangibles for AGAMREE®	36,000	2,286	33,714
Total	$ 227,712	$ 52,351	$ 175,361

The following table presents the Company's intangible assets at December 31, 2023 (in thousands):

	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Intangible assets:			
License and acquired intangibles for RUZURGI®	$ 33,569	$ 3,418	$ 30,151
License and acquired intangibles for FYCOMPA®	158,143	29,673	128,470
License and acquired intangibles for AGAMREE®	36,000	572	35,428
Total	$ 227,712	$ 33,663	$ 194,049

The Company amortizes its definite-lived intangible assets using the straight-line method, which is considered the best estimate of economic benefit, over its estimated useful life. The estimated useful life used for this purpose for RUZURGI®, FYCOMPA® and AGAMREE® was approximately 14.5 years, 5 years and 10.5 years, respectively.

The Company recorded approximately $0.6 million and $1.2 million in amortization expense related to the licensed and acquired intangibles for RUZURGI® during the three and six months ended June 30, 2024, within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income. The Company recorded approximately $7.9 million and $15.8 million in amortization expense related to the licensed and acquired intangibles for FYCOMPA® during the three and six months ended June 30, 2024, within cost of sales in the consolidated statement of operations and comprehensive income. The Company recorded approximately $0.8 million and $1.7 million in amortization expense related to the licensed and acquired intangibles for AGAMREE® during the three and six months ended June 30, 2024, within cost of sales in the consolidated statement of operations and comprehensive income. The Company recorded approximately $0.6 million and $1.2 million in amortization expense related to the licensed and acquired intangibles for RUZURGI® during the three and six months ended June 30, 2023, within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income. The Company recorded approximately $7.9 million and $13.9 million in amortization expense related to the licensed and acquired intangibles for FYCOMPA® during the three and six months ended June 30, 2023, within cost of sales in the consolidated statement of operations and comprehensive income. The Company recorded no amortization expense related to the licensed and acquired intangibles for AGAMREE® during the three and six months ended June 30, 2023. Amortization of the FYCOMPA®, RUZURGI® and AGAMREE® intangible assets are reported together as amortization of intangible assets in the consolidated statements of operations and comprehensive income.

The following table presents future amortization expense the Company expects for its intangible assets (in thousands):

2024 (remaining six months)	$ 18,690
2025	37,378
2026	37,378
2027	37,378
2028	7,705
Thereafter	36,832
Total	$ 175,361

At June 30, 2024 and December 31, 2023, the weighted average amortization period remaining for intangible assets was 6.0 years and 6.5 years, respectively.

If all or a portion of the intangible assets are deemed not recoverable, the Company would estimate the fair value of the assets and record an impairment loss. There were no impairment charges recognized on definite-lived intangibles for the three and six months ended June 30, 2024 or 2023.

10.Accrued Expenses and Other Liabilities.

Accrued expenses and other liabilities consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued preclinical and clinical trial expenses	$ 516	$ 1,015
Accrued professional fees	4,726	4,730
Accrued compensation and benefits	7,295	8,883
Accrued license fees	16,852	24,437
Accrued purchases	398	192
Operating lease liability	385	369
Accrued gross-to-net revenue liabilities*	40,507	6,877
Accrued income tax	15	729
Due to licensor	11,960	12,540
Accrued interest payable	1,376	1,031
Accrued charitable contributions	800	—
Other	372	465
Current accrued expenses and other liabilities	85,202	61,268
Lease liability – non-current	2,991	3,188
Due to licensor – non-current	1,230	2,497
Other – non-current	1,166	485
Non-current accrued expenses and other liabilities	5,387	6,170
Total accrued expenses and other liabilities	$ 90,589	$ 67,438

* During 2023, the Company sold FYCOMPA® through a Transition Service Agreement with Eisai. Effective January 1, 2024, FYCOMPA® is being sold and distributed through a 3PL organization.

11.Collaborative and Licensing Arrangements.

Endo, Inc.

In December 2018, the Company entered into a collaboration and license agreement (Collaboration) with Endo, Inc. (formerly, Endo International plc) (Endo), for the further development and commercialization of generic Sabril® (vigabatrin) tablets through Endo's U.S. Generic Pharmaceuticals segment, doing business as Par Pharmaceutical, Inc. (Par). Under the Collaboration, Endo assumes all development, manufacturing, clinical, regulatory, sales and marketing costs under the collaboration, while the Company is responsible for exercising commercially reasonable efforts to develop, or cause the development of, a final finished, stable dosage form of generic Sabril® tablets.

In October 2023, Endo informed the Company that it has discontinued work on the Collaboration for development and commercialization of vigabatrin and that it wished to terminate the arrangement. As the Company proceeds with the termination process, the Company does not expect the end of the collaboration to have a material impact on the Company's consolidated financial statements. See Note 17 (Subsequent Events).

KYE Pharmaceuticals, Inc.

In August 2020, the Company entered into a collaboration and license agreement with KYE Pharmaceuticals, Inc. (KYE), for the commercialization of FIRDAPSE® in Canada.

Under the agreement, Catalyst granted KYE an exclusive license to commercialize and market FIRDAPSE® in Canada. KYE assumes all selling and marketing costs under the collaboration, while the Company is responsible for supply of FIRDAPSE® based on the collaboration partner's purchase orders.

Under the terms of the agreement, the Company will receive an up-front payment, has received payment upon transfer of Marketing Authorization and delivery of commercial product, received payment for supply of FIRDAPSE®, and will receive milestone payments and a sharing of defined net profits upon commercialization from KYE consisting of a mid-double-digit percent of net sales of FIRDAPSE®. The Company has also agreed to the sharing of certain development expenses. Unless terminated earlier in accordance with its terms, the collaboration continues in effect until the date that is ten years following the commercial launch of the product in Canada.

11.Collaborative and Licensing Arrangements (continued).

This agreement is in form identified as a collaborative agreement and the Company has concluded for accounting purposes that it also represents a contract with a customer. This is because the Company grants to KYE a license and provides supply of FIRDAPSE® in exchange for consideration, which are outputs of the Company's ongoing activities. Accordingly, the Company has concluded that this collaborative arrangement will be accounted for pursuant to Topic 606.

The collaborative agreement included a nonrefundable upfront license fee that was recognized upon transfer of the license based on a determination that the right is provided as the intellectual property exists at the point in time in which the license is granted.

Revenue from sales of FIRDAPSE® by KYE is recognized in the quarter in which the sales occurred.

Revenues from the arrangement with KYE for the three and six months ended June 30, 2024 and 2023 were not material. Revenue is included in license and other revenue in the accompanying consolidated statements of operations and comprehensive income. Expenses incurred, net have been included in selling, general and administrative expenses in the accompanying consolidated statements of operations and comprehensive income.

DyDo Pharma, Inc.

On June 28, 2021, the Company entered into a license agreement with DyDo Pharma, Inc. (DyDo), for the development and commercialization of FIRDAPSE® in Japan.

Under the agreement, DyDo has joint rights to develop FIRDAPSE®, and exclusive rights to commercialize the product, in Japan. DyDo is responsible for funding all clinical, regulatory, marketing and commercialization activities in Japan, while the Company is responsible for clinical and commercial supply based on purchase orders, as well as providing support to DyDo in its efforts to obtain regulatory approval for the product from the Japanese regulatory authorities.

Under the terms of the agreement, the Company has earned an up-front payment and may earn further development and sales milestones for FIRDAPSE®, as well as revenue on product supplied to DyDo.

The Company has concluded that this license agreement will be accounted for pursuant to Topic 606. The agreement included a nonrefundable upfront license fee that was recognized upon the effective date of the agreement as the intellectual property exists at the point in time in which the right to the license is granted. The Company determined the granting of the right to the license is distinct from the supply of FIRDAPSE® and represents a separate performance obligation in the agreement.

The agreement includes milestones that are considered a sales-based royalty in which the license is deemed to be the predominant item to which these milestones relate. Revenue will be recognized when the latter of (a) the subsequent sale occurs, or (b) the performance obligation to which the sales-based royalty has been allocated has been satisfied. Additionally, the agreement includes regulatory milestone payments which represent variable consideration, and due to uncertainty are fully constrained and only recognized when the uncertainty is subsequently resolved. For clinical and commercial supply of the product, the Company will recognize revenue when the Customer obtains control of the Company's product, which will occur at a point in time which is generally at time of shipment.

There were no revenues from the arrangement with DyDo for the three and six months ended June 30, 2024. There were revenues of $0.3 million and $0.5 million from the arrangement with DyDo for the three and six months ended June 30, 2023, respectively, which is included in product revenue, net in the accompanying consolidated statements of operations and comprehensive income.

12.Commitments and Contingencies.

In May 2019, the FDA approved a NDA for RUZURGI®, Jacobus Pharmaceuticals' version of amifampridine (3,4-DAP), for the treatment of pediatric LEMS patients (ages 6 to under 17). In June 2019 the Company filed suit against the FDA and several related parties challenging this approval and related drug labeling. Jacobus later intervened in the case. The Company's complaint, which was filed in the federal district court for the Southern District of Florida, alleged that the FDA's approval of RUZURGI® violated multiple provisions of FDA regulations regarding labeling, resulting in misbranding in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); violated the Company's statutory rights to Orphan Drug Exclusivity and New Chemical Entity Exclusivity under the FDCA; and was in multiple other respects arbitrary, capricious, and contrary to law, in violation of the Administrative Procedure Act. Among other remedies, the suit sought an order vacating the FDA's approval of RUZURGI®.

12.Commitments and Contingencies (continued).

On July 30, 2020, the Magistrate Judge considering this lawsuit filed a Report and Recommendation in which the Magistrate Judge recommended to the District Judge handling the case that the District Judge grant the FDA's and Jacobus' motions for summary judgment and deny the Company's motion for summary judgment. On September 29, 2020, the District Judge adopted the Report and Recommendation of the Magistrate Judge, granted the FDA's and Jacobus' motions for summary judgment, and dismissed the Company's case. The Company appealed the District Court's decision to the U.S. Court of Appeals for the 11th Circuit. The case was fully briefed in early 2021, and oral argument was held in March 2021.

On September 30, 2021, a three-judge panel of 11th Circuit judges issued a unanimous decision overturning the District Court's decision. The appellate court adopted the Company's argument that the FDA's approval of RUZURGI® violated the Company's rights to Orphan Drug Exclusivity and remanded the case to the District Court with orders to enter summary judgment in the Company's favor. In November 2021, Jacobus filed a motion seeking rehearing of the case from the full 11th Circuit, which motion was denied in January 2022. Further, in January 2022, Jacobus filed motions with both the 11th Circuit and the U.S. Supreme Court seeking a stay of the 11th Circuit's ruling indicating that it would seek a review of the 11th Circuit's decision from the U.S. Supreme Court. Both stay motions were denied, and on January 28, 2022, the 11th Circuit issued a mandate directing the District Court to enter summary judgment in the Company's favor. The District Court entered that order on January 31, 2022. On February 1, 2022, the FDA informed Jacobus that, consistent with the Court of Appeals for the 11th Circuit's September 30, 2021 decision in favor of Catalyst, the final approval of the RUZURGI® NDA was switched to a tentative approval until the 7-year orphan-drug exclusivity (ODE) for FIRDAPSE® has expired.

On July 11, 2022, the Company settled certain of its disputes with Jacobus. In connection with the settlement, the Company licensed the rights to develop and commercialize RUZURGI® in the U.S. and Mexico (the Territory). Simultaneously, the Company purchased, among other intellectual property rights, Jacobus' U.S. patents related to RUZURGI®, its new drug applications in the U.S. for RUZURGI®, and certain RUZURGI® inventory previously manufactured by Jacobus. At the same time, the Company received a license from Jacobus for use of its know-how related to the manufacture of RUZURGI®. Further, the Company settled its patent case against Jacobus, which was dismissed without prejudice. Finally, Jacobus agreed that until the later of (i) the expiration of the royalty term or (ii) December 31, 2034, Jacobus and its affiliates, will not, directly or indirectly, research, develop, manufacture, commercialize, distribute, use or otherwise exploit any product competitive to FIRDAPSE® or RUZURGI® in the Territory, and Laura Jacobus, the sole shareholder of Jacobus, and two of Jacobus' other officers, also signed individual non-competition agreements containing the same terms.

In connection with the settlement with Jacobus, the Company agreed to pay the following consideration to Jacobus:

- $30 million of cash, of which $10 million was paid at the closing of the settlement on July 11, 2022, $10 million was paid on the first anniversary of the closing, and the remaining $10 million will be paid on the second anniversary of the closing. See Note 17 (Subsequent Events);
- An annual royalty on the Company's net sales (as defined in the License and Asset Purchase Agreement between Catalyst and Jacobus) of amifampridine products in the U.S. equal to: (a) for calendar years 2022 through 2025, 1.5% (with a minimum annual royalty of $3.0 million per year), and (b) for calendar years 2026 through the expiration of the last to expire of the Company's FIRDAPSE® patents in the U.S., 2.5% (with a minimum annual royalty of $5 million per year); provided, however, that the royalty rate may be reduced and the minimum annual royalty may be eliminated under certain circumstances; and
- If the Company were to receive a priority review voucher for FIRDAPSE® or RUZURGI® in the future, 50% of the consideration paid by a third-party to acquire that voucher will be paid to Jacobus.

The Company's New Drug Submission filing for FIRDAPSE® for the symptomatic treatment of LEMS was approved when Health Canada issued a Notice of Compliance, or NOC, on July 31, 2020. In August 2020, the Company entered into a license agreement with KYE Pharmaceuticals, or KYE, pursuant to which the Company licensed to KYE the Canadian rights for FIRDAPSE® for the treatment of LEMS. On August 10, 2020, Health Canada issued a NOC to Medunik (Jacobus' licensee in Canada for RUZURGI®) for the treatment of LEMS. Shortly thereafter, the Company initiated a legal proceeding in Canada seeking judicial review of Health Canada's decision to issue the NOC for RUZURGI® as incorrect and unreasonable under Canadian law due to Medunik's use of the Company's protected data in its application. After two decisions by the trial judge to quash the RUZURGI® approval and remand the matter back to Health Canada, the Canadian Federal Appellate Court overturned the trial judge's decision. The Minister subsequently reapproved RUZURGI®'s NOC for Canada in 2023. The Company does not expect the approval of RUZURGI® in Canada to have a material impact on the Company's consolidated financial statements.

12.Commitments and Contingencies (continued).

In January 2023, the Company received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising that they had each submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the U.S. The notice letters each alleged that the six patents listed in the FDA Orange Book covering FIRDAPSE® are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, the Company had 45 days from receipt of the notice letters to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court to trigger a stay precluding the FDA from approving any ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. In that regard, after conducting the necessary due diligence, the Company filed lawsuits on March 1, 2023 in the U.S. District Court for the District of New Jersey against each of the three generic drug manufacturers who notified the Company of their ANDA submissions, thus triggering the stay. Further, in October 2023, the Company received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer, and the Company filed a similar lawsuit against the manufacturer in November 2023. See Note 17 (Subsequent Events). The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance that the Company will prevail in this litigation. However, the Company is vigorously defending its intellectual property for FIRDAPSE® in this litigation and believes that its patent estate will protect FIRDAPSE® from generic competition for the life of its patents.

On February 20, 2023, the Company received a Paragraph IV Certification Notice Letter from a company that appears to have filed the first ANDA for the oral suspension formulation for FYCOMPA®. The same company sent a similar letter to the Company later in February with a similar certification for the tablet formulation for FYCOMPA®, the fourth such certification for this formulation. Both of these letters were paragraph IV certifications of non-infringement, non-validity, and unenforceability to the ‘497 patent for FYCOMPA® but each application, like the previous Paragraph IV notices from ANDA filers, for FYCOMPA® tablets does not challenge the ‘571 patent. Similar to the actions with the FIRDAPSE® Paragraph IV Certifications described above, after due diligence the Company filed lawsuits on April 5, 2023, in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified the Company of their ANDA submissions for both FYCOMPA® formulations, thus triggering the 30-month stay for each application. This lawsuit was settled in June 2024. As part of this settlement, this Paragraph IV filer agreed not to commercialize their proposed ANDA products for both the oral suspension formulation of FYCOMPA® and for FYCOMPA® tablets until at least December 15, 2025.

Additionally, from time to time the Company may become involved in legal proceedings arising in the ordinary course of business. Except as set forth above, the Company believes that there is no other litigation pending at this time that could have, individually or in the aggregate, a material adverse effect on its results of operations, financial condition, or cash flows.

13.Agreements.

a.LICENSE AGREEMENT FOR FIRDAPSE®. On October 26, 2012, the Company entered into a license agreement with BioMarin Pharmaceutical, Inc. (BioMarin) for the North American rights to FIRDAPSE®. Under the license agreement, the Company pays: (i) royalties to the licensor for seven years from the first commercial sale of FIRDAPSE® equal to 7% of net sales (as defined in the license agreement) in North America for any calendar year for sales up to $100 million, and 10% of net sales in North America in any calendar year in excess of $100 million; and (ii) royalties to the third-party licensor of the rights sublicensed to the Company for seven years from the first commercial sale of FIRDAPSE® equal to 7% of net sales (as defined in the license agreement between BioMarin and the third-party licensor) in any calendar year for the duration of any regulatory exclusivity within a territory and 3.5% for territories in any calendar year in territories without regulatory exclusivity.

On May 29, 2019, the Company and BioMarin entered into an amendment to the Company’s license agreement for FIRDAPSE®. Under the amendment, the Company has expanded its commercial territory for FIRDAPSE®, which originally was comprised of North America, to include Japan. Additionally, the Company’s commercial territory will be expanded under the license agreement to include most of Asia, as well as Latin America, upon the acceptance by the Pharmaceuticals and Medical Devices Agency (PMDA) of a Japan MAA for FIRDAPSE® for LEMS. Under the amendment, the Company will pay royalties to its licensor on net sales in Japan of a similar percentage to the royalties that the Company is currently paying under its original license agreement for North America.

On December 18, 2023, DyDo filed a Japan NDA with the PMDA, which was accepted for filing upon its submission. As a result, the Company’s territory automatically expanded on that date to include most of Asia and Latin America.

In January 2020, the Company was advised that BioMarin has transferred substantially all of its rights under the license agreement to SERB S.A., and SERB S.A. is now the Company’s licensor under the license agreement.

13.Agreements (continued).

b.LICENSE AGREEMENT FOR RUZURGI®. On July 11, 2022 (the Effective Date), the Company entered into an exclusive license agreement with Jacobus Pharmaceutical Company, Inc. (Jacobus), for the rights to develop and commercialize RUZURGI® in the U.S. and Mexico.

Pursuant to the terms of the license agreement, the Company paid Jacobus a $10 million up-front payment on the Effective Date and also paid an additional $10 million on the first annual anniversary of the Effective Date (July 11, 2023). The Company is obligated to pay an additional $10 million on the second annual anniversary of the Effective Date (July 11, 2024). See Note 17 (Subsequent Events). The Company is also obligated to pay tiered royalty payments on net sales (as defined in the license agreement) of all of the Company's amifampridine products in the U.S. that range from 1.25% to 2.5% based on whether there is a competing product or generic version of FIRDAPSE® being marketed or sold in the U.S.

A minimum royalty payment exists annually for calendar years from the Effective Date through 2025 of $3 million, provided that such minimum annual royalty payment shall be prorated in the first calendar year of the agreement. As these minimum payments are both probable and estimable, they are included in the purchase price of the agreement and any royalties in excess of this amount will be charged to cost of sales as revenue from product sales is recognized. A minimum royalty payment exists annually for calendar years from 2026 through the expiration of the royalty term (which ends when there is no valid claim under the Company's FIRDAPSE® patents in the U.S.) of $5 million unless a competing product or generic version of FIRDAPSE® is being marketed or sold in the U.S. If these minimum payments become probable in the future, the Company would recognize a contingent liability at that time with an offset to the value of the intangible asset acquired. Any royalties in excess of this amount will be charged to cost of sales as revenue from product sales is recognized. Royalties over the minimum, if any, will be paid based on the agreement terms on a quarterly basis.

Assets acquired as part of the license agreement include among other intellectual property rights, Jacobus' U.S. patents related to RUZURGI®, its new drug applications in the U.S. for RUZURGI®, its Trademark for RUZURGI®, the Orphan Drug Designation for RUZURGI® and a license from Jacobus for use of its know-how related to the manufacture of RUZURGI®.

Additionally, the Company also purchased from Jacobus approximately $4.1 million of RUZURGI® inventory previously manufactured by Jacobus, which was recorded as an expense in research and development expenses in the consolidated statement of operations and comprehensive income for 2022.

Under business combination guidance, the screen test states that if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the set is not considered a business and is accounted for as an asset acquisition. The Company has determined that the screen test was not met. However, the Company determined that the acquisition did not meet the definition of a business under ASC 805, Business Combination. The Company believes that the licensing agreement and other assets acquired from Jacobus are similar and considered them all to be intangible assets with the exception of the inventory acquired. As the screen test was not met, further determination was required to determine that the Company had not acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business, and therefore, determined that this was an asset acquisition. The Company accounted for the Jacobus license agreement as an asset acquisition under ASC 805-50, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes consideration given.

The total purchase price was allocated to the acquired assets based on their relative fair values, as follows (in thousands):

License and acquired intangibles	$	33,569
Acquired research and development inventory expensed from asset acquisition		4,130
Total purchase price	$	37,699

The straight-line method is used to amortize the license and acquired intangibles, as disclosed in Note 9 (License and Acquired Intangibles, Net).

c.ACQUISITION OF U.S. RIGHTS FOR FYCOMPA®. On January 24, 2023, the Company acquired the U.S. Rights for FYCOMPA® (perampanel) CIII a commercial stage epilepsy asset, from Eisai. The aggregate consideration for the acquisition was $164.2 million in cash, including the reimbursement of certain liabilities and the payment of transaction costs.

13.Agreements (continued).

Eisai was eligible to receive a contingent payment of $25 million if a certain regulatory milestone was met. As meeting the regulatory milestone was not probable, the Company did not recognize any amount related to the milestone payments in the purchase price. Additionally, after the loss of patent exclusivity for FYCOMPA®, the Company may be obligated to pay certain royalties to Eisai on net sales of FYCOMPA®. As the transaction is accounted for as an asset acquisition under U.S. GAAP, the Company will recognize the royalty payments in cost of sales as revenue from product sales is recognized.

Royalties commencing on loss of exclusivity for each calendar year during the royalty term equal to 12% on net sales greater than $10 million and less than $100 million, 17% on net sales of greater than $100 million and less than $125 million and 22% on net sales greater than $125 million prior to the date of generic entry. Royalties equal to 6% on net sales greater than $10 million and less than $100 million, 8.5% on net sales of greater than $100 million and less than $125 million and 11% on net sales greater than $125 million after the date of generic entry.

The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the acquisition of FYCOMPA® (in thousands):

Base cash payment	$	160,000
Cash paid for pro-rated prepaid expenses		1,576
Reimbursement on base purchase price[(i)]		(3,238)
Transaction costs[(ii)]		5,870
Total purchase consideration	$	164,208

(i)Recorded in prepaid expenses and other current assets in the accompanying consolidated balance sheet as of the acquisition date and reimbursement was fully applied as of June 30, 2023.

(ii)As of June 30, 2024, the full $5.9 million has been paid in cash.

The acquisition of FYCOMPA® has been accounted for as an asset acquisition in accordance with FASB ASC 805-50. The Company accounted for the acquisition of FYCOMPA® as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset, the FYCOMPA® product rights. The FYCOMPA® product rights consist of certain patents and trademarks, at-market contracts and regulatory approvals, marketing assets, and other records, and are considered a single asset as they are inextricably linked. ASC 805-10-55-5A includes a screen test, which provides that if substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not considered to be a business. ASC 805 requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes consideration given.

The total purchase price was allocated to the acquired assets based on their relative fair values, as follows (in thousands):

Inventory	$	4,100
Prepaid expenses and other current assets (samples)		130
Prepaid commercialization expenses		1,576
Property and equipment, net		433
License and acquired intangibles for FYCOMPA®		158,143
Accrued preclinical and clinical trial expenses		(174)
Total purchase consideration	$	164,208

The straight-line method is used to amortize the license and acquired intangibles, as disclosed in Note 9 (License and Acquired Intangibles, Net).

d.LICENSE AGREEMENT FOR AGAMREE® (VAMOROLONE). In July 2023, the Company completed its acquisition from Santhera of an exclusive license for North America for AGAMREE® (vamorolone), a treatment for patients suffering with DMD which was approved by the FDA on October 26, 2023. On March 13, 2024, the Company announced the U.S. commercial launch of AGAMREE® for the treatment of DMD in patients aged two years or older. The license is for exclusive commercial rights in the U.S., Canada, and Mexico, as well as the right of first negotiation in Europe and Japan should Santhera pursue partnership opportunities in those jurisdictions. Additionally, the Company will hold North American rights for any future approved indications of AGAMREE®. The Company made an all-cash initial payment of $75 million at the closing of the acquisition to acquire the license.

13.Agreements (continued).

Under the license agreement, the Company pays: (i) royalties to the licensor until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 5% of net sales (as defined in the license agreement) in North America for any calendar year for sales equal to or less than $100 million (prior to December 31, 2025 only), 7% of net sales for sales in excess of $100 million and up to $200 million, 9% of net sales for sales in excess of $200 million and up to $300 million, 11% of net sales for sales in excess of $300 million; and (ii) royalties to the third-party licensor of the rights sublicensed to the Company until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 7% of net sales (as defined in the license agreement) in North America for any single calendar year for sales equal to or less than $250 million, 8.5% of net sales for sales in excess of $250 million and up to $500 million, 10% of net sales for sales in excess of $500 million and up to $750 million, 12% of net sales for sales in excess of $750 million and up to $1 billion, 13% of net sales for sales in excess of $1 billion and up to $2 billion and 15% of net sales for sales in excess of $2 billion. Furthermore, the Company may pay Santhera sales-based milestones of up to $105 million as well as up to 11% percent royalties for all additional indications and milestones of up to $50 million for the first three additional indications.

Simultaneously, the Company made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's post reverse-split ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction), which are traded on the SIX Swiss Exchange, at an investment price of CHF 9.477 per share (corresponding to a mutually agreed volume-weighted average price prior to signing), with the funds invested into Santhera to be used by Santhera for Phase IV studies in DMD and further development of additional indications for AGAMREE®. The Company may also be obligated under certain circumstances to make milestone payments and to pay royalties to Santhera.

The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the acquisition of AGAMREE® and the strategic equity investment (in thousands):

Initial cash payment	$	75,000
Investment in Santhera		13,465
Transaction costs		6,513
Total purchase consideration	$	94,978

The transaction has been accounted for as an asset acquisition in accordance with ASC 805-50. The Company accounted for the transaction as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset, the rights to develop, commercialize and manufacture AGAMREE®. The AGAMREE® rights consist of certain licenses and regulatory approvals and are considered a single asset as they are inextricably linked. ASC 805-10-55-5A includes a screen test, which provides that if substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not considered to be a business. Additionally, the Company did not acquire a substantive process. ASC 805 requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes consideration given. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the non-financial assets based on relative fair values.

The total purchase price was allocated to the acquired assets based on their relative fair values, as follows (in thousands):

License and acquired intangibles for AGAMREE® (vamorolone) (IPR&D)	$	81,513
Investment in Santhera[(i)]		13,465
Total purchase consideration	$	94,978

(i) The fair value of the investment in Santhera was determined based on the closing market price (CHF 8.25) of Santhera shares and the exchange rate (1.1537) of CHF to USD on the date the shares were transferred, July 19, 2023.

In accordance with FASB ASC 730-10-25, as AGAMREE® (vamorolone) had not achieved regulatory approval when acquired, the portion of the purchase price allocated to the IPR&D asset acquired (which includes all transaction costs related to the transactions with Santhera) was immediately expensed to research and development. Milestone payments made are either expensed as research and development or capitalized as a developed asset based on when regulatory approval is obtained. As the transaction is accounted for as an asset acquisition under U.S. GAAP, the Company will recognize all sales-based milestone and royalty payments in cost of sales as revenue from product sales is recognized.

13.Agreements (continued).

Following the approval of the NDA for AGAMREE® on October 26, 2023, the Company became obligated to make a milestone payment of $36 million to Santhera. The $36 million payment was made during the fourth quarter of 2023. The Company capitalized the $36 million payment which is amortized using the straight-line method over the product's estimated useful life of 10.5 years.

The strategic equity investment in Santhera is accounted for as an investment in equity securities, and is recognized as a non-current asset, as the Company does not intend on selling the shares within 12 months. Since Santhera shares have a readily determinable fair value, the investment will be measured quarterly at fair value with changes reported in earnings in other income, net in the accompanying consolidated statement of operations and comprehensive income.

e.AGREEMENTS FOR DRUG MANUFACTURING, DEVELOPMENT, PRECLINICAL AND CLINICAL STUDIES. The Company has entered into agreements with contract manufacturers for the manufacture of commercial drug and drug and study placebo for the Company's trials and studies, with contract research organizations (CRO) to conduct and monitor the Company's trials and studies and with various entities for laboratories and other testing related to the Company's trials and studies. The contractual terms of the agreements vary, but most require certain advances as well as payments based on the achievement of milestones. Further, these agreements are cancellable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

14.Income Taxes.

The Company's effective income tax rate was 24.5% and 21.5% for the six months ended June 30, 2024 and 2023, respectively. Differences in the effective tax and the statutory federal income tax rate of 21% are driven by state income taxes, fluctuations in the value of investments and anticipated annual permanent differences offset by equity compensation deductions.

The Company had no uncertain tax positions as of June 30, 2024 and December 31, 2023.

15.Stockholders' Equity.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share. At June 30, 2024 and December 31, 2023, no shares of preferred stock were outstanding.

Common Stock

The Company has 200,000,000 shares of authorized common stock, par value $0.001 per share. At June 30, 2024 and December 31, 2023, 118,521,366 and 107,121,549 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

Share Repurchases

In March 2021, the Company's Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of the Company's common stock, pursuant to a repurchase plan under Rule 10b-18 of the Securities Act. The share repurchase program commenced on March 22, 2021. No shares were repurchased during the three and six months ended June 30, 2024 and 2023.

2020 Shelf Registration Statement

On July 23, 2020, the Company filed a shelf registration statement with the SEC to sell up to $200 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the "2020 Shelf Registration Statement"). The 2020 Shelf Registration Statement (file no. 333-240052) was declared effective by the SEC on July 31, 2020. The Company's 2020 Shelf Registration Statement expired on July 31, 2023.

2023 Shelf Registration Statement

On September 8, 2023, the Company filed a shelf registration statement with the SEC to sell up to $500 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the "2023 Shelf Registration Statement"). The 2023 Shelf Registration Statement (file no. 333-274427) became effective upon filing. On January 9, 2024, the Company completed a public offering of 10 million shares of its common stock, raising net proceeds of approximately $140.7 million under the Company's 2023 Shelf Registration Statement.

16.Stock Compensation.

For the three and six months ended June 30, 2024 and 2023, the Company recorded stock-based compensation expense as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 403	$ 351	$ 912	$ 690
Selling, general and administrative	4,005	2,947	11,744	5,500
Total stock-based compensation	$ 4,408	$ 3,298	$ 12,656	$ 6,190

Stock Options

As of June 30, 2024, there were outstanding stock options to purchase 13,754,600 shares of common stock, of which stock options to purchase 8,670,753 shares of common stock were exercisable.

During the three and six months ended June 30, 2024, the Company granted seven-year term options to purchase an aggregate of 47,500 and 840,995 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $3.6 million and $9.0 million, respectively, during the three and six months ended June 30, 2024.

During the three and six months ended June 30, 2023, the Company granted seven-year term options to purchase an aggregate of 704,500 and 1,045,000 shares, respectively, of the Company's common stock to employees. The Company recorded stock-based compensation related to stock options totaling $2.6 million and $4.8 million, respectively, during the three and six months ended June 30, 2023.

During the three and six months ended June 30, 2024, options to purchase 491,840 shares and 1,156,272 shares, respectively, of the Company's common stock were exercised, with proceeds of $2.0 million and $3.6 million, respectively, to the Company.

During the three and six months ended June 30, 2023, options to purchase 556,909 shares and 1,104,866 shares, respectively, of the Company's common stock were exercised, with proceeds of $0.6 million and $1.9 million, respectively, to the Company.

As of June 30, 2024, there was approximately $32.9 million of unrecognized compensation expense related to non-vested stock option awards granted under the 2014 and 2018 Stock Incentive Plans. The cost is expected to be recognized over a weighted average period of approximately 2.9 years.

Restricted Stock Units

The Company granted no restricted stock units and 35,693 restricted stock units during three and six months ended June 30, 2024, respectively. The Company granted no restricted stock units during the three and six months ended June 30, 2023. During the three and six months ended June 30, 2024, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.8 million and $3.7 million, respectively. During the three and six months ended June 30, 2023, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0.7 million and $1.4 million, respectively.

As of June 30, 2024, there was approximately $7.0 million of unrecognized compensation expense related to non-vested restricted stock units granted under the 2018 Stock Incentive Plan. The cost is expected to be recognized over a weighted average period of approximately 3.0 years.

17.Subsequent Events.

In July 2024, a termination and mutual release agreement was finalized between Endo and the Company that discontinued work on the collaboration for development and commercialization of vigabatrin. The end of the collaboration does not have a material impact on the Company's consolidated financial statements.

In July 2024, the Company paid the final $10 million installment to Jacobus Pharmaceutical Company, Inc. of the $30 million up front payment due from its July 2022 acquisition of RUZURGI® as described in Note 12 (Commitments and Contingencies).

In July 2024, the Company entered into a license, supply and commercialization agreement with KYE granting KYE the exclusive Canadian commercial rights to market AGAMREE® in Canada for the treatment of DMD and other indications. Under the agreement, KYE will be responsible for obtaining regulatory approval of the product from Health Canada and the Company will supply product to KYE. Further, the Company will receive an upfront payment from KYE and will be eligible to receive further reimbursement and sales milestones and sales royalties for AGAMREE®.

On July 30, 2024, the Company settled its patent litigation with the fourth of the ANDA filers for FIRDAPSE®. In that settlement, the ANDA filer acknowledged both the validity of the Company's FIRDAPSE® patents and also the infringement by the ANDA filer's product of the Company's patents. As part of the settlement, the ANDA filer also agreed not to commercialize its product until the earlier of all FIRDAPSE® patents expiration or the entry into the market of another ANDA product meeting certain conditions.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Introduction

Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to provide an understanding of our financial condition, changes in financial condition and results of operations. The discussion and analysis is organized as follows:

•Overview. This section provides a general description of our business and information about our business that we believe is important in understanding our financial condition and results of operations.

•Basis of Presentation. This section provides information about key accounting estimates and policies that we followed in preparing our consolidated financial statements for the second quarter of fiscal 2024.

•Critical Accounting Policies and Estimates. This section discusses those accounting policies that are both considered important to our financial condition and results of operations and require significant judgment and estimates on the part of management in their application. All of our significant accounting policies, including the critical accounting policies, are also summarized in the notes to our interim consolidated financial statements that are included in this report.

•Results of Operations. This section provides an analysis of our results of operations for the three and six months ended June 30, 2024 as compared to the three and six months ended June 30, 2023.

•Liquidity and Capital Resources. This section provides an analysis of our cash flows, capital resources, off-balance sheet arrangements, and outstanding commitments, if any.

•Caution Concerning Forward-Looking Statements. This section discusses how certain forward-looking statements made throughout this MD&A and in other sections of this report are based on management's present expectations about future events and are inherently susceptible to uncertainty and changes in circumstance.

OVERVIEW

We are a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare and difficult to treat diseases. We currently market three drug products, FIRDAPSE® (amifampridine), FYCOMPA® (perampanel), and AGAMREE® (vamorolone). We are also currently seeking to further expand our product portfolio, with a focus on acquiring the rights to late-stage products to treat rare (orphan) central nervous system and adjacent rare (orphan) diseases. With an unwavering patient focus embedded in everything we do, we are committed to providing innovative, best-in-class medications with the hope of making a meaningful impact on those affected by these conditions.

Our flagship U.S. commercial product is FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome, or LEMS, for adults and for children six years of age and older. Further, on January 24, 2023, we closed our acquisition of the U.S. rights to FYCOMPA® from Eisai Co., Ltd. (Eisai) and are now marketing that product in the United States (U.S.). FYCOMPA® (perampanel) CIII is a prescription medication used alone or with other medicines to treat focal onset seizures with or without secondarily generalized seizures in people with epilepsy ages four and older and with other medicines to treat primary generalized tonic-clonic seizures in people with epilepsy ages 12 and older. Finally, on July 18, 2023, we closed our acquisition from Santhera Pharmaceuticals Holding, Inc. (Santhera) of an exclusive license for North America for vamorolone, a novel corticosteroid treatment for patients suffering from Duchenne muscular dystrophy (DMD). On October 26, 2023, the FDA approved AGAMREE® (vamorolone) oral suspension 40 mg/ml for the treatment of DMD in patients ages two years and older, and on March 13, 2024, we announced the U.S. commercial launch of AGAMREE®.

FIRDAPSE®

On November 28, 2018, we received approval from the FDA for our new drug application, or NDA, for FIRDAPSE® Tablets 10 mg for the treatment of adult patients (ages 17 and above) with LEMS, and in January 2019, we launched FIRDAPSE® in the United States. Further, on September 29, 2022, the FDA approved our supplemental NDA (sNDA) to expand the indicated age range for FIRDAPSE® Tablets 10 mg to include pediatric patients six years of age and older for the treatment of LEMS. Additionally, on May 30, 2024, we reported that the FDA had approved our sNDA increasing the indicated maximum daily dosage of FIRDAPSE® tablets for the treatment of LEMS from 80 mg to 100 mg. We believe that this most recent sNDA approval will offer healthcare providers and patients greater flexibility in treatment regimens for the management of LEMS.

We sell FIRDAPSE® through a field force experienced in neurologic, central nervous system or rare disease products consisting at this time of approximately 35 field personnel, including sales (Regional Account Managers), thought leader liaisons and patient

assistance and insurance navigation support (Patient Access Liaisons). We also have a field-based force of 11 medical science liaisons who are helping educate the medical community about scientific literature concerning LEMS and FIRDAPSE®. Additionally, we use non-personal promotion to reach the 20,000 neurologists who are potential LEMS treaters and the 16,000 oncologists who might be treating a LEMS patient who also has small cell lung cancer. Further, we continue to make available at no-cost a LEMS voltage gated calcium channel antibody diagnostic testing program for use by physicians who suspect that one of their patients may have LEMS and wish to reach a definitive diagnosis.

Finally, we are continuing to expand our digital and social media activities to introduce our products and services to potential patients and their healthcare providers. We also work with several rare disease advocacy organizations (including the Myasthenia Gravis Foundation of America, the National Organization for Rare Disorders, and the LEMS Family Association) to help increase awareness and level of support for patients living with LEMS and to provide education for the physicians who treat these rare diseases and the patients they treat.

We are supporting the distribution of FIRDAPSE® through Catalyst Pathways®, our personalized treatment support program for patients who enroll in it. Catalyst Pathways® is a single source for personalized treatment support, education and guidance through the challenging dosing and titration regimen required to reach an effective therapeutic dose. The program also includes distributing the drug through a very small group of exclusive specialty pharmacies (primarily AnovoRx), which is consistent with the way that most drug products for ultra-orphan diseases are distributed and dispensed to patients. We believe that by using specialty pharmacies in this way, the difficult task of navigating the health care system is far better for the patient needing treatment for their rare disease and the health care community in general.

In order to help patients with LEMS afford their medication, we, like other pharmaceutical companies which are marketing drugs for ultra-orphan conditions, have developed an array of financial assistance programs to reduce out of pocket costs that makes FIRDAPSE® accessible and affordable. A co-pay assistance program has been designed to reduce commercial patients' out of pocket costs to $0 whenever possible. Our FIRDAPSE® co-pay assistance program is not available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, VA, DoD, or TRICARE. However, we are donating, and committing to continue to donate, money to qualified, independent charitable foundations dedicated to providing assistance to any U.S. LEMS patients in financial need, who meet those independent organizations guidelines. In addition, Catalyst has a safety net program in place for patients who are uninsured and underinsured. Subject to compliance with regulatory requirements, our goal is that no LEMS patient is ever denied access to their medication for financial reasons.

We were advised by our sub-licensee for FIRDAPSE® in Japan, DyDo Pharma, Inc. (DyDo), that on December 18, 2023, they filed a Japan NDA with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan seeking approval to commercialize FIRDAPSE® for the treatment of LEMS in Japan. The review period is expected to be approximately nine months from the submission date, and there can be no assurance that the Japan NDA filing made by DyDo will be approved.

Further, upon acceptance of the Japan NDA by the PMDA on December 18, 2023, our license for FIRDAPSE® automatically expanded to include other key markets in Asia and Latin America, and we are currently seeking opportunities to expand FIRDAPSE®'s global footprint through strategic partnerships (with the current focus on the Asia Pacific and Latin American regions). However, no such arrangements have been entered into to date.

We hold six patents for FIRDAPSE® that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), the earliest of which expires in 2032 and the latest of which expires in 2037. We also have orphan drug exclusivity (ODE) for the product that will not expire until November 2025, and no Abbreviated New Drug Application (ANDA) for the product can be finally approved by the FDA until the ODE exclusivity period has expired. Nevertheless, generic drug manufacturers are permitted to file applications for the product challenging our patents, and in January 2023, we received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising that they had each submitted an ANDA to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the U.S. The notice letters each alleged that the six patents protecting FIRDAPSE® that are listed in the Orange Book in connection with FIRDAPSE® are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the Federal Food, Drug and Cosmetic Act (FDCA), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, we had 45 days from receipt of the notice letters to determine if there were grounds to bring a lawsuit and, if so, to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court, which would trigger a statutory stay precluding the FDA from final approval of the subject ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first in all cases (but not earlier than the expiration of orphan drug exclusivity on November 28, 2025). In that regard, after conducting the necessary due diligence, we filed lawsuits on March 1, 2023 in the U.S. District Court for the District of New Jersey against each of the three generic drug manufacturers who notified us of their ANDA submissions, thus triggering the stay. All of these lawsuits are progressing.

Further, in October 2023, we received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer, and we filed a similar lawsuit against this manufacturer in November 2023 in the U.S. District Court for the District of New Jersey. On July 30, 2024, we settled this patent litigation with the fourth of the ANDA filers to file an ANDA for FIRDAPSE®. In that

settlement, the ANDA filer acknowledged both the validity of our FIRDAPSE® patents and also the infringement by the ANDA filer's product of our patents. As part of the settlement, the ANDA filer agreed not to commercialize its product until the earlier of all FIRDAPSE® patents expiration or the entry into the market of another ANDA product meeting certain conditions.

The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance to whether we will prevail in this litigation. However, we are vigorously defending our intellectual property for FIRDAPSE® in this litigation and we believe that our patent estate will protect FIRDAPSE® from generic competition for the life of our patents.

FYCOMPA®

On December 17, 2022, we entered into an agreement with Eisai for the acquisition of the U.S. rights to FYCOMPA® (perampanel) CIII. FYCOMPA® is a selective non-competitive antagonist of AMPA receptors, the major subtype of ionotropic glutamate receptors. It was the first, and still the only, drug of its class to be approved for epilepsy. Studies suggest that AMPA receptor antagonism can lead to reduced overstimulation and anticonvulsant effects, as well as inhibiting seizure generation and spread. FYCOMPA® is a controlled substance and is approved with a box warning label. FYCOMPA® is used to treat certain types of focal onset seizures (seizures that involve only one part of the brain) in adults and children four years of age and older. It is also used in combination with other medications to treat certain types of primary generalized tonic-clonic seizures (also known as a “grand mal” seizure, a seizure that involves the entire body) in adults and children 12 years of age or older. Perampanel is in a class of medications called anticonvulsants. It works by decreasing abnormal electrical activity in the brain.

On January 24, 2023, we closed our acquisition of the U.S. rights to FYCOMPA®. In connection with the acquisition, we purchased Eisai’s regulatory approvals and documentation, product records, intellectual property, inventory, and other matters relating to the U.S. rights for FYCOMPA®, in exchange for an upfront payment of $160 million in cash. We also agreed to pay Eisai royalty payments after patent protection for FYCOMPA® expires, which royalty payments will be reduced upon generic equivalents to FYCOMPA® entering the market.

In conjunction with the closing of the asset purchase, we entered into two additional agreements, a Transition Services Agreement (TSA) and a Supply Agreement. Under the TSA, a U.S. subsidiary of Eisai provided us with certain transitional services, and under the Supply Agreement, Eisai agreed to manufacture FYCOMPA® for us for at least seven years at prices listed in the Supply Agreement (to be updated on a yearly basis). The transition services provided under the TSA ended on December 31, 2023.

We sell FYCOMPA® through a field force experienced in epilepsy products consisting at this time of approximately 30 field personnel, including sales (Regional Account Managers) and payor reimbursement (National Account Managers). We also have a field-based force of seven medical science liaisons who are helping educate the medical community who treat epilepsy about scientific literature regarding epilepsy and FYCOMPA®. Further, effective January 1, 2024, FYCOMPA® is being sold and distributed through a 3PL organization.

We are supporting patients using FYCOMPA® through an Instant Savings Card Program. Through the program, eligible commercially insured patients could pay as little as $10 for their FYCOMPA® co-pay (with a maximum savings of $1,300 per year). The FYCOMPA® Instant Savings Card Program is not available to patients enrolled in state or federal healthcare programs, including Medicare, Medicaid, Department of Veterans Affairs (VA), Department of Defense (DoD), or TRICARE.

Patent protection for FYCOMPA® is primarily derived from two patents listed in the FDA’s Orange Book. The first, U.S. patent no. 6,949,571 (the ‘571 patent), will expire on May 23, 2025, including patent term extension. The second FYCOMPA® patent in the Orange Book is U.S. Patent No. 8,772,497 (the ‘497 patent), which expires on July 1, 2026. The ‘497 patent, which covers the API used in both FYCOMPA® tablets and oral solution, has been the subject of previous Paragraph IV certifications from three ANDA filers for the tablet formulation, which were not contested by Eisai prior to our acquisition of the drug. Following our acquisition of the drug, we attempted to obtain an extension of the patent term for the '571 patent, which was ultimately unsuccessful. As a result, the '571 patent will expire on May 23, 2025 and the initial ANDA filers who did not challenge this patent may seek approval of their ANDA applications on or after that date.

In February 2023 we received a Paragraph IV certification for the '571 patent from an ANDA filer for two applications, one for the FYCOMPA® tablets and another for the FYCOMPA® oral suspension. After due diligence we filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified us of their ANDA submissions alleging infringement of both patents. In June 2024, we settled the pending Paragraph IV litigation with the Paragraph IV filer for both ANDAs. As part of that settlement, this Paragraph IV filer agreed not to commercialize their proposed ANDA products for both the oral suspension formulation of FYCOMPA® and for FYCOMPA® tablets until at least December 15, 2025.

AGAMREE®

On June 19, 2023, we entered into a License and Collaboration Agreement (AGAMREE® License Agreement) and an Investment Agreement (Investment Agreement) with Santhera. Under the AGAMREE® License Agreement, we contracted to obtain an exclusive North America license, manufacturing and supply agreement for Santhera’s investigational product candidate,

AGAMREE® (vamorolone), a novel corticosteroid for the treatment of DMD. Under the Investment Agreement, we agreed to make a strategic investment into Santhera.

Both transactions closed on July 18, 2023. Under the AGAMREE® License Agreement, upon closing we made a $75 million payment to Santhera in return for the exclusive North American license for AGAMREE®. In addition to the rights to commercialize the product in North America, the AGAMREE® License Agreement provides us with the right of first negotiation for AGAMREE® in Europe and Japan should Santhera pursue partnership opportunities in those territories. Additionally, we will hold the North American rights to any future approved indications for AGAMREE®. Finally, under our AGAMREE® License Agreement with Santhera, we have agreed to purchase commercial supply of AGAMREE® from Santhera at agreed upon rates.

Concurrent with the closing of the AGAMREE® License Agreement, we made a strategic investment into Santhera in which we acquired 1,414,688 of Santhera's ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction) at an investment price of CHF 9.477 per share, with the approximately $15.7 million USD in equity investment proceeds to be used by Santhera for Phase IV studies of AGAMREE® in DMD and future development of additional indications for AGAMREE®. On August 5, 2024, the closing price of Santhera's common shares on the SIX Swiss Exchange was CHF 8.52 (approximately $9.95 USD) per share.

On October 26, 2023, the U.S. FDA approved Santhera's NDA for AGAMREE® for use in treating DMD in patients aged two years and older. Shortly thereafter, as part of the previously described transaction, Santhera transferred the approved New Drug Application to us. Additionally, following approval of the NDA for the drug, we became obligated to make a milestone payment of $36 million to Santhera, which we paid during the 2023 fourth quarter. We may also be obligated to pay future regulatory and commercial milestone payments to Santhera tied to calendar year sales of AGAMREE®, as well as commercial royalties.

On March 13, 2024, we announced the U.S. commercial launch of AGAMREE® for the treatment of DMD in patients aged two years or older. During the first quarter of 2024 in connection with our preparation for the commercial launch of AGAMREE® we incurred substantial commercialization expenses, including sales, marketing, analytical infrastructure, patient services, patient advocacy, and other commercialization related expenses. Due to the synergy of this product with our existing neuromuscular franchise, in connection with the launch of AGAMREE® we have only needed to add approximately 10 additional members to our commercial team to market the product. We are further supporting the distribution of AGAMREE® through our Catalyst Pathways® patient services program to ensure that patients have access to a dedicated, personalized support team that assists families through the AGAMREE® patient journey, from answering questions to coordinating financial assistance programs for eligible patients. Finally, we are intending to donate funds to one or more qualified, independent charitable financial foundations who assist U.S. DMD patients in accessing their medication, to the extent permitted by each such organization's guidelines.

On July 23, 2024 we entered into a license, supply and commercialization agreement with KYE Pharmaceuticals, Inc. (KYE) granting KYE the exclusive Canadian commercial rights to market AGAMREE® in Canada for DMD and other indications. Under the agreement, KYE (which is also the Company's sublicensee for FIRDAPSE® in Canada) will be responsible for obtaining regulatory approval of the product from Health Canada (of which there can be no assurance), and we will supply product to KYE. Further, we will receive an upfront payment from KYE and will be eligible to receive further reimbursement and sales milestones and sales royalties for AGAMREE®. Also, KYE has advised us that they expect to file an application with Health Canada seeking approval to commercialize AGAMREE® in Canada in early 2025. There can be no assurance that any such application when and if filed will be successful.

Finally, we have established a joint steering committee with Santhera that is overseeing the lifecycle management and development of AGAMREE® for additional indications beyond DMD.

DMD, the most common form of muscular dystrophy, is a rare and life-threatening neuromuscular disorder characterized by progressive muscle dysfunction, ultimately leading to loss of ambulation, respiratory failure, and fatality. Current standard treatment for DMD involves corticosteroids, which often come with significant side effects. It is estimated that between 11,000 and 13,000 patients in the U.S. are affected by DMD, with approximately 70% of patients currently receiving a corticosteroid treatment. Steroids are expected to remain the backbone of therapy for DMD patients and dosed concomitantly with other therapies.

AGAMREE®'s unique mode of action is based on differential effects on glucocorticoid and mineralocorticoid receptors and modifying further downstream activity. As such, it is considered a novel corticosteroid that we hope has the potential to demonstrate comparable efficacy to corticosteroids, with the potential for a better-tolerated side effect profile. This mechanism of action may allow vamorolone to emerge as an effective alternative to the current standard of care corticosteroids in children, adolescents, and adult patients with DMD. In that regard, we are preparing to launch a long-term registry study of AGAMREE®, which we have designated as the SUMMIT study, which aims to gather long-term patient safety and quality of life data, offering a deeper understanding of the product's potential long-term benefits for patients.

On October 13, 2023, Santhera announced that the European Union's Committee for Medicinal Products for Human Use (CHMP) adopted a positive position in favor of AGAMREE® for the treatment of DMD patients aged four and older. In its recommendation for approval, CHMP acknowledged that there was a positive benefit-risk profile of AGAMREE® in such patient

population, including certain safety benefits of AGAMREE® compared to standard of care corticosteroids in the treatment of DMD. Further, on December 18, 2023, the European Commission (EC) granted to Santhera marketing authorization for AGAMREE® for the treatment of DMD in patents ages four years and older and on January 12, 2024, Santhera announced that AGAMREE® had received approval by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. Finally, on January 15, 2024, Santhera announced that AGAMREE® was commercially launched in Germany.

In the United States, AGAMREE® has New Chemical Entity exclusivity that expires in October 2028. AGAMREE® also enjoys Orphan Drug Exclusivity expiring in October 2030. AGAMREE® is further protected by six Orange Book listed patents expiring as early as May 28, 2029 and as late as July 16, 2040. The Company has also requested Patent Term Extension and will update the relevant expiration date in the Orange Book upon a final determination by the USPTO. The earliest a generic manufacturer could file an ANDA is October 26, 2027. If we were to pursue a patent infringement action if any such ANDA challenges any of AGAMREE®'s Orange Book patents, then the automatic statutory 30-month stay would prevent FDA approval of such ANDA until April 26, 2031.

Business Development

We continue to advance our strategic initiatives and portfolio expansion efforts, focusing on broadening and diversifying our rare (orphan) Neurology product portfolio with innovative therapies that address critical unmet medical needs and expanding the geographical footprint of our existing products. In that regard, we are currently exploring clinically differentiated and adequately de-risked opportunities, with a keen focus on products to treat rare (orphan) central nervous system (CNS) and adjacent rare (orphan) diseases. These prospects include evaluating companies with existing commercial drug products or drugs in development, for potential partnerships, licensing, geographical expansion opportunities with our existing products, and/or asset acquisitions. We continue to employ a disciplined, comprehensive, and exhaustive approach to identifying and evaluating opportunities that we believe will add significant value to our company over the near, mid, and long term. However, other than the recent sublicense described above between the Company and KYE for AGAMREE® in Canada, no definitive agreements have been entered into to-date, and there can be no assurance that any of the Company's business development initiatives will be successful.

Capital Resources

At June 30, 2024, we had cash and cash equivalents of approximately $375.7 million. Based on our current financial condition and forecasts of available cash, we believe that we have sufficient funds to support our operations for at least the next 12 months. There can be no assurance that we will continue to be successful in commercializing FIRDAPSE®, FYCOMPA® and AGAMREE®, or that we will continue to be profitable and cash flow positive. Further, there can be no assurance that if we need additional funding in the future, whether such funding will be available to us on acceptable terms.

Basis of Presentation

Revenues.

During the three and six months ended June 30, 2024, we generated revenues from U.S. product sales of FIRDAPSE®, FYCOMPA®, and AGAMREE®. We expect these revenues to fluctuate in future periods based on our sales of our products. We received approval from Health Canada on July 31, 2020, for FIRDAPSE® for the symptomatic treatment of LEMS and as of December 31, 2020, our sub-licensee KYE Pharmaceuticals launched FIRDAPSE® in Canada. During the three and six months ended June 30, 2024, revenues generated under our collaboration agreement with KYE Pharmaceuticals were immaterial. We expect our revenues from the KYE collaboration agreement to fluctuate in future periods based on our collaborator's ability to sell FIRDAPSE® in Canada.

For the three and six months ended June 30, 2024, no revenues were generated under our collaborative agreement with Endo. During the fourth quarter of 2023, Endo advised us that they are discontinuing work on the collaboration for development and commercialization of vigabatrin and that they wished to terminate the arrangement. As of the date of this report, the agreement has been terminated.

For the three and six months ended June 30, 2024, we generated no revenues from our collaborative agreement with DyDo. We expect our revenue from the DyDo license agreement to fluctuate in future periods based on DyDo's ability to meet various regulatory and potential sales milestones set forth in such agreement.

The Company relies on Change Healthcare, a subsidiary of UnitedHealth Group, to process patient claims for its products to Medicare Part D plans and all other payors for reimbursement. On February 22, 2024, UnitedHealth Group announced that on February 21, 2024, Change Healthcare's information technology systems were impacted by a cybersecurity incident. The Change Healthcare cybersecurity incident did not impact our day-to-day operations; however, we experienced a delay in patient claims to certain non-Medicare payors in certain states.

Cost of Sales.

Cost of sales consists of third-party manufacturing costs, freight, royalties, and indirect overhead costs associated with sales of our products. Cost of sales may also include period costs related to certain inventory manufacturing services, inventory adjustments charges, unabsorbed manufacturing and overhead costs and manufacturing variances.

Research and Development Expenses.

Our research and development expenses consist of costs incurred for company-sponsored research and development activities, support for selected investigator-sponsored research, and support for our commercial activities. The major components of research and development costs include preclinical study costs, clinical manufacturing costs, clinical study and trial expenses, insurance coverage for clinical trials, consulting, and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs related to our product development efforts and support for our commercial efforts. Prior to January 2023, all of our research and development resources were devoted to the development of FIRDAPSE® and two previously discontinued R&D projects, CPP-109 (our version of vigabatrin), and CPP-115, and until we acquire or license new products, we currently expect that our future development costs will be attributable principally to the continued development and commercial support of FIRDAPSE®, FYCOMPA® and AGAMREE®.

Our expense accruals for clinical studies and trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study and trial sites and clinical research organizations (CROs). In the normal course of our business we contract with third parties to perform various clinical study and trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or milestones, the successful enrollment of patients, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the clinical study or trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to preclinical and clinical studies or trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies or trials at a given point in time, we could be required to record significant additional research and development expenses in future periods. Preclinical and clinical study and trial activities require significant up-front expenditures. We anticipate paying significant portions of a study or trial's cost before they begin and incurring additional expenditures as the study or trial progresses and reaches certain milestones.

Selling, General and Administrative Expenses.

Since 2019, we have incurred substantial commercialization expenses for FIRDAPSE®, including sales, marketing, patient services, patient advocacy and other commercialization related expenses. We are also now incurring substantial commercialization expenses for FYCOMPA® and AGAMREE®.

Our general and administrative expenses consist primarily of salaries and personnel expenses for accounting, corporate, compliance, and administrative functions. Other costs include administrative facility costs, regulatory fees, insurance, and professional fees for legal (including litigation cost), information technology, accounting, and consulting services.

Amortization of Intangible Assets.

Amortization of intangible assets consists of the amortization of the FYCOMPA® product rights, which are amortized using the straight-line method over its estimated useful life of 5 years, and the RUZURGI® product rights, which are amortized using the straight-line method over its estimated useful life of 14.5 years. We also capitalized the $36 million of milestone payment paid to Santhera during the fourth quarter of 2023 which is being amortized over the product's estimated useful life of 10.5 years.

Stock-Based Compensation.

We recognize expense for the fair value of all stock-based awards to employees, directors, and consultants in accordance with U.S. GAAP. For stock options, we use the Black-Scholes option valuation model in calculating the fair value of the awards.

Income Taxes.

Our effective income tax rate is the ratio of income tax expense over our income before income taxes.

Recently Issued Accounting Standards.

For discussion of recently issued accounting standards, please see Note 2, "Basis of Presentation and Significant Accounting Policies," in the consolidated financial statements included in this report.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. For a full discussion of our accounting policies, please refer to Note 2 on the Financial Statements included in our 2023 Annual Report on Form 10-K that we filed with the SEC on February 28, 2024. Our most critical accounting policies and estimates include: accounting for revenue recognition, valuation of intangible assets, stock-based compensation and valuation allowance for deferred tax assets. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors that we believe are reasonable based on the circumstances, the results of which form our management's basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our 2023 Annual Report on Form 10-K.

Results of Operations

Revenues.

For the three and six months ended June 30, 2024, we recognized total revenues of $122.7 million and $221.2 million, respectively, compared to $99.6 million and $184.9 million, respectively, in the same periods of 2023. FIRDAPSE® net sales were approximately $77.4 million and $144.2 million, respectively, for the three and six months ended June 30, 2024 compared to $64.9 million and $122.4 million, respectively, for the three and six months ended June 30, 2023. FYCOMPA® net sales were approximately $36.5 million and $67.0 million, respectively, for the three and six months ended June 30, 2024 compared to $34.6 million for the three months ended June 30, 2023 and $62.4 million for the period between January 24, 2023 (date of acquisition) and June 30, 2023. AGAMREE® net sales were approximately $8.7 million for the three months ended June 30, 2024 and $9.9 million for the period between March 13, 2024 (date of commercial launch) and June 30, 2024.

Net revenues from product sales of FIRDAPSE® increased by 19.2% and 17.8%, respectively, from the three and six month periods ended June 30, 2023 compared to the three and six month periods ended June 30, 2024. Product revenue for FYCOMPA® during the three and six months ended June 30, 2024 were affected by differences in variable consideration (gross-to-net) compared to the three months ended June 30, 2024 and the period between January 24, 2023 (date of acquisition) and June 30, 2023, when revenues were booked under Eisai's cost arrangements with distributors and government authorities. Starting on January 1, 2024, all such costs are tied to arrangements between us and those distributors and government agencies, which costs are higher than Eisai's costs, thereby increasing the gross-to-net deductions for FYCOMPA® and correspondingly decreasing FYCOMPA® net product revenue. In the first quarter of the calendar year, like many companies in our industry, we are also impacted by the reset of patient insurance deductibles.

For both the three and six months ended June 30, 2024, we also recognized $0.1 million in license and other revenue. For the three and six months ended June 30, 2023, we also recognized $0.1 million and $0.2 million, respectively, in license and other revenue.

Cost of Sales.

Cost of sales was approximately $15.4 million and $27.9 million, respectively, for the three and six months ended June 30, 2024, compared to $12.0 million and $22.0 million, respectively, for the three and six months ended June 30, 2023. Cost of sales in both periods consisted principally of royalty payments, which are based on net revenue as defined in the applicable license agreements. For FIRDAPSE®, royalties are payable on the terms set forth below in Liquidity and Capital Resources—*Contractual Obligations and Arrangements*, and increase by 3% when net sales (as defined in the applicable license agreement) exceed $100 million in any calendar year. Cost of sales for FYCOMPA® in both periods consisted of product costs and excludes the amortization of the FYCOMPA® intangible assets. Cost of sales for AGAMREE® for the three and six months ended June 30, 2024 consisted of royalties payable on the terms set forth below in Liquidity and Capital Resources—*Contractual Obligations and Arrangements*, product costs and excludes the amortization of the AGAMREE® intangible asset. See Note 9 of the Notes to Unaudited Consolidated Financial Statements included elsewhere in this report.

Amortization of Intangible Assets.

Amortization of intangible assets was approximately $9.3 million and $18.7 million, respectively, for the three and six months ended June 30, 2024 compared to $8.5 million and $15.0 million, respectively, for the three and six months ended June 30, 2023. Amortization of intangible assets consists of the amortization of the FYCOMPA® rights, which are amortized using the straight-line

method over its estimated useful life of 5 years, and the RUZURGI® rights, which are amortized using the straight-line method over its estimated useful life of 14.5 years. We also capitalized a $36 million milestone payment paid to Santhera during the fourth quarter of 2023, which is being amortized over the product's estimated useful life of 10.5 years.

Research and Development Expenses.

Research and development expenses for the three months ended June 30, 2024 and 2023 were approximately $3.0 million and $4.0 million, respectively, and represented approximately 4% and 7% of total operating costs and expenses, respectively. Research and development expenses for the three months ended June 30, 2024 and 2023 were as follows (in thousands):

	For the Three Months Ended June 30,		Change	
	2024	2023	$	%
Research and development expenses	$ 2,582	$ 3,603	(1,021)	(28.3)
Employee stock-based compensation	403	351	52	14.8
Total research and development expenses	$ 2,985	$ 3,954	(969)	(24.5)

Research and development expenses for the six months ended June 30, 2024 and 2023 were approximately $5.6 million and $7.5 million, respectively, and represented approximately 4% and 7% of total operating costs and expenses, respectively. Research and development expenses for the six months ended June 30, 2024 and 2023 were as follows (in thousands):

	For the Six Months Ended June 30,		Change	
	2024	2023	$	%
Research and development expenses	$ 4,654	$ 6,826	(2,172)	(31.8)
Employee stock-based compensation	912	690	222	32.2
Total research and development expenses	$ 5,566	$ 7,516	(1,950)	(25.9)

Research and development expenses remained relatively consistent for the three and six months ended June 30, 2024, when compared to the same periods in 2023. For the three and six months ended June 30, 2024, research and development expenses primarily consisted of costs relating to development activities supporting our commercial products. For the three and six months ended June 30, 2023, research and development expenses also included costs relating to closing out sites for both our MuSK-MG clinical trial and our previously operated expanded access program, as well as costs for development activities supporting our commercial products.

We expect that research and development expenses will continue to be significant in 2024 and beyond as we execute on our strategic initiative and portfolio expansion efforts, with a keen focus on acquiring products to treat rare and difficult to treat diseases.

Selling, General and Administrative Expenses.

Selling, general and administrative expenses for the three months ended June 30, 2024 and 2023 were approximately $40.7 million and $28.4 million, respectively, and represented approximately 59% and 54% of total operating costs and expenses, respectively. Selling, general and administrative expenses for the three months ended June 30, 2024 and 2023 were as follows (in thousands):

	For the Three Months Ended June 30,		Change	
	2024	2023	$	%
Selling	$ 26,247	$ 18,312	7,935	43.3
General and administrative	10,478	7,137	3,341	46.8
Employee stock-based compensation	4,005	2,947	1,058	35.9
Total selling, general and administrative expenses	$ 40,730	$ 28,396	12,334	43.4

Selling, general and administrative expenses for the six months ended June 30, 2024 and 2023 were approximately $87.7 million and $58.1 million, respectively, and represented approximately 63% and 57% of total operating costs and expenses,

respectively. Selling, general and administrative expenses for the six months ended June 30, 2024 and 2023 were as follows (in thousands):

	For the Six Months Ended June 30,		Change	
	2024	2023	$	%
Selling	$ 51,568	$ 36,076	15,492	42.9
General and administrative	24,356	16,538	7,818	47.3
Employee stock-based compensation	11,744	5,500	6,244	113.5
Total selling, general and administrative expenses	$ 87,668	$ 58,114	29,554	50.9

For the three and six months ended June 30, 2024, selling, general and administrative expenses increased approximately $12.3 million and $29.6 million, respectively, compared to the same periods in 2023. This was primarily attributable to an approximately $12.0 million increase in employee compensation and stock-based compensation related to annual merit increases and an increase in headcount resulting from the acquisitions of FYCOMPA® and AGAMREE®, an approximately $9.9 million increase in commercialization expenses related to the launch of AGAMREE® and to the timing of our commitments to make contributions to 501(c)(3) organizations supporting LEMS patients of approximately $1.1 million. Further, an approximately $3.9 million increase in stock-based compensation expense is related to the retirement of two former executive officers, which was recorded during the first quarter of 2024 upon lapse of the applicable revocation periods under the agreements with these former executives.

We expect that selling, general and administrative expenses will continue to be substantial in future periods as we continue our efforts to increase our revenues from FIRDAPSE®, continue our efforts to market FYCOMPA® and AGAMREE®, and take steps to further expand our business.

Stock-*Based Compensation.*

Total stock-based compensation for the three and six months ended June 30, 2024 was $4.4 million and $12.7 million, respectively, and for the three and six months ended June 30, 2023 was $3.3 million and $6.2 million, respectively. In the first half of 2024 and 2023, grants were principally for stock options relating to year-end bonus awards and grants to new employees.

Other Income, Net.

We reported other income, net in all periods, primarily relating to interest on our investment of our cash and cash equivalents of $1.5 million and $3.5 million for the three and six months ended June 30, 2024 compared to $1.8 million and $3.5 million for the three and six months ended June 30, 2023.

Since Santhera's shares are traded on the SIX Swiss Exchange, they have a readily determinable fair value, and as a result the investment is measured quarterly, at fair value, with changes reported in other income, net.

The components of other income, net were as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Interest income (expense), net	$ 3,804	$ 1,813	$ 6,911	$ 3,517
Net gains (losses) recognized during the period on equity securities	(2,262)	—	(3,406)	—
Total other income, net	$ 1,542	$ 1,813	$ 3,505	$ 3,517

Income Taxes.

Our effective income tax rate was 24.5% and 21.5% for the six months ended June 30, 2024 and 2023, respectively. Differences in our effective tax and the statutory federal income tax rate of 21% are driven by state income taxes, fluctuations in the value of investments and anticipated annual permanent differences offset by equity compensation deductions. Our effective tax rate is affected by many factors, including the number of stock options exercised in any period, and our effective tax rate is likely to fluctuate in future periods.

We had no uncertain tax positions as of June 30, 2024 and December 31, 2023.

Net Income.

Our net income was $40.8 million and $64.1 million, respectively, for the three and six months ended June 30, 2024 ($0.35 and $0.55, respectively, per basic share and $0.33 and $0.52, respectively, per diluted share) as compared to net income of $37.8 million

and $67.3 million, respectively, for the three and six months ended June 30, 2023 ($0.36 and $0.64, respectively, per basic share and $0.33 and $0.59, respectively, per diluted share).

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through multiple offerings of our securities and revenues from product sales. At June 30, 2024 we had cash and cash equivalents aggregating $375.7 million and working capital of $382.1 million. At December 31, 2023, we had cash and cash equivalents aggregating $137.6 million and working capital of $143.3 million. At June 30, 2024, substantially all of our cash and cash equivalents were deposited with one financial institution, and such balances were in excess of federally insured limits. Further, as of such date, substantially all such funds were invested in money market accounts.

On September 8, 2023, we filed a shelf registration statement with the SEC to sell up to $500 million of common stock, preferred stock, warrants to purchase common stock, debt securities and units consisting of one or more of such securities (the 2023 Shelf Registration Statement). The 2023 Shelf Registration Statement (file no. 333-274427) became effective upon filing. On January 9, 2024, we completed a public offering of 10 million shares of our common stock under the 2023 Shelf Registration Statement, raising net proceeds of approximately $140.7 million.

Based on forecasts of available cash, we believe that we have sufficient resources to support our currently anticipated operations for at least the next 12 months from the date of this report. There can be no assurance that we will remain profitable or that we will be able to obtain any additional funding that we may require in the future.

In the future, we may require additional working capital to support our operations depending on our future success with FIRDAPSE®, FYCOMPA® and AGAMREE® sales, or the products we acquire and continue to develop and whether our results continue to be profitable and cash flow positive. There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us if and when it is required.

In that regard, our future funding requirements will depend on many factors, including:

- the cost of diligence in seeking potential acquisitions and of the completion of such acquisitions, if any future acquisitions occur;
- future clinical trial results;
- the scope, rate of progress and cost of our clinical trials and other product development activities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the amount of net revenues that we report from sales of FIRDAPSE®, FYCOMPA® and AGAMREE®;
- the effect of competition and market developments;
- the cost of filing and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in other products.

We may raise additional funds through public or private equity offerings, debt financings, corporate collaborations or other means. We also may seek governmental grants for a portion of the required funding for our clinical trials and preclinical trials. We may further seek to raise capital to fund additional product development efforts or product acquisitions, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

Cash Flows.

Net cash provided by operating activities was $96.1 million and $42.8 million, respectively, for the six months ended June 30, 2024 and 2023. During the six months ended June 30, 2024, net cash provided by operating activities was primarily attributable to our net income of $64.1 million, an increase of $24.9 million in accrued expenses and other liabilities, $12.7 million in stock-based

compensation, $18.9 million in amortization of intangible assets and depreciation and $3.8 million in non-cash expenses. This was partially offset by increases of $3.7 million in accounts receivable, net, $2.4 million in inventory and $11.0 million prepaid expenses and other current assets, decreases of $7.7 million in accounts payable and $0.2 million in operating lease liability and $3.4 million in deferred taxes. During the six months ended June 30, 2023, net cash provided by operating activities was primarily attributable to our net income of $67.3 million, a decrease of $0.2 million in inventory, an increase of $0.4 million in accounts payable, $6.2 million in stock-based compensation, $15.2 million in amortization of intangible assets and depreciation and $0.3 million of non-cash expenses. This was partially offset by increases of $32.4 million in accounts receivable, net, $1.9 million in prepaid expenses and other current assets and decreases of $7.6 million in accrued expenses and other liabilities and $0.2 million in operating lease liability and $4.8 million in deferred taxes. The increase in accounts receivable, net, primarily relates to sales of FYCOMPA®, which has a longer cash collection cycle than FIRDAPSE®.

Net cash used in investing activities was $0.2 million for the six months ended June 30, 2024, consisting primarily of purchases of property and equipment. Net cash used in investing activities was $162.4 million for the six months ended June 30, 2023, consisting primarily of payment in connection with the FYCOMPA® asset acquisition.

Net cash provided by financing activities during the six months ended June 30, 2024 was $142.2 million, consisting primarily of proceeds from the issuance of common stock. Net cash used in financing activities during the six months ended June 30, 2023 was $0.1 million, consisting primarily of payment of liabilities arising from asset acquisition and payment of employee withholding tax related to stock-based compensation partially offset by proceeds from the exercise of stock options.

Contractual Obligations and Arrangements.

We have entered into the following contractual arrangements with respect to sales of FIRDAPSE®:

- *Payments due under our license agreement for FIRDAPSE®.* We currently pay the following royalties under our license agreement:
  - Royalties to our licensor for seven years from the first commercial sale of FIRDAPSE® equal to 7% of net sales (as defined in the FIRDAPSE® License Agreement) in North America for any calendar year for sales up to $100 million, and 10% of net sales in North America in any calendar year in excess of $100 million; and
  - Royalties to the third-party licensor of the rights sublicensed to us from the first commercial sale of FIRDAPSE® equal to 7% of net sales (as defined in the FIRDAPSE® License Agreement between BioMarin and the third-party licensor) in any calendar year for the duration of regulatory exclusivity within a territory and 3.5% for territories in any calendar year in territories without regulatory exclusivity.

For the three and six months ended June 30, 2024, we recognized an aggregate of approximately $11.5 million and $20.4 million, respectively, of royalties payable under these license agreements, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income. For the three and six months ended June 30, 2023, we recognized an aggregate of approximately $9.2 million and $16.8 million, respectively, of royalties payable under these license agreements, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income.

Further, if DyDo is successful in obtaining the right to commercialize FIRDAPSE® in Japan, we will pay royalties to our licensor on net sales in Japan equal to a similar percentage to the royalties that we are currently paying for non-U.S. sales under our original FIRDAPSE® License Agreement for North America.

- *Payments due to Jacobus.* In connection with our July 2022 settlement with Jacobus, we agreed to pay the following consideration to Jacobus:
  - $30 million of cash, of which $10 million was paid at the closing of the settlement on July 11, 2022, $10 million was paid on the first anniversary of closing and the remaining $10 million was paid on the second anniversary of closing;
  - An annual royalty on Catalyst's net sales (as defined in the License and Asset Purchase Agreement between Catalyst and Jacobus) of amifampridine products in the U.S. equal to: (a) for calendar years 2022 through 2025, 1.5% (with a minimum annual royalty of $3.0 million per year), and (b) for calendar years 2026 through the expiration of the last to expire of Catalyst's FIRDAPSE® patents in the U.S., 2.5% (with a minimum annual royalty of $5 million per year); *provided, however*, that the royalty rate may be reduced and the minimum annual royalty may be eliminated under certain circumstances; and
  - If Catalyst were to receive a priority review voucher for FIRDAPSE® or RUZURGI® in the future, 50% of the consideration paid by a third-party to acquire that voucher will be paid to Jacobus.

For the three and six months ended June 30, 2024, we recognized an aggregate of approximately $1.2 million and $2.1 million, respectively, of royalties payable to Jacobus. For the three and six months ended June 30, 2023, we recognized an aggregate of approximately $0.9 million and $1.7 million, respectively, of royalties payable to Jacobus.

We have entered into the following contractual arrangements with respect to sales of FYCOMPA®:

- *Payments due under our asset purchase agreement for FYCOMPA®.* In connection with our asset purchase agreement with Eisai Co., Ltd. (Eisai):

  - We paid at closing a $160 million upfront cash payment, plus $1.6 million for reimbursement of certain prepayments. Eisai was also eligible to receive a contingent payment of $25 million if a patent term extension for FYCOMPA® was approved until June 8, 2026 by the USPTO, which request for reconsideration of the patent term extension was denied by the USPTO;

  - Royalties commencing on loss of exclusivity for each calendar year during the royalty term equal to 12% on net sales greater than $10 million and less than $100 million, 17% on net sales of greater than $100 million and less than $125 million and 22% on net sales greater than $125 million prior to the date of generic entry. Royalties equal to 6% on net sales greater than $10 million and less than $100 million, 8.5% on net sales of greater than $100 million and less than $125 million and 11% on net sales greater than $125 million after the date of generic entry.

  - Concurrently with the acquisition, the parties entered into two related agreements: (i) a short-term TSA for commercial and manufacturing services (to which transition services ended on December 31, 2023) and (ii) a long-term Supply Agreement for the manufacturing of FYCOMPA®. Under the TSA, a U.S. subsidiary of Eisai provided certain commercial and manufacturing services to the Company for a transition period following the closing of the acquisition. Further, under the Supply Agreement, Eisai will manufacture FYCOMPA® for the Company for a period of seven years (or such longer period as is set forth in the Supply Agreement) following the closing of the acquisition.

We have entered into the following contractual arrangements with respect to AGAMREE® (vamorolone):

- *Payments due under our license agreement for AGAMREE®.* In connection with our recent acquisition from Santhera:

  - At closing we paid a $75 million initial cash payment.

  - In the fourth quarter of 2023, following regulatory approval of Santhera's NDA by the FDA, we paid a regulatory milestone payment of $36 million. We are also obligated to pay additional regulatory milestone payments upon regulatory approval by the FDA in the U.S. of an NDA for the product for the first, second, and third additional indications in the amounts of $50 million, $45 million, and $45 million, respectively.

  - Under the license agreement, we pay: (i) royalties to the licensor until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 5% of net sales (as defined in the license agreement) in North America for any calendar year for sales equal to or less than $100 million (prior to December 31, 2025 only), 7% of net sales for sales in excess of $100 million and up to $200 million, 9% of net sales for sales in excess of $200 million and up to $300 million, 11% of net sales for sales in excess of $300 million; and (ii) royalties to the third-party licensor of the rights sublicensed us until the later of expiration of product exclusivity or ten years from the first commercial sale of AGAMREE® equal to 7% of net sales (as defined in the license agreement) in North America for any single calendar year for sales equal to or less than $250 million, 8.5% of net sales for sales in excess of $250 million and up to $500 million, 10% of net sales for sales in excess of $500 million and up to $750 million, 12% of net sales for sales in excess of $750 million and up to $1 billion, 13% of net sales for sales in excess of $1 billion and up to $2 billion and 15% of net sales for sales in excess of $2 billion. Furthermore, we may pay Santhera sales-based milestones of up to $105 million as well as up to 11% percent royalties for all additional indications and milestones of up to $50 million for the first three additional indications.

  - We are obligated to pay sales-based milestone payments if the applicable amount of net sales of all products in the territory in a single calendar year reach one of more of the net sales threshold levels set forth in the AGAMREE® License Agreement.

  - Until January 1, 2026, we are obligated to purchase all of the requirements for product solely from Santhera, and Santhera is required to manufacture, supply, and sell product to us at an agreed upon supply price.

  - Simultaneously with entering into the license agreement, we made a strategic equity investment into Santhera by acquiring 1,414,688 of Santhera's ordinary shares (representing approximately 11.26% of Santhera's outstanding ordinary shares immediately following the transaction) at an investment price of CHF 9.477 per share

(corresponding to a mutually agreed volume-weighted average price prior to signing), with the approximately $15.7 million USD in equity investment proceeds, inclusive of the approximately $13.5 million USD fair value of the investment in Santhera and approximately $2.2 million USD of transaction costs included in acquired in-process research and development, to be used by Santhera for Phase IV studies in DMD and further development of additional indications for AGAMREE®.

For the three and six months ended June 30, 2024, we recognized an aggregate of approximately $0.9 million and $1.0 million, respectively, of royalties payable under this license agreement, which is included in cost of sales in the accompanying consolidated statements of operations and comprehensive income.

We also have entered into the following contractual arrangements:

- *Purchase commitment*. We have entered into a purchase commitment with a contract manufacturing organization for approximately $0.5 million per year. The agreement expires in December 2024.

- *Lease for office space*. We operate our business in leased office space in Coral Gables, Florida. We lease approximately 10,700 square feet of office space and we pay annual rent of approximately $0.5 million.

Off-Balance Sheet Arrangements.

We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

Caution Concerning Forward-Looking Statements

This report contains “forward-looking statements”, as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, “believes”, “anticipates”, “proposes”, “plans”, “expects”, “intends”, “may”, and other similar expressions are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or other achievements to be materially different from any future results, performances or achievements expressed or implied by such forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the section entitled “Item 1A – Risk Factors.”

The continued successful commercialization of FIRDAPSE® (amifampridine), FYCOMPA® (perampanel) CIII, and AGAMREE® (vamorolone) are highly uncertain. Factors that will affect our success include the uncertainty of:

- Whether we will be able to continue to successfully market and sell FIRDAPSE®, FYCOMPA®, and AGAMREE® while maintaining full compliance with applicable federal and state laws, rules and regulations;

- Whether our estimates of the size of the market for FIRDAPSE® for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) will prove to be accurate;

- Whether the daily dose of FIRDAPSE® taken by patients changes over time and affects our results of operations;

- Whether we will be able to locate LEMS patients who are undiagnosed or are misdiagnosed with other diseases;

- Whether patients will discontinue from the use of our products at rates that are higher than historically experienced or are higher than we project;

- Whether new FIRDAPSE®, FYCOMPA®, and AGAMREE® patients can be successfully titrated to stable therapy;

- Whether we can continue to market our products on a profitable and cash flow positive basis;

- Whether we will be able to demonstrate, to the satisfaction of the FDA and third-party payors, whether AGAMREE® offers advantages compared to corticosteroids or competitor’s products;

- Whether DMD patients transitioning to current or future gene therapy treatments will delay initiating use of AGAMREE® while waiting for access to such gene therapy or stop their AGAMREE® therapy during the course of their gene therapy treatment;

- Whether the acquisition of the North American license for AGAMREE® will prove to be accretive to our EBITDA and EPS in 2024 and beyond;

- Whether any revenue or earnings guidance that we provide to the public market will turn out to be accurate;

- Whether payors will provide coverage and reimburse for our products at the price that we charge for our products;

•The ability of our third-party suppliers and contract manufacturers to supply sufficient product to meet our customers' needs in future periods;

•The ability of our third-party suppliers and contract manufacturers to maintain compliance with current Good Manufacturing Practices (cGMP);

•The ability of those third parties that distribute our products to maintain compliance with applicable law;

•Our ability to maintain compliance with applicable rules relating to our patient assistance programs for our products;

•Our ability to maintain compliance with the applicable rules that relate to our contributions to 501(c)(3) organizations that support patients in financial need;

•The scope of our intellectual property and the outcome of any challenges to our intellectual property, and, conversely, whether any third-party intellectual property presents unanticipated obstacles for FIRDAPSE®, FYCOMPA®, or AGAMREE®;

•Whether there will be a post-closing review by antitrust regulators of our previous acquisition transactions, and the outcome of any such reviews if they occur;

•Whether we will be able to acquire additional drug products under development, complete development required to commercialize such products, and thereafter, if such products are approved for commercialization, successfully market such products;

•Whether our patents will be sufficient to prevent generic competition for FIRDAPSE® and AGAMREE® after our orphan drug exclusivity for each product expires;

•Whether we will be successful in our litigation to enforce our patents against the Paragraph IV challengers who have filed Abbreviated New Drug Applications (ANDAs) seeking to introduce generic versions of FIRDAPSE®;

•Whether we will be able to continue successfully marketing FYCOMPA® after its patents expire in 2025;

•The impact on our profits and cash flow of adverse changes in reimbursement and coverage policies or regulations from government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators, or the impact of pricing pressures enacted by industry organizations, the federal government or the government of any state, including as a result of increased scrutiny over pharmaceutical pricing or otherwise;

•Changes in the healthcare industry and the effect of political pressure from and actions by the President, Congress and/or medical professionals seeking to reduce prescription drug costs, and changes to the healthcare industry occasioned by any future changes in laws relating to the pricing of drug products, including changes made in the Inflation Reduction Act of 2022, or changes in the healthcare industry generally;

•Whether we and Santhera can successfully develop additional indications for AGAMREE® and obtain the ability to commercialize the product for these additional indications;

•The state of the economy generally and its impact on our business;

•The scope, rate of progress and expense of future clinical trials and studies, pre-clinical studies, proof-of-concept studies, and our other drug development activities, and whether any trials and studies we undertake will be successful;

•Our ability to complete any clinical trials and studies that we may undertake on a timely basis and within the budgets we establish for such trials and studies;

•Whether FIRDAPSE® can be successfully commercialized in Canada on a profitable basis through KYE Pharmaceuticals, our collaboration partner in Canada;

•Whether AGAMREE® will be approved by Health Canada for commercialization in Canada and whether, if the product is approved, KYE can successfully commercialize it in Canada;

•Whether KYE will successfully file an application seeking to commercialize AGAMREE® in Canada by early 2025 or at all;

•The impact on sales of FIRDAPSE® in the U.S. if an amifampridine product is purchased in Canada for use in the U.S.;

•Whether DyDo will be able to obtain approval to commercialize FIRDAPSE® in Japan; and

- Whether our plans to expand the reach of FIRDAPSE® and AGAMREE® into other global regions will be successful;
- System failures or security or data breaches due to cyber-attacks, or cyber intrusions, including ransomware, phishing attacks and other malicious intrusions whether it occurs directly to us or indirectly through third-parties.

Our current plans and objectives are based on assumptions relating to the continued commercialization of FIRDAPSE®, FYCOMPA®, and AGAMREE® and on our plans to seek to acquire or in-license additional products. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. Considering the significant uncertainties inherent in the forward-looking statements we have made herein, which reflect our views only as of the date of this report, you should not place undue reliance upon such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Market risk represents the risk of changes in the value of market risk-sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Our exposure to interest rate risk is currently confined to our cash and cash equivalents that are from time to time invested in highly liquid money market funds and U.S. Treasuries. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

ITEM 4. CONTROLS AND PROCEDURES

a.We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2024, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act, was recorded, processed, summarized or reported within the time periods specified in the rules and regulations of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports was accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

b.During the three months ended June 30, 2024, there were no changes in our internal controls or in other factors that could have a material effect, or are reasonably likely to have a material effect, on our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Paragraph IV Patent Litigation

In January 2023, we received Paragraph IV Certification Notice Letters from three generic drug manufacturers advising that they had each submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the U.S. The notice letters each alleged that the six patents listed in the FDA Orange Book in connection with FIRDAPSE® are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in these ANDA submissions. Under the FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, we had 45 days from receipt of the notice letters to determine if there were grounds to bring a lawsuit and, if so, to commence patent infringement lawsuits against these generic drug manufacturers in a federal district court, which would trigger a statutory stay precluding the FDA from final approval of the subject ANDAs until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. In that regard, after conducting the necessary due diligence, we filed lawsuits on March 1, 2023 in the U.S. District Court for the District of New Jersey against each of the three generic drug manufacturers who notified us of their ANDA submissions, thus triggering the stay. All of these lawsuits are progressing.

Further, in October 2023, we received a Paragraph IV Certification Notice Letter from a fourth generic drug manufacturer, and we filed a similar lawsuit against the manufacturer in November 2023. On July 30, 2024, we settled this patent litigation with the fourth of the ANDA filers for FIRDAPSE®. In the settlement, the ANDA filer acknowledged both the validity of our FIRDAPSE® patents and also the infringement by the ANDA filer's product of our patents. As part of the settlement, the ANDA filer also agreed not to commercialize its product until the earlier of all FIRDAPSE® patents expiration or the entry into the market of another ANDA product meeting certain conditions.

The outcome of patent litigation with Paragraph IV challengers is always uncertain and there can be no assurance to whether we will prevail in this litigation. However, we are vigorously defending our intellectual property for FIRDAPSE® in this litigation and we believe that our patent estate will protect FIRDAPSE® from generic competition for the life of our patents.

On February 20, 2023, we received a Paragraph IV Certification Notice Letter from a company that appears to have filed the first ANDA for the oral suspension formulation for FYCOMPA®. The same company sent a similar letter to us later in February with a similar certification for the tablet formulation for FYCOMPA®, the fourth such certification for this formulation. Both of these letters were Paragraph IV certifications of non-infringement, non-validity, and unenforceability to the ‘497 patent for FYCOMPA® but each application, like the previous Paragraph IV notices from ANDA filers, for FYCOMPA® tablets does not challenge the ‘571 patent. Accordingly, the FDA may not approve any ANDA prior to expiration of the ‘571 patent on May 23, 2025. After due diligence we filed lawsuits on April 5, 2023 in the U.S. District Court for the District of New Jersey against the drug manufacturer who notified us of their ANDA submissions for both FYCOMPA® formulations, thus triggering the 30 month stay for each application. In June 2024, we settled this lawsuit. As part of the settlement, this Paragraph IV filer agreed to not seek to commercialize its ANDA products for both the oral suspension formulation of FYCOMPA® and FYCOMPA® tablets until at least December 15, 2025.

Other Litigation

From time to time we may become involved in legal proceedings arising in the ordinary course of business. Other than as set forth above, we believe that there is no litigation pending at this time that could have, individually or in the aggregate, a material adverse effect on our results of operations, financial condition or cash flows.

ITEM 1A. RISK FACTORS

There are many factors that affect our business, our financial condition, and the results of our operations. In addition to the information set forth in this quarterly report, you should carefully read and consider “Item 1A. Risk Factors” in Part I, and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, of our 2023 Annual Report on Form 10-K filed with the SEC, which contain a description of significant factors that might cause our actual results of operations in future periods to differ materially from those currently expected or desired.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

In March 2021, our Board of Directors approved a share repurchase program that authorizes the repurchase of up to $40 million of our common stock, pursuant to a repurchase program under Rule 10b-18 of the Securities Act (the “Share Repurchase Program”). The Share Repurchase Program commenced on March 22, 2021 and currently expires in March 2025.

At present, we are not purchasing shares under our share repurchase program, but rather we are retaining cash for use in our business development activities.

During the three months ended June 30, 2024, we did not repurchase any of our common stock. As of June 30, 2024, approximately $21 million remains available for share repurchases under the Share Repurchase Program. However, at present the Company has elected to retain cash for business development activities rather than making repurchases of its shares.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

10.1	License, Supply and Commercialization Agreement between the Company and KYE Pharmaceuticals, Inc., dated as of July 23, 2024*
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

*Certain identified information has been excluded from this exhibit because it is both (i) not material, and (ii) would likely cause competitive harm to the Company if publicly disclosed.

SIGNATURES

Pursuant to the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Catalyst Pharmaceuticals, Inc.

By: /s/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer

Date: August 7, 2024

Exhibit 10.1

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

TEXT OMITTED FROM THIS EXHIBIT IS MARKED WITH [***]

LICENSE, SUPPLY AND COMMERCIALIZATION AGREEMENT

This License, Supply and Commercialization Agreement, is made as of July 23, 2024 (the " **Effective Date**"), by and between **Catalyst Pharmaceuticals Inc.**, having a place of business at 355 Alhambra Circle, Suite 801, Coral Gables, Florida 33155 USA (" Catalyst"), and **KYE Pharmaceuticals Inc.**, having a place of business at 2233 Argentia Rd. Suites 302 & 302A, Mississauga ON, L5N 2X7 (" **KYE**"). Each of KYE and Catalyst may be referred to herein as a "**Party**" or collectively as the " **Parties**".

RECITALS

WHEREAS, Catalyst has entered into a Cooperation, Supply and Commercialization Agreement with Santhera Pharmaceuticals (Schweiz) AG and Santhera Pharmaceuticals Holding AG (together "**Santhera**"), effective as of June 19, 2023 (the " **Santhera Agreement**") pursuant to which Santhera has licensed to Catalyst certain intellectual property rights in relation to the Product in North America (including the Territory);

WHEREAS KYE has the facilities to register, import, promote, sell, market and distribute the Product in the Territory;

AND WHEREAS KYE desires to obtain from Catalyst a sub-license of certain intellectual property rights in relation to the Product in the Territory for the purpose, *inter alia*, of commercialization in the Territory, and Catalyst is willing to grant such rights and licenses to such intellectual property rights, and to supply the Product to KYE, on the terms and conditions set forth herein.

NOW THEREFORE in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

1.1 "Additional Indication" means indications other than the Initial Indication.

1.2 "Affiliate" with respect to a Party or other Person, means any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party or such other Person. For purposes of this definition only, "control" herein means (a) the direct or indirect ownership of more than fifty percent (50.0%) (or such maximum lesser percentage allowed to be owned by a foreign owner in a particular jurisdiction) of the outstanding voting securities of such Party or other Person, or (b) if such Person directly or indirectly possesses the power to direct or cause the direction of the management and policies of a Party or other Person by any means whatsoever.

1.3 "Agreement" means this License, Supply and Commercialization Agreement, together with all exhibits attached hereto, as the same may be modified and in effect from time to time.

1.4 "Applicable Laws" means all applicable laws, statutes, codes, regulations, judgments, orders, implementing legislation, or ordinances of any kind whatsoever of a Governmental Authority, as any of the same may be amended from time to time, and all applicable directives, regulations, promulgations, codes, guidance and guidelines promulgated thereunder and having jurisdiction over or related to the Development, Manufacturing, and/or Commercialization of the Compound and/or the Product including, to the extent applicable, good laboratory practices, good clinical practices, Good Manufacturing Practices, Good Distribution Practices, and good warehousing practices.

1.5 "Authorized Generic Product" means, with respect to a product sold by or on behalf of KYE (or any of its permitted sublicensees) in the Territory for a particular indication, any product that (a) is approved for sale in the Territory in reliance on the prior Regulatory Approval of such Product as obtained by KYE or its permitted sublicensee for the relevant indication(s) as determined by the applicable Regulatory Authority; and (b) is sold by KYE or a sublicensee or Affiliate of KYE.

1.6 "Business Day" means any day other than a Saturday or a Sunday in the U.S., or a bank or other public holiday in the city of Miami, Florida, U.S. or in the city of Toronto, Ontario. For the avoidance of doubt, references in this Agreement to "days" shall mean calendar days.

1.7 "Calendar Quarter" means each of the three (3) month periods beginning from January 1, April 1, July 1, and October 1.

1.8 "Calendar Year" means the period from January 1 to December 31 of a year.

1.9 "Catalyst" has the meaning set forth in the ingress to the Recitals.

1.10 "Commercialize", "Commercializing" and "Commercialization" means to market, advertise, promote, distribute, sell, offer for sale, store, import, export, offer pricing and obtain reimbursement approvals for any of the foregoing. Commercialization shall not include any activity comprising Manufacturing or Development.

1.11 "Commercially Reasonable Efforts" means the carrying out of obligations under this Agreement with those efforts and resources that KYE would reasonably use were it developing or commercializing its own pharmaceutical compound or product that is of similar market and profit potential and of similar risk profile at a similar stage in its product life as the Product, taking into account available pre-clinical and clinical data, anticipated product labeling, anticipated financial return, relevant medical and clinical considerations, anticipated regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due. It is understood that the potential for the Product may change from time to time based upon changing scientific, business, marketing, return on investment and other relevant considerations. Commercially Reasonable Efforts will be determined on a market-by-market and indication-by-indication basis for a particular Product, and it is anticipated that the level of efforts will change over time, reflecting changes in the status of the Product and the markets involved.

1.12 "Competing Product" means any product (irrespective of its formulation) that (a) is Developed, Commercialized, or has received Regulatory Approval for the treatment of any indication for which the Product has received Regulatory Approval in the Territory (or, prior to that time, for one or more of the same indication(s) for which a Product is being Developed in the Territory); (b) is a steroidal drug; and (c) is not the Product.

1.13 "Compound" means 17α, 21-dihydroxy-16α-methyl-pregna-1,4,9(11)-triene-3,20-dione, otherwise known as VBP-15, verolone or vamorolone, together with its pro-drugs, esters (including 2-((10S,13S,16R,17R)-17-hydroxy-10,13,16-trimethyl-3-oxo-6,7,8,10,12,13,14,15,16,17-decahydro-3H-cyclopenta[a]phenanthren-17-yl)-2-oxoethyl acetate), enantiomers, solid forms (e.g. polymorphs and non-crystalline solid forms) and metabolites, including hydrates, solvates and salts (including hydrates and solvates of salts), and cocrystals of any of the aforementioned.

1.14 "Control" or "Controlled" means, with respect to any information or intellectual property right, possession by a Party of the ability (whether by ownership, license or otherwise) to assign, grant access to or grant a license or sublicense under such intellectual property rights or information to the other Party of the scope set forth herein ("Access"), without breaching the terms of any agreement or other arrangement with a Third Party as of the time such Party would first be required hereunder to grant the other Party such Access.

1.15 "Cover" or "Covering" means, with respect to a Product, that the making, using, selling, offering for sale or importing of such Product would, but for a license granted under the Licensed Patents, infringe a valid claim of the Licensed Patents in the Territory.

1.16 "Debarred Entity" shall mean a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b), or by any other Governmental Authority under similar Applicable Laws of another jurisdiction, or an employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity.

1.17 "Defective Product" means a Product which has not been Manufactured in material compliance with Applicable Laws, including Good Manufacturing Practices, or the Quality Agreement (as defined in Section 10.2 (Quality Requirements)), it being clarified that unless otherwise agreed by the Parties, a Product may not be deemed a "Defective Product" if the alleged defect is solely attributable to KYE's acts or omissions (e.g. in terms of proper storage of the Product after receipt), or if the alleged defect solely results from following KYE's written information and instructions.

1.18 "Develop", "Developing" and "Development" mean non-clinical (including potential development of formulation) and clinical research and/or development activities reasonably related to or intended to lead to the generation and submission of data and information to a Regulatory Authority. Development shall not include any activity comprising Manufacturing or Commercialization.

1.19 "Dispute" means any dispute between the Parties regarding the validity, interpretation, construction or governance of, the compliance with, or the breach or termination of this Agreement.

1.20 "Dollars" or "$" means the lawful currency of Canada, unless otherwise stated in this Agreement. For further clarity, (i) Dollars, in respect of the Supply Price, shall mean the lawful currency of the United States; and (ii) Dollars, in respect of the Royalties, Initial Payment, First Commercial Sale Payment, and milestone payments set out in Article 3, shall mean the lawful currency of Canada.

1.21 "FDA" means the U.S. Food and Drug Administration or any successor agency that is responsible for Regulatory Approval of pharmaceutical products in the U.S.

1.22 "Field" means the treatment and/or prevention of all human diseases and conditions.

1.23 "First Commercial Sale" means, with respect to the Territory, the first sale, on an arm's length basis, to a Third Party for monetary value of a Product for use or consumption by an end-user after all Regulatory Approvals that are required for the Commercialization of such Product in the Territory have been obtained.

1.24 "First Commercial Sale Year" means the Calendar Year in which the First Commercial Sale of the Product occurs.

1.25 "Food and Drugs Act" means Canada's *Food and Drugs Act* (R.S., 1985, c. F-27), as it may be amended from time to time.

1.26 "Food and Drug Regulations" means Canada's *Food and Drug Regulations* (C.R.C., c. 870), as they may be amended from time to time.

1.27 "Force Majeure" means occurrences beyond the reasonable control of the Party affected, including acts of God, embargoes, terrorism, materials shortages or failure of any supplier (where such shortage or failure is attributable to an event of Force Majeure suffered by such supplier), fire, flood, epidemic, explosion, earthquake, hurricanes, storms, tornadoes, pandemics, riots, wars, civil disorder, failure of public utilities or common carriers, rebellion or sabotage, and including, without limitation, governmental restrictions not arising due to any act or omission of the affected Party; provided, however, that the payment of amounts due and owing hereunder shall not be excused by reason of a Force Majeure affecting the payor.

1.28 "GAAP" means the Generally Accepted Accounting Principles in the U.S., as established by the Financial Accounting Standards Board ("FASB") and included in the Accounting Standards Codification (" ASC") consistently applied and effective for the specified period.

1.29 "Good Distribution Practice" means standards, practices and procedures regarding the importing, warehousing, storage, shipping, and distribution of pharmaceutical products promulgated or endorsed by a Regulatory Authority or any Applicable Laws.

1.30 "Good Manufacturing Practices" means good manufacturing practices as described in Part C, Division 2 of the Food and Drug Regulations, and any guidelines or principles published from time to time under such regulations, as applicable, in each case as amended, updated or replaced from time to time.

1.31 "Governmental Authority" means any nation or government, any provincial, state, regional, local or other political subdivision thereof, any supranational organization of sovereign states, and any entity, department, commission, bureau, agency, authority, board, court, official or officer, domestic or foreign, exercising executive, judicial, regulatory or administrative functions of or pertaining to government.

1.32 "Government Official" means any official, officer, director, employee, agent or representative of (1) a national, federal, provincial, regional, territorial, state, district, municipal or local government or of any agency, board or instrumentality thereof; (2) an entity owned or controlled by a Governmental Authority; or (3) a public international organization.

1.33 "Gross Sales" means, with respect to a given period of time in the Territory, the gross amount recognized in the consolidated GAAP revenue accounts in respect to sales of the Product for such country by KYE, its Affiliates, or permitted sublicensees.

1.34 "Health Canada" means the Canadian federal agency that is responsible for Regulatory Approval of pharmaceutical products in Canada.

1.35 "ICC" means International Chamber of Commerce.

1.36 "Improvements" means any modifications, alterations, improvements or enhancements relating to the Compound, any Product, its formulation or methods of use or manufacture, including all technical information, Know-How, discoveries and inventions relating thereto, that are made, developed or otherwise acquired by either Party during the Term, whether or not patented or patentable.

1.37 "Initial Indication" means the treatment of Duchenne Muscular Dystrophy.

1.38 "Know-How" means all proprietary information, inventions (whether or not patentable), Improvements, practices, formulae, trade secrets, techniques, methods, procedures, knowledge, results, test data (including pharmacological, toxicological, pharmacokinetic and non-clinical and clinical information and test data, analytical and quality control data, related reports, structure-activity relationship data and statistical analyses), protocols, master files, processes, process diagrams, vendor lists, specifications, models, designs, correspondence, Regulatory Filings and other information regarding discovery, Manufacture, Development, pricing, cost, and Commercialization. Know-How shall not include any Patent Right.

1.39 "KYE" has the meaning set forth in the ingress to the Recitals.

1.40 "Licensed Intellectual Property" means Licensed Patents and Licensed Know-How.

1.41 "Licensed Know-How" means any and all Know-How, regardless of form, related to the Compound or Product, including data used by Catalyst for obtaining Regulatory Approvals, (a) Controlled by Catalyst or any of its Affiliates as of the Effective Date or (b) that comes into the Control of Catalyst or any of its Affiliates during the Term, in each case that is not in the public domain.

1.42 "Licensed Patents" means (a) the patents and patent applications listed on Exhibit A (Licensed Patents).

1.43 "Manufacture" and "Manufacturing" mean all activities related to (a) developing the ability to manufacture clinical and commercial quantities of a compound or product, and (b) the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, labeling, shipping, and holding of a compound or product or any intermediate thereof, including process development, process qualification and validation, scale-up, non-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.44 "NDS" means a new drug submission, as that term is used in the Food and Drug Regulations, filed with and accepted for filing by Health Canada.

1.45 "Net Sales" means [***].

1.46 "Party" has the meaning set forth in the ingress to the Recitals.

1.47 "Patent Challenge" means any dispute or challenge of the validity, patentability or enforceability of any Licensed Patent or any claim thereof, in any legal or administrative proceedings, including in a court of law, before the Canadian Intellectual Property Office or other agency or tribunal in any jurisdiction, without limitation, by reexamination, post-grant review or declaratory judgment action.

1.48 "Patent Expiration Date" means the expiration date of the last to expire valid claim of an issued and unexpired patent (which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal) of the Licensed Patents in the Territory, Covering the Compound or the Product, the Manufacturing of the Compound or the Product, and/or the Product's use in the Field in the Territory.

1.49 "Patent Rights" means any and all patents and patent applications, including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, certificates of supplementary protection, and the like of any such patents and patent applications, and foreign equivalents of the foregoing.

1.50 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture company, Governmental Authority, association or other entity.

1.51 "Product" means a finished drug product containing the Compound in any formulation, dosage, strength, presentation, or package configuration, and for any mode of administration. Without limiting the foregoing, Product shall include an Authorized Generic Product.

1.52 "Product Exclusivity" means (a) any period during which Health Canada grants data protection pursuant to section C.08.004.1 of the Food and Drug Regulations, including pediatric extension, in respect of the Product or (b) the period from the Effective Date to the Patent Expiration Date, whichever of (a) and (b) is longer.

1.53 "Product Specifications" means the specifications of the Product (including Product packaging) set forth in the Quality Agreement, as may be subsequently amended by the Parties.

1.54 "Prosecution and Maintenance" or "Prosecute and Maintain" with respect to a particular Patent Right, means all activities associated with the preparation, filing, prosecution and maintenance of such Patent Right (and patent application(s) derived from such Patent Right), as well as re-examinations, reissues, applications for patent term adjustments and extensions, certificates of supplementary protection and the like with respect to that Patent Right.

1.55 "Regulatory Approval" means (a) any approvals, licenses, permits, registrations or authorizations of, notice to, or filing with any federal, provincial or local regulatory agency, department, bureau or other governmental entity of any jurisdiction, wherever located in the world, for which a Party, an Affiliate of a Party, or a Third Party acting on behalf of a Party or its Affiliate is the applicant, sponsor, licensee, permittee or holder as of the Effective Date, or becomes the applicant, sponsor, licensee, permittee or holder thereafter, necessary for the clinical testing, Manufacture, Commercialization or other use of a Product in a regulatory jurisdiction (including notices of compliance issued pursuant to section C.08.004 of the Food and Drug Regulations and drug establishment licenses) or (b) any subset of the foregoing as the context may require.

1.56 "Regulatory Authority" means any national, provincial, or local regulatory agency, department, bureau, commission, council, or other Governmental Authority involved in granting Regulatory Approval in the Territory, including Health Canada.

1.57 "Regulatory Documentation" means all Regulatory Filings, correspondence, meeting minutes, and other materials reflecting submissions or communications with a Regulatory Authority concerning the Compound or any Product and all supporting documents with respect thereto, including all adverse event files and complaint files; and safety and quality databases and adverse event information.

1.58 "Regulatory Filings" means all applications, filings, submissions, approvals, such as NDSs (including supplements, amendments, pre- and post-approvals, and pricing and reimbursement approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations) or waivers with respect to the testing, research, Development, registration, Manufacture (including formulation), and/or Commercialization of a Product made to or received from any Regulatory Authority in a regulatory jurisdiction.

1.59 "Royalty" or "Royalties" means the royalty payments due to Catalyst pursuant to Article 4 (Royalties).

1.60 "Royalty Term" means [***].

1.61 "Sales Deductions and Allowances" means the actual amount of sales deductions determined under GAAP and recorded as reduction to GAAP Gross Sales of the Product by KYE or its Affiliates or sublicensees for: (i) trade, cash, prompt-pay and quantity discounts and rebates paid, credited, accrued or actually taken, including cash rebates to patients, co-payment programs and compassionate supply; (ii) current and retroactive price reductions and allowances actually allowed or subsequently granted and measured from the billed amount when credited or included in billing; (iii) credits or allowances granted or made upon claims, rejections or returns of the Product including recalls and regardless of the Party requesting such recalls; (iv) price adjustments and billing errors; (v) governmental and other rebates, discounts, prices reductions, charge-backs and similar types of reductions imposed by or granted to a Governmental Authority (or equivalents thereof) including but not limited to managed health care organizations; pharmacy benefit managers (or equivalents thereof); federal, provincial, local and other governments, their agencies and purchasers and reimbursers; when credited or included in billing (which might be retroactive and subsequent the period of Gross Sales recognition).

1.62 "Supply Price" means the net price actually paid by Catalyst to its supplier for finished Product after all discounts, rebates and other price adjustments in final packaged form for the Territory plus [***] percent ([***]%) plus freight and shipping costs.

1.63 "Tax" or "Taxes" means any and all taxes, assessments, levies, tariffs, duties or other charges or impositions in the nature of a tax imposed by any Governmental Authority, including income, estimated income, gross receipts, profits, business, license, occupation, franchise, capital stock, real or personal property, sales, use, transfer, value added, employment or unemployment, social security, disability, alternative or add-on minimum, customs, excise, stamp, environmental, commercial rent or withholding taxes.

1.64 "Term" means [***].

1.65 "Territory" means Canada.

1.66 "Third Party" means a person or entity other than Catalyst and its Affiliates, and KYE and its Affiliates.

1.67 "Trademark" means the Product-specific trademarks, whether registered or non-registered, for use on and in connection with any Products in any region of the Territory under this Agreement.

1.68 "Unit" means one (1) bottle of one hundred (100) ml of solution of Compound containing four (4) grams of active pharmaceutical ingredient.

ARTICLE 2 LICENSE

2.1 *Licenses*. Subject to the terms and conditions of this Agreement, Catalyst hereby grants to KYE, (a) the exclusive, royalty-bearing, non-transferable and non sub-licensable (except as set forth in Section 2.6 (Sublicensing) license to the Licensed Intellectual Property to (i) Commercialize the Product in the Field in the Territory during the Term on the conditions set forth in this Agreement; and (ii) Commercialize an Authorized Generic Product in the Field in the Territory during the Term after Product Exclusivity, in each case of (i) and (ii) on the on the conditions set forth in this Agreement and subject to Catalyst's rights pursuant to Section 2.4 (Reserved Rights and Grant-Back License to Catalyst) and Section 2.5 (Special Access Programme) (the "**Exclusive License**"). For greater certainty, milestone payments and Royalties shall be payable in respect of such Products, including Authorized Generic Products, as set out in Articles 3 and 4. For clarity, this Agreement shall not imply any right of KYE under any Licensed Intellectual Property to make, use or sell any active pharmaceutical ingredient other than the Compound.

2.2 *Restrictions*. KYE shall not use or register the Regulatory Documentation or any information or data contained therein, in any jurisdiction other than the Territory, or for any purpose except as contemplated under this Agreement. KYE shall not market any Product in any jurisdiction outside of the Territory. KYE shall use Commercially Reasonable Efforts to ensure that no Third Party to which KYE has supplied the Products promotes, markets, distributes or offers to distribute such Product outside the Territory. In the event KYE becomes aware of any such actions outside the Territory, KYE shall immediately notify Catalyst, and shall use its best efforts (at its sole cost and expense) to cause the cessation of such actions. For further clarity, the right to the Development and Manufacture of the Product or Compound, including Additional Indications, shall be retained by Catalyst and its licensors, and unless expressly stated otherwise in this Agreement, this Agreement shall not imply any right of KYE to the Development or Manufacture of the Product or Compound inside or outside of the Territory. Without limiting the foregoing, Catalyst shall retain the right to engage and interact with patient advocacy groups together with KYE in the Territory with respect to Development activities involving the Product or Compound with respect to the Initial Indication, including in respect of Canada's Special Access Programme as set out in sections C.08.010 and C.08.011 of the Food and Drug Regulations. Catalyst shall communicate to KYE Catalyst's Development activities involving the Product or the Compound in the Territory in respect of the Initial Indication. For greater certainty, Catalyst shall not be permitted to bind KYE to obligations in the Territory with respect to Development activities.

2.3 *Transfer of Licensed Know-How*. Promptly following the Effective Date, subject to Catalyst receipt of the Initial Payment, Catalyst shall disclose or transfer copies of all Licensed Know-How necessary or reasonably useful to practice the Exclusive License to KYE (excluding any such Licensed Know-How related to the Manufacture of the Compound or Products).

2.4 *Reserved Rights and Grant-Back License to Catalyst* . For greater certainty, Catalyst reserves the right under the Licensed Intellectual Property, and KYE shall grant and hereby grants to Catalyst, during the Term, a non-exclusive, sublicensable, royalty-free license under the intellectual property, including Patent Rights and Know-How, Controlled by KYE or its Affiliates, to the extent required for Catalyst and its Affiliates and its permitted subcontractors to (a) perform its obligations or exercise its rights under this Agreement (b) conduct, or engage in, any global Additional Development (as defined in Section 6.2 (Additional Development)) activities relating to the Compound or Products in the Territory and outside of the Territory, and (c) Manufacture or have Manufactured the Compound or Products (i) in the Territory for supply to KYE in accordance with this Agreement and (ii) outside of the Territory.

2.5 *Clinical Trial Access Continuation.* For the purposes of this Agreement, "Studies" means Health Canada approved clinical trials of the Product, active as of the Effective Date. Upon the Effective Date, a reasonable transition period not to exceed six (6) months will be implemented to transition any such Studies from the current manager to KYE. For greater certainty, after such transition, all regulatory approvals and requirements, operational costs and oversight of such Studies shall be KYE's responsibility; provided, however, that Catalyst shall supply the Product at no charge for such Studies until a notice of compliance is obtained from Health Canada to market the Product in the Territory. No new patients shall be enrolled in such Studies after the Effective Date without the prior written approval of both KYE and Catalyst.

2.6 *Bridging Program for Participants in Studies.* For the purposes of this Subsection "Bridging Program" means a reduction in Product costs granted by KYE for a limited time to patients enrolled in the Studies, should there be a delay in such patient's drug insurance coverage for the Product after such time that KYE receives a notice of compliance from Health Canada to market the Product in the Territory. Catalyst agrees to cover the costs of the Products for any such Bridging Program in the Territory for patients enrolled in the Studies; provided however, that Catalyst's obligation to cover the Product costs of such Bridging Program shall only apply (i) to Study patients prescribed the Product for on-label indications based on Health Canada's product monograph; (ii) to Study patients who have drug insurance coverage, but such insurance does not yet cover the Product; and (iii) for eight (8) months after KYE receives a notice of compliance from Health Canada to market the Product in the Territory. At all times during the Term, KYE shall be responsible for all requirements, operational costs and oversight of any such Bridging Program.

2.7 *Additional Bridging Program and Compassionate Use Program.* For the purposes of this Agreement, "Compassionate Use Program" means a reduction in Product costs below the Supply Price granted by KYE for a specified time to patients should such patients not have drug insurance or they cannot otherwise afford the Product after KYE receives a notice of compliance from Health Canada to market the Product in the Territory. For the purposes of this Subsection "Additional Bridging Program" means a reduction in Product costs below the Supply Price granted by KYE for a limited time to patients should there be a delay in such patients' drug insurance coverage for the Product after all Participants in Studies have been bridged per Section 2.6. KYE and Catalyst agree to equally share in the costs of the Products for any such Additional Bridging Program and Compassionate Use Program in the Territory; provided however, that Catalyst's obligation to share in the Product costs of such Compassionate Use Program shall only apply to patients prescribed the Product for on-label indications based on Health Canada's product monograph. At all

times during the Term, KYE shall be responsible for all requirements, operational costs and oversight of any such Compassionate Use Program. For clarity at the program's commencement, patients who do not have drug insurance shall not be eligible for the Bridging Program and may only be considered for eligibility in the Compassionate Use Program. Prior to any subsequent changes in eligibility criteria in the Compassionate Use Program, KYE will consult with Catalyst to reach agreement between the Parties on such changes.

2.8 *Special Access Programme.* Prior written consent of both Parties shall be required to fulfill any requests for the Product in the Territory authorized by Canada's Special Access Programme as set out in sections C.08.010 and C.08.011 of the Food and Drug Regulations.

2.9 *Sublicensing*. KYE shall not sub-license the licenses granted in Section 2.1 (Licenses), including to KYE Affiliates, without the prior written consent of Catalyst or as expressly authorized under this Agreement. KYE shall remain responsible for KYE's and any such sublicensee's compliance with all applicable obligations under this Agreement. KYE shall remain responsible for all payments and other obligations under this Agreement arising from activities of its Affiliates and permitted sublicensees. KYE shall provide Catalyst with an abstract of each sublicense agreement with any sublicensee (which may have financial and other sensitive information redacted) in English, within five (5) Business Days after execution of each sublicense agreement.

2.10 *No Implied Licenses.* Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Know-How or other information disclosed to it by the other Party or under any Patent Rights, Know-How or other intellectual property rights held by the other Party or its Affiliates.

2.11 *Non-Compete.* During the Term, KYE shall not, and shall cause its Affiliates and permitted sublicensees with respect to the Compound or Products, not to, engage (independently or for or with any Third Party) in Manufacturing, Developing or Commercializing any Competing Product in the Territory or outside of the Territory.

ARTICLE 3 MILESTONE PAYMENTS

3.1 *Initial Payment*. KYE shall pay to Catalyst a non-refundable and non-creditable one-time initial payment in the amount of [***] Dollars ($[***]) due within 10 (ten) Business Days of receipt of an invoice from Catalyst to be issued to KYE following the Effective Date (the "Initial Payment").

3.2 *First Commercial Sale Payment*. KYE shall pay to Catalyst a non-refundable and non-creditable one-time payment in the amount of [***] Dollars ($[***]) due within thirty (30) Business Days following the First Commercial Sale (the "First Commercial Sale Payment").

3.3 *Public Reimbursement Milestones*. KYE shall pay to Catalyst non-refundable and non-creditable payments upon achieving public plan reimbursement through the listing of the Product on the formulary of the applicable public drug plan in each of the key provinces of the Territory (being Ontario, Quebec, Alberta and British Columbia), as follows: (i) [***] Dollars ($[***]) upon obtainment of public reimbursement in Ontario; (ii) [***] Dollars ($[***]) upon obtainment of public reimbursement in Quebec; (iii) [***] Dollars ($[***]) upon obtainment of public reimbursement in Alberta; and (iv) [***] Dollars ($[***]) upon obtainment of public reimbursement in British Columbia. KYE shall notify Catalyst no later than five (5) days after achieving the applicable public plan reimbursement. Following notice by KYE of the achievement of the applicable public plan reimbursement set forth in this Section 3.3 (Public Reimbursement Milestone), Catalyst will invoice KYE for the applicable milestone payment(s). Each such milestone payment shall be due within thirty (30) Business Days after receipt by KYE of the corresponding invoice for such milestone payment issued by Catalyst.

3.4 *Sales-Based Milestones*. KYE shall pay to Catalyst the non-refundable, non-creditable amounts set forth in the table below if the applicable amount of Net Sales of all Products in the Territory in a single Calendar Year reach one or more of the Net Sales threshold levels set forth below. KYE shall notify Catalyst no later than twenty (20) days after the end of a Calendar Year during which any sales-based milestone event below was achieved. Each such sales-based milestone payment shall only be payable without duplication upon first achievement of such milestone and no amounts shall be due for subsequent or repeated achievement of sales-based milestones. In the event that in a given Calendar Year more than one Net Sales threshold level below is achieved, KYE shall pay to Catalyst a separate, additional milestone payment with respect to each such threshold level that is achieved in such Calendar Year. Following notice by KYE of the achievement of a milestone event set forth in this Section 3.4 (Sales-Based Milestones), Catalyst will invoice KYE for the applicable milestone payment(s). Each such milestone payment shall be due within thirty (30) Business Days after receipt by KYE of the corresponding invoice for such milestone payment issued by Catalyst.

Event	Milestone Payment Amount
(1) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to [***] Dollars ($[***]) or more.	[***] Dollars ($[***])
(2) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to [***] Dollars ($[***]) or more.	[***] Dollars ($[***])
(3) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to [***] Dollars ($[***]) or more.	[***] Dollars ($[***])
(4) Net Sales of Product in the Territory in the Field in a single Calendar Year amounting to [***] Dollars ($[***]) or more.	[***] Dollars ($[***])

ARTICLE 4 - ROYALTIES

4.1 *Royalties.* KYE shall pay Catalyst a Royalty, on the Net Sales during the Royalty Term, as set out in the table below. All Royalties due to Catalyst under this Agreement will be paid quarterly in Dollars, within thirty (30) days after receipt by KYE of the valid Royalty invoice issued by Catalyst for the corresponding Calendar Quarter as set forth in the table below.

Net Sales	Marginal Royalty Rate as a Percentage of Net Sales
For Net Sales of Product in the Territory in the Field during a single Calendar Year equal to or less than [***] Dollars ($[***])	[***] percent ([***]%)
For Net Sales of Product in the Territory in the Field during a single Calendar Year greater than [***] ($[***])	[***] percent ([***]%) on Net Sales in excess of [***] Dollars ($[***])

4.2 **[Intentionally Deleted**].

4.3 *Quarterly Royalty Report*. During the period commencing on the First Commercial Sale of any Product by KYE or its permitted sublicensees and ending on the reporting date following expiration of the obligation of KYE to pay Royalties in respect of any Calendar Quarter in which Royalties accrue, KYE shall deliver to Catalyst quarterly written reports for the preceding Calendar Quarter for each Product showing the Net Sales of such Product subject to Royalty payments sold by or on behalf of KYE and/or its permitted sublicensees during the reporting period in Dollars and local currency. Such reports will also include detailed information regarding Gross Sales, Sales Deductions and Allowances, Net Sales of Product on which Royalties are paid, and amount of Royalties due or, if no Royalties are due, a statement that no Royalties are due for such Product. KYE shall translate the amount of such Net Sales at the foreign exchange rates used for the preparation of the consolidated financial statements of KYE under GAAP for the same period and consistently applied. Royalty reports shall be due twenty (20) days from the end of the respective Calendar Quarter. Upon receipt of such Royalty report, Catalyst will issue a Royalty invoice which is due and payable by KYE thirty (30) days from the receipt of such invoice.

ARTICLE 5 PAYMENTS

5.1 *Payments.* All payments required to be made under this Agreement are to be paid in Dollars. All payments to Catalyst shall be made by wire transfer to Catalyst's account in accordance with Catalyst Wire Payment Instructions to be provided separately at the time of execution and such instructions shall only be amended by written notice that is separately confirmed by telephone call by KYE.

5.2 *Late Payments*. In the event that any invoiced amount hereunder is not made when due, such outstanding payment shall accrue interest at an annual rate of the lower of (i) [***] percent ([***]%) or (ii) the maximum amount permitted by Applicable Law, computed from the date such payment was due until the date the payment was made.

5.3 *Taxes.*

(i) The amounts set forth herein for all payments made pursuant to this Agreement are exclusive of indirect Taxes imposed in the Territory, including value added Tax surcharges and customs. If indirect Taxes are chargeable in respect of any such payments, KYE shall pay such indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an indirect Taxes invoice in the appropriate form issued by Catalyst in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. The Parties shall cooperate and use all reasonable efforts to obtain exemption, zero-rating, or other preferential treatment in respect of any indirect Tax.

(ii) KYE is responsible for deducting all deductions or withholding Taxes or similar Taxes (if any) under the applicable Tax law from the sums otherwise payable by it hereunder and paying the Taxes to the proper Tax authorities within the time required by Applicable Law. Any available receipts reflecting the payment of withheld Taxes shall be provided to Catalyst. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce Tax withholding or similar obligations, consistent with Applicable Laws, in respect of payments made by KYE to Catalyst under this Agreement. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding Taxes, value added Taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax, value added Tax or similar obligations, and pursuant to an applicable bilateral income Tax treaty.

5.4 *Audit Rights*.

(i) *Audits for Payment; Incorrect Payments*. Upon at least twenty (20) days' prior written notice, but not more frequently than once each Calendar Year, Catalyst shall have the right, at its own cost and expense except as provided hereinafter, for the purpose of verifying the accuracy of any payments required to be made to Catalyst

pursuant to this Agreement, to audit all such relevant records in the possession or under the Control of KYE, its Affiliates and its permitted sublicensees. Catalyst shall not be entitled to audit any Calendar Quarter more than once. All audits shall be conducted during normal business hours reasonably acceptable to the Parties at the offices of KYE, its Affiliates or permitted sublicensees in a manner as to not unnecessarily interfere with normal business activities, by an independent certified public accounting firm of internationally recognized standing reasonably acceptable to KYE, and no later than three (3) years after the end of the Calendar Quarter to which they pertain. Prior to the commencement of any such audit, the accounting firm conducting such audit for Catalyst shall enter into a confidentiality agreement with KYE. Such accounting firm shall disclose to Catalyst only the results of its audit, including the amount of any underpayment or overpayment. The accounting firm shall provide copies of its final report to both KYE and Catalyst. KYE shall pay Catalyst the amount of any previous underpayment indicated by such audit within twenty (20) days of the date an audit report so concluding is provided to KYE, plus interest thereon at the rate of the lower of (i) [***] percent ([***]%) per annum or (ii) the maximum amount permitted by Applicable Law, calculated based on the number of days elapsed from the date payment was originally due until the date payment is made. Catalyst shall reimburse KYE the amount of any previous excess payment indicated by such audit within twenty (20) days of the date an audit report so concluding is provided to Catalyst. Catalyst shall bear the cost of such audit provided that in the event the audit indicates an aggregate underpayment to Catalyst for any period in excess of [***] percent ([***]%), KYE shall bear the reasonable costs of such audit.

ARTICLE 6 DEVELOPMENT

6.1 *Development*. KYE shall not conduct any Development with the Compound or Product without first obtaining the prior written consent of Catalyst. For the avoidance of doubt, KYE agrees that it will not directly or indirectly conduct or sponsor, or cooperate with any Third Party in conducting or sponsoring, any clinical trials of the Compound or Products without prior written approval of Catalyst, which Catalyst may grant or withhold in Catalyst's sole discretion.

6.2 *Additional Development.* If KYE proposes to conduct Development of the Compound or Product in the Field, including Development of Product for any Additional Indication or label expansion or modification ("Additional Development"), then KYE shall provide Catalyst with a written proposal of such Additional Development (the "Additional Development Proposal"), including a synopsis of the proposed Development activities related to such Additional Development, the potential role of Catalyst with respect to such Additional Development, the anticipated timeline for such Additional Development, proposed reporting to Catalyst regarding such Additional Development, the proposed clinical trial protocols or designs, if applicable, and the estimated costs associated with such Additional Development.

6.3 *Additional Development Proposal*. Within twenty (20) days of receipt of an Additional Development Proposal, the Parties shall meet to review and consider the Additional Development Proposal, including considering whether such proposal is reasonably likely to have a material adverse effect on obtaining or maintaining Regulatory Approval of any Product or Commercializing any Product, in either case, in other territories. Catalyst may approve or refuse such Additional Development at its sole discretion. Where Catalyst has provided its written consent for the Additional Development by KYE, KYE shall conduct such Additional Development strictly in accordance with the Additional Development Proposal as agreed to in writing by Catalyst.

ARTICLE 7 REGULATORY

7.1 *Regulatory Approvals*. During the Term of this Agreement, KYE shall (i) use Commercially Reasonable Efforts to obtain all Regulatory Approvals for the Commercialization of the Product in the Territory; (ii) shall file and maintain all Regulatory Filings and Regulatory Approvals in good standing; and (iii) shall be solely responsible for and bear any costs and expenses to obtain and maintain any Regulatory Approvals for the Product in the Territory. During the Term of this Agreement, KYE shall be the holder of and shall own all Regulatory Filings and Regulatory Approvals for the Products in the Territory.

7.2 *Obligations for Product Exclusivity.* KYE shall use Commercially Reasonable Efforts to obtain maximum Product Exclusivity for the Product and Compound, by (i) filing and maintaining data protection in respect of the Product pursuant to section C.08.004.1 of the Food and Drug Regulations and (ii) timely filing patent lists for the Licensed Patents to pursue their listing on the Patent Register maintained by Health Canada pursuant to subsection 4(1) of the *Patented Medicines (Notice of Compliance) Regulations* (SOR/93-133).

7.3 *Regulatory Authority Interactions*. KYE shall: (a) promptly provide Catalyst with reasonable advance written notice of any material Regulatory Filings, and any material meetings, telephone conferences or other discussions or correspondence made by KYE with any Regulatory Authority in the Territory, that pertain to the Product or Compound (b) afford representatives of Catalyst a reasonable opportunity to comment on such Regulatory Filings and proposed reply correspondence or other communications with Regulatory Authorities, and (c) incorporate in good faith Catalyst's reasonable comments on the same. KYE shall provide Catalyst with copies of all such Regulatory Filings and shall promptly notify Catalyst with respect to any material changes or material matters that may arise in connection with any Regulatory Approval of the Product in the Territory.

7.4 *Labeling and Packaging.* Without limiting Section 7.3, KYE shall provide a copy of all proposed labeling and packaging, including the product monograph (and any material revisions thereto) for each Product in the Territory prior to the submission of such labeling and packaging to a Regulatory Authority by KYE. KYE will consider and discuss in good faith any reasonable comments of Catalyst prior to finalization of the labelling and packaging for submission to the Regulatory Authority.

7.5 *Threatened Agency Action.* Each of KYE and Catalyst shall promptly notify the other in writing of any information that they receive regarding any threatened or pending action by a Regulatory Authority that it reasonably determines may affect (a) the safety or efficacy of the Products in the Territory or (b) the continued importation, use, marketing, distribution, reimbursement, offering to sell, selling or otherwise disposing of or offering to dispose of the Product in the Territory.

7.6 *Pricing and Reimbursement Regulators.* For greater certainty, KYE shall solely be responsible for interactions and obligations with any Regulatory Authorities that are responsible for the pricing and reimbursement in relation to the Products in the Territory, including the Patented Medicines Pricing Review Board and provincial and federal public drug insurance plans, but shall keep Catalyst reasonably informed of such discussions. KYE shall also be solely responsible for, and shall use Commercially Reasonable Efforts to, negotiate with private insurers to prioritize private insurance coverage of the Product.

7.7 *Further Assistance*. Each Party agrees to provide in a timely manner such assistance in connection with the other Party exercising its rights or fulfilling its responsibilities described in this Section 7.7 (Further Assistance) as such other Party may reasonably request, including making applicable personnel available to address regulatory matters. Each Party shall be responsible for its own reasonable out-of-pocket costs and expenses incurred in providing such assistance.

7.8 *Right of Reference*. Excluding Additional Developments conducted by or on behalf of Catalyst or its licensors, each Party hereby grants to the other Party and its sublicensees the free and perpetual right to reference, subject to the confidentiality obligations of Article 15 (Confidentiality) the (a) toxicology, safety, CMC and/or clinical trial information and data, and (b) Regulatory Filings, in each case of (a) and (b) pertaining to the Product in the Field submitted by or on behalf of such Party and/or its sublicensees to applicable Regulatory Authorities (the "Right of Reference"). For clarity, KYE shall not have the right to use or reference data or other Know-How for which Santhera has not granted Catalyst sublicensing rights in the Territory under the Santhera Agreement. For further clarity, KYE shall not have the right to use or reference the data or other Know-How generated from Additional Development conducted by Catalyst or its licensors, without the prior written consent of Catalyst.

7.9 The grantee-Party (and its licensees and sublicensees) may use the Right of Reference solely for the purposes of seeking, obtaining and maintaining Regulatory Approvals and Commercializing Products in the grantee-Party's permitted territor(ies), which shall be limited to Canada in the case of KYE, and otherwise performing its obligations under this Agreement. Each grantor-Party agrees to provide an appropriate letter of authorization upon request of the other Party to enable use of the Right of Reference, where necessary.

ARTICLE 8 PHARMACOVIGILANCE AND SAFETY

8.1 *Safety Data Exchange Agreement*. At least [***] months (or such other time period agreed by the Parties) in advance of any Regulatory Approval of the Product in the Territory, the Parties (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) will enter into a written safety data exchange agreement, which may include as additional parties Santhera or Catalyst's other licensors if applicable, setting

forth the pharmacovigilance procedures for and responsibilities of the Parties with respect to the Compound and Products, such as safety data sharing, adverse events reporting and safety signal and risk management (the "Safety Data Exchange Agreement"), which agreement shall be amended by the Parties from time to time as necessary to comply with any changes in Applicable Laws or guidance received from Regulatory Authorities. Such Safety Data Exchange Agreement will provide for the receipt, investigation, recording, communication, and exchange by the Parties of information that a Party becomes aware of in the Territory and globally concerning adverse events in or involving a research subject or, in the case of non-clinical studies, an animal in a toxicology study, and the seriousness thereof, and other safety data, including any such information and other safety data received by either Party from a Third Party (subject to receipt of any required consents from such Third Party). All procedures and responsibilities set forth in the Safety Data Exchange Agreement shall be in accordance with, and enable the Parties to fulfill, local, national and international regulatory reporting obligations under Applicable Laws (including to the extent applicable, obligations contained in ICH guidelines). Subject to compliance with Applicable Law, each Party hereby agrees to comply with its respective obligations under the Safety Data Exchange Agreement (as the Parties may agree to modify it from time to time) and to cause its Affiliates and licensees and sublicensees (as applicable) to comply with such obligations. It is understood that each Party and its Affiliates and licensees and sublicensees (as applicable) will have the right to disclose safety data if such disclosure is reasonably necessary to comply with Applicable Laws and Regulatory Authority regulations and requirements. To the extent there is any inconsistency between the terms of the Safety Data Exchange Agreement, once executed, and the terms of this Agreement, the terms of the Safety Data Exchange Agreement shall govern.

8.2 *Pharmacovigilance Compliance.* KYE shall be responsible, at its cost and expense, for pharmacovigilance with respect to the Products in the Territory and shall be responsible for the collection, assessment, and safety reporting of individual case safety reports to Regulatory Authorities, and submitting aggregated report(s), risk management plan and responses to any requests from Regulatory Authorities, with respect to Products in the Territory, and for sharing such information with Catalyst for its compliance with regulatory requirements outside the Territory, in each case subject to and in compliance with Applicable Law and the Safety Data Exchange Agreement.

8.3 *Privacy and Protection of Personal Information* . Each Party shall ensure that the exchange of data under this Agreement shall comply with Applicable Laws, including any applicable legislation on privacy and protection of personal information. To the extent necessary, the Parties shall enter into separate agreements covering relevant aspects of the data exchange and the further processing of such data.

ARTICLE 9 COMMERCIALIZATION

9.1 *Commercialization Diligence*. KYE shall use Commercially Reasonable Efforts to Commercialize the Product throughout the entire Territory. KYE shall fulfill its obligations hereunder in compliance with all Applicable Laws. KYE shall, at its own costs and expenses, perform all commercial launch readiness and launch activities, including

market development, liaising with patient advocacy groups, key opinion leader development, market access strategy, market research, pricing research activities for the Product in the Territory. For the sole purpose of KYE's Commercialization of the Product in the Territory, Catalyst will make available to KYE marketing plans, promotional materials, medical presentations and other communication tools used by Catalyst in the promotion of the Product outside the Territory. KYE shall have the right but not the obligation to modify and use such materials in the Territory

9.2 *Rolling Sales Forecast.* KYE shall develop and submit a proposed marketing plan for the Product to Catalyst within six (6) months after the Effective Date. The marketing plan will include a twelve (12) month rolling sales forecast for the Product within the Territory and activity plans including recommendations for positioning, sales tactics and promotional programs.

9.3 *Commercialization Report.* Upon the request of Catalyst, no more than once per Calendar Year, KYE shall send Catalyst a confidential written report reasonably summarizing KYE's Commercialization activities concerning the Product in the Territory during the previous twelve (12) month period, including representative samples of marketing and medical information materials used by KYE in communicating with relevant stakeholders.

9.4 *Annual Meeting.* The Parties shall meet on an annual basis to discuss KYE's Development, Regulatory and Commercialization activities and plan. Such meetings shall permit for the exchange of information between the Parties, including in respect of progress updates on Product activities in the Territory. If at any time Catalyst has a reasonable basis to believe that KYE is in breach of its Commercialization diligence obligations under this Section 9.1 (Commercialization Diligence), then Catalyst may so notify KYE, specifying the basis for its belief, and, without limitation to any other right or remedy available to Catalyst hereunder, at Catalyst's request, the Parties shall meet within twenty (20) days after such notice to discuss in good faith Catalyst's concerns and KYE's Commercialization plans in the Territory.

9.5 *Selling Price.* KYE shall be solely responsible for determining actual selling price of the Product to customers in the Territory; provided however, that KYE shall obtain Catalyst's approval in writing, not to be unreasonably withheld, of any list price of the Product to customers in the Territory below CAD $1,350 ([***] Canadian dollars) per Unit. KYE shall ensure that all mandatory reports to the Patented Medicines Pricing Review Board and any reports to provincial or federal government public drug insurance plans related to the reimbursement or supply of the Product are timely and accurately submitted.

9.6 *Commercialization and Compliance with Agreement and Applicable Laws* . KYE shall, and shall cause its Affiliates, permitted sublicensees and employees, including members of its sales force to, comply with this Agreement and all Applicable Laws with respect to the Commercialization of Products.

9.7 *No Commercialization by KYE Outside of Territory* . For greater certainty, KYE shall not, and shall cause its Affiliates and permitted sublicensees not to, (a) Commercialize, including market, distribute or sell, the Products or Compound outside of the Territory, or (b) sell the Products to, or otherwise support, any Third Parties for the purpose of Commercializing, including marketing, distributing or reselling, the Products outside of the Territory.

ARTICLE 10 MANUFACTURE AND SUPPLY

10.1 *Supply*. KYE shall purchase all of its requirements for the Product exclusively from Catalyst, and Catalyst shall Manufacture or have Manufactured, supply and sell to KYE all of KYE's and its permitted sublicensees' Product requirements. For greater certainty, KYE shall not conduct, or have conducted, any Manufacture of the Compound or Product without first obtaining the prior written consent of Catalyst.

10.2 *Quality Requirements*. Catalyst shall have Manufactured the Product in accordance with the Product Specifications, the Quality Agreement (as defined in this Section 10.2) and all Applicable Laws, including Good Manufacturing Practices. The Parties shall negotiate in good faith and enter into a Quality Agreement customary in the industry no later than three (3) months before the anticipated First Commercial Sale of the Product in the Territory (the "Quality Agreement"). The Parties shall determine the Product Specifications, and any later amendments thereto, in such Quality Agreement.

10.3 *Forecasting.* No later than six (6) months prior to the expected First Commercial Sale of the Product, and monthly thereafter, on or before the tenth (10th) day of each calendar quarter, KYE shall deliver to Catalyst in writing a non-binding rolling forecast for reasonably anticipated monthly orders of Product over the subsequent twelve (12) months (each, a "Forecast"). The quantities of Product forecasted to be ordered for the first six (6) months of each rolling Forecast shall represent binding obligations of KYE to purchase from Catalyst (each, a "Binding Forecast").

10.4 *Supply Price*. Catalyst shall supply to KYE the Product at the Supply Price. The Supply Price shall not be increased more than once each Calendar Year; provided that, if in any Calendar Year, Catalyst's actual Manufacturing costs attributable to Manufacturing Product in primary packaging or Catalyst's costs attributable to having the primary packaged Product processed into the secondary packaged Product by a subcontractor increase by ten percent (10.0%) or more over the preceding Calendar Year, Catalyst shall provide prompt written notice to KYE of such increase and the Parties shall discuss options for addressing such increase and managing the Supply Price for Product.

10.5 *Purchase Orders*. KYE shall provide to Catalyst written purchase orders for the Product (each, a " Purchase Order"), each of which shall specify the quantity of Product ordered and the delivery date, as well as a specification as to which quantities of Product are to be supplied. The minimum Purchase Order quantity is (a) 750 Units of Product, or multiples thereof until the end of the First Commercial Sale Year and (b) 750 Units of Product, or multiples thereof in and after the next Calendar Year of the First Commercial Sale Year.

10.6 *Limits on Order Quantities and Delivery Times.* With respect to any given month, KYE shall not without Catalyst's written approval (not to be unreasonably withheld, conditioned or delayed), submit Purchase Orders for Product that aggregate more than ten percent (10.0%) over the forecasted amounts for such month contained in the most recent Binding Forecast delivered hereunder. The specified delivery date of a Purchase Order shall be at least one hundred twenty (120) days to a maximum of one hundred sixty (160) days after the date of such Purchase Order, provided that the specified delivery date for the first Purchase Order shall be at least one hundred forty (140) days after the date of the first Purchase Order. For any late deliveries made by Catalyst more than one hundred and sixty (160) days after the Purchase Order date, the Supply Price will be reduced to the net price actually paid by Catalyst to its supplier for finished Product after all discounts, rebates and other price adjustments in final packaged form for the Territory plus freight and shipping costs.

10.7 *Confirmation of Purchase Orders.* Within fifteen (15) Business Days after receipt of a Purchase Order placed pursuant to this Section 10.7, Catalyst shall confirm such Purchase Order in writing. Subject to Catalyst's obligations regarding the Binding Forecast, Catalyst may reject any Purchase Order, if such Purchase Order does not comply with this Article 10 (Manufacture and Supply). A Purchase Order will be deemed accepted if KYE does not receive Catalyst's written rejection within fifteen (15) Business Days after receipt of said Purchase Order by Catalyst.

10.8 *Purchase Orders Governed by Agreement.* Any Purchase Orders submitted by KYE or permitted sublicensees shall reference this Agreement and shall be governed exclusively by the terms contained herein. Any provision in any Purchase Order, invoice, or similar document furnished by KYE or permitted sublicensees that is in any way inconsistent with the terms and conditions set forth in this Agreement is hereby rejected, unless expressly provided otherwise in writing by Catalyst.

10.9 *Satisfaction of Purchase Orders.* Any Purchase Order will be deemed to have been fully satisfied, as to quantity, if the quantity of Product actually delivered to KYE or permitted sublicensees is within ninety percent (90.0%) and one hundred ten percent (110.0%) of the quantity set forth in the applicable accepted Purchase Order, provided that for Purchase Orders made within six (6) months from Regulatory Approval in the Territory, the permissible range is within seventy-five percent (75.0%) and one hundred twenty-five percent (125.0%) of the quantity set forth in the applicable accepted Purchase Order.

10.10 *Product Packaging.* KYE shall be solely responsible to ensure that the agreed Product Specifications for the product packaging comply with all labelling, bar coding, serialization, regulatory, customs, or other requirements under the Applicable Laws in the Territory.

10.11 *Delivery; Storage and Handling; Product Risk.* [***]

10.12 *Acceptance and Rejection by KYE; Defective Product.* [***]

10.13 *Complaints; Safety Notifications; Recall*. Each of the Parties shall maintain, or cause to be maintained, such traceability or other records as are necessary to permit a recall, withdrawal, field alert or similar action (each, a "Recall") regarding the Product. If a Party becomes aware of any Product complaints in or with relevance to the Territory, including complaints on quality, safety, advertising, labeling, packaging or Commercialization of the Product in the Territory by a Regulatory Authority or (other) Governmental Authority, or any information on harm actually or potentially caused to a patient, user or other person, or if a Party considers a Recall necessary, such Party shall promptly notify the other Party.

10.14 *Safety Notification.* Unless otherwise provided in the Safety Data Exchange Agreement entered into by the Parties in relation to the Product, in case a Product might cause, or already has caused harm to a patient, user or other person, each Party shall notify the other Party in writing (such notification, a "Safety Notification") as soon as the respective Party has knowledge of such. Safety Notifications associated with complaints on Products are to be communicated to the following:

by telephone to Primevigilance at [***], with an email copy to [***].

10.15 *Product Recalls.* In the event that a Recall in the Territory regarding Product becomes necessary or KYE is required to disseminate information regarding such Product, KYE shall notify Catalyst promptly and Catalyst shall provide KYE with all reasonable assistance in connection with such Recall. To the extent that a Recall of the Product in the Territory is caused by KYE, its Affiliates, or its permitted sublicensees or subcontractors, KYE shall bear all costs and expenses associated with such Recall, shall have no right to a reimbursement or free-of-charge replacement delivery of recalled Product, and shall reimburse Catalyst for the reasonable out-of-pocket costs incurred by Catalyst arising from the Recall, and applicable fees and penalties, if any, provided that Catalyst may also claim indemnification of Loss (as defined in Section 16.1 (KYE Indemnification) as a result of any Third Party claims, actions, or judgments related to the Recall as stipulated under Section 16.1 (KYE Indemnification).

ARTICLE 11 INTELLECTUAL PROPERTY

11.1 *Catalyst Inventions*. As between the Parties, Catalyst shall have and retain title to all intellectual property made by its employees, agents or other persons acting under its authority during the Term. For greater certainty, as between the Parties, Catalyst or its licensors shall own all intellectual property right, title and interest in and to (i) the Compound, (ii) the Products, (iii) the Licensed Intellectual Property, and (iv) any other Know-How, intellectual property or discoveries, in each case developed by or on behalf of Catalyst during the Term.

11.2 *Product Intellectual Property*. Intellectual property relating to the Compound or Product, including Improvements, shall, as between the Parties, be owned by Catalyst or its licensors regardless of whether (i) conceived by or on behalf of a Party or any of its Affiliates without the inventive contribution of any representative of the other Party or (ii) conceived jointly with the inventive contribution of representatives of Catalyst or any of its Affiliates and of representatives of KYE or any of its Affiliates, whether or not also jointly with a Third Party.

11.3 *Improvements.* KYE shall promptly report to Catalyst in writing each Improvement and shall reasonably cooperate to memorialize in writing an invention disclosure for each Improvement and shall require all of its employees, Affiliates, and any Third Parties working in relation to this Agreement with it or on its behalf, to assign (or otherwise convey rights) to Catalyst any Improvements made by such employee, Affiliate or Third Party, and to cooperate with KYE in connection with KYE's obligations under this Agreement. KYE agrees, and ensures that its respective employees, Affiliates, agents, or Third Parties agree to execute all papers and otherwise assist KYE as reasonably required, to perfect in Catalyst the rights, title and other interests owned by Catalyst under this Article 11 (Intellectual Property). KYE hereby assigns and automatically and in full transfers to Catalyst all rights, title and other interests it holds or acquires during the Term, and which Catalyst is entitled to under this Article 11 (Intellectual Property).

11.4 *Exploitation of Improvements, Patent Rights, etc.* Subject to the licenses granted to KYE in Section 2.1 (Grant to KYE), KYE may not exploit, during or after the Term of this Agreement, any Improvements, or Patent Rights, Know-How or other intellectual property rights held by Catalyst or its licensors, in any field, nor grant any licenses or sublicenses thereunder, without the prior written consent of Catalyst.

11.5 *Licensed Patents.* As between the Parties, Catalyst through its licensors, shall be responsible for the Prosecution and Maintenance of the Licensed Patents in the Territory, including all expenses relating to the Prosecution and Maintenance of such Licensed Patents. KYE shall, at Catalyst or its licensor's expense, cooperate with Catalyst in a timely manner, including by providing necessary information and assistance as Catalyst may reasonably request, in respect of any such actions to be taken, such as filing of patent term extension applications and certificate of supplementary protection applications or their equivalents in the Territory where applicable.

11.6 *Trademarks*. The Products shall be sold in the Territory under Catalyst and its licensors' Trademark "AGAMREE"; provided, however, that if a Canadian Regulatory Authority requires that KYE use a trademark other than "AGAMREE" to identify the Products in the Territory, any alternate Trademarks shall be subject to Catalyst's prior written approval, which shall not be unreasonably withheld or delayed. For greater certainty, any such alternate Trademark shall, as between the Parties, be owned by Catalyst or its licensors.

11.7 *Use of Trademarks.* For the Term of this Agreement, KYE shall be entitled (as part of the license grant set forth in Article 2 (License Grants)) to use Catalyst and its licensors' Trademarks solely for Commercializing the Product in the Territory. As between the Parties, Catalyst or its licensors shall be responsible for the registration, maintenance, and enforcement of the Trademarks in the Territory at its own costs and shall keep KYE reasonably informed thereof. KYE shall not challenge or, directly or indirectly, assert any right, title or interest in or to the Trademarks or any application for registration or registration thereof. At the request and expense of Catalyst, KYE shall execute and deliver all documents that Catalyst or its licensor reasonably deems necessary or appropriate to maintain any registration in the Territory of the Trademarks, or to facilitate the making or granting of an application for registration of the Trademarks.

11.8 *Adherence to Guidelines.* KYE shall comply with and adhere to the Trademark guidelines, as provided by Catalyst from time to time, including with respect to the use of promotional materials, advertising materials and training materials with respect to the Products in the Territory and the packaging and labeling for the Products in the Territory.

ARTICLE 12 LITIGATION

12.1 *Litigation*. Subject to Section 12.2, in relation to the Territory, each Party shall promptly provide written notice to the other Party during the Term of this Agreement of (a) any known infringement or suspected infringement of any Licensed Know-How, Trademarks, Licensed Patent or Improvement by a Third Party in the Territory; or (b) any suit or other legal action commenced against KYE or Catalyst, or their respective Affiliates or permitted sublicensees, or Third Parties, in respect of Compound and/or Product(s) in the Territory, including alleged infringement of Third Party intellectual property rights. As between the Parties, Catalyst shall be responsible to take appropriate action in relation to infringements, suspected infringements, patent-related Third Party suits, litigation matters or other legal action related to any Licensed Know-How, Licensed Patent, Trademark, Improvement, the Compound and/or Product(s) at its sole cost and expense and by counsel of its own choice. KYE shall execute all documents and participate in such suits to the extent reasonably requested by Catalyst, including joining as a co-party as may be necessary. Catalyst shall have the right to control settlement in respect of any such action; provided that Catalyst shall not, except with the approval of KYE (which approval shall not be unreasonably withheld or delayed), consent to entry of any settlement which does not include the giving by the claimant or plaintiff to KYE of a release from all liability in respect to such claim.

12.2 If either Party or any of its Affiliates receives a notice of allegation pursuant to the *Patented Medicines (Notice of Compliance) Regulations* with respect to any Licensed Patent from a Third Party seeking a notice of compliance under the Food and Drug Regulations for a drug, it shall notify the other Party of such notice of allegation within three (3) days after receipt thereof. KYE shall be entitled to exercise any rights provided to a “first person” under the *Patented Medicines (Notice of Compliance) Regulations* to prevent the issuance of a notice of compliance, including applying to a court for an order prohibiting the Minister of Health from issuing a notice of compliance to the Third Party, provided that KYE shall keep Catalyst informed of developments and consider reasonable requests of Catalyst in respect of such court proceedings. Catalyst shall be responsible for covering all reasonable legal fees of KYE with respect to such court proceedings.

ARTICLE 13 TERM AND TERMINATION

13.1 *Term.* The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with this Article 13, shall remain in force, in the Territory until the end of the Royalty Term in the Territory (the “Initial Term”). At the end of the Initial Term or any renewal term, the Initial Term or renewal term will automatically renew for an additional [***] if Net Sales of the Product in the last year of the Initial Term or any renewal term exceeds [***] Dollars ($[***]). If Net Sales of the Product in the last year of the Initial Term or any renewal term do not exceed [***] Dollars ($[***]), the Agreement will only renew upon mutual agreement of both Parties.

13.2 *Termination due to Profit Margin Event.* [***].

13.3 *Termination Right of Catalyst for Failure to Timely Receive Initial Payment.* Should the full amount of the Initial Payment not be received by Catalyst within the deadline set forth in Section 3.1 (Initial Payment), Catalyst shall have the right to immediately terminate this Agreement by written notice to KYE.

13.4 *Termination for Cause.*

(i) Either Party may terminate this Agreement, at any time during the Term in the event the other Party commits a material breach of its obligations under this Agreement by giving written notice of such breach specifying in reasonable detail the claimed breach to the breaching Party if such breach remains uncured for ninety (90) days (or thirty (30) days in the case of the breach of a payment obligation, other than a payment obligation disputed in good faith unless unresolved sixty (60) days after its due date), measured from the date written notice of such breach specifying in reasonable detail the claimed breach is given to the breaching Party; provided, however, if such breach (other than breach of a payment obligation) is not susceptible of cure within the stated period and the breaching Party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional one hundred twenty (120) days.

(ii) If the allegedly breaching Party disputes in good faith the allegation that there has been a material breach (including a good faith dispute regarding the payment of money), then such Party may contest the allegation in accordance with Article 17 (Governing Law; Dispute Resolution) and, provided that the allegedly breaching Party gives written notice to the other Party of such dispute and initiates dispute resolution procedures during the applicable cure period, such cure period will toll upon the initiation of such dispute resolution procedures. If, as a result of such dispute resolution process, it is finally determined pursuant to Article 17 (Governing Law; Dispute Resolution) that the breaching Party committed a material breach of this Agreement, then the applicable cure period will resume and if the breaching Party does not cure such material breach within the remainder of such cure period (as such cure period may be extended pursuant to Section 13.4(i), then this Agreement will terminate effective as of the expiration of such cure period. This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the applicable cure period. Any such dispute resolution proceeding will not suspend any obligations of either Party hereunder and each Party will use reasonable efforts to mitigate any damages. If, as a result of such dispute resolution proceeding, it is determined that the breaching Party did not commit such material breach (or such material breach was cured in accordance with Section 13.4(i) then no termination of this Agreement will be effective, and this Agreement will continue in full force and effect.

13.5 *Termination by Catalyst Without Cause* . After the end of the Royalty Term, Catalyst shall have the right, exercisable upon one hundred eighty (180) days' prior written notice to KYE, to terminate this Agreement, in its entirety if the Royalty Term has expired in the Territory.

13.6 *Termination on Insolvency of a Party*. Either Party shall be entitled to terminate this Agreement by notice to the other Party, if at any time during the Term, (i) the other Party files for, or is subject to, the institution of bankruptcy, liquidation, receivership, reorganization or compromise of debts or similar proceedings, including, without limitation pursuant to Title 11, U.S. Code (the "Bankruptcy Code"), the Bankruptcy and Insolvency Act (Canada), the Companies' Creditors Arrangement Act (Canada), the Winding-up and Restructuring Act (Canada) (collectively, the "Canadian Insolvency Statutes") or any reorganization, arrangement or compromise of debt under the laws of its jurisdiction of incorporation, (ii) the other Party assigns all or a substantial portion of its assets for the benefit of creditors, (iii) a receiver, trustee, custodian or similar official is appointed for the other Party's business, (iv) a substantial portion of the other Party's business is subject to attachment or similar process, or (v) the other Party is unable to pay its debts as they fall due, makes an admission in writing of its inability to pay its debts as they mature or as they become due, acknowledges its insolvency or otherwise becomes bankrupt or insolvent (however evidenced). All rights and licenses granted under or pursuant to any clause of this Agreement are for the purposes of Section 365(n) of the Bankruptcy Code licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code (and any equivalent provisions under the bankruptcy or insolvency laws of any other relevant jurisdiction, including without limitation, the Canadian Insolvency Statutes). The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code, the Canadian Insolvency Statutes or other Applicable Laws in any jurisdiction provided that they comply with the terms of this Agreement.

13.7 *Termination by Catalyst for Patent Challenge.* Except to the extent the following is unenforceable under the Applicable Laws of a particular jurisdiction, Catalyst may terminate this Agreement in its entirety with thirty (30) days' written notice to KYE if KYE or its Affiliates or sublicensees commences a Patent Challenge with respect to any Licensed Patent, unless such action is withdrawn during such thirty (30)-day period.

13.8 *Effects of Early Termination by Catalyst* . If Catalyst terminates this Agreement pursuant to Section 13.4 (Termination for Cause), Section 13.6 (Termination on Insolvency of a Party), or Section 13.7 (Termination by Catalyst for Patent Challenge), upon written request by Catalyst provided to KYE within ten (10) Business Days after the effective date of such termination, KYE shall, at no cost to Catalyst, (a) provide Catalyst all Regulatory Documentation for Products in the Territory in its possession, (b) assign to Catalyst, or provide Catalyst access, to the Regulatory Documentation regarding the Product in the Territory Controlled by KYE, (c) transfer, and cause each of its Affiliates to transfer, to Catalyst any Regulatory Approvals for the Product in the Territory, (d) provide to Catalyst any instruments, assignments and documents necessary to give effect to the transfer of the

Regulatory Approvals to Catalyst. Upon Catalyst's request, KYE shall (A) provide Catalyst with copies of all data generated by KYE in the course of Commercializing of the Products by or on behalf of KYE, and (B) grant Catalyst a non-exclusive (or exclusive), sublicensable license under the Patent Rights, Know-How and other intellectual property Controlled by KYE or its Affiliates, to the extent required for Catalyst and its Affiliates and its sublicensees to conduct, or engage in, Commercializing the Products in the Territory (and, at Catalyst's request, outside the Territory). Catalyst shall be free to use such Regulatory Approvals and Regulatory Documentation and, subject to such written agreement by the Parties, any related data in the further Development and/or Commercialization of the Product in the Field in and outside of the Territory. In addition, KYE shall reasonably cooperate with Catalyst, at Catalyst's cost and expense, to facilitate orderly winddown of the Commercialization of Products in the Territory or, subject to written agreement by the Parties as described above, transition of the Commercialization of Products in the Territory to Catalyst or its designee including (i) assigning, upon request of Catalyst, any agreements or arrangements with Third Party vendors to Commercialize Products or, to the extent any such Third Party agreement or arrangement is not assignable to Catalyst, reasonably cooperating with Catalyst to arrange to continue to provide such services for a reasonable time after termination; and (ii) to the extent that KYE or its Affiliate or permitted sublicensee is performing any activities described above in (i), reasonably cooperating with Catalyst to transfer such activities to Catalyst or its designee and continuing to perform such activities on Catalyst's behalf for a reasonable time after termination. The Parties shall discuss and establish appropriate arrangements with respect to safety data exchange after the Term.

13.9 *Other Effects of Termination*. Upon termination of this Agreement:

(i) all licenses granted under this Agreement by either Party to the other Party, and any sublicenses granted by either Party under any such license, shall automatically terminate, and KYE, its Affiliates and terminated sublicensees shall refrain from using the Licensed Intellectual Property and Catalyst's trademarks with immediate effect, and shall not hold themselves out as being Catalyst's licensees;

(ii) the Party that has Confidential Information (as defined in Section 15.1 (Confidential Information)) of the other Party shall destroy or return (at the discretion of the Disclosing Party (as defined in Section 15.2 (Obligations of Confidentiality and Non-Use)) all such Confidential Information in its possession as of the effective date of termination (with the exception of one copy of such Confidential Information, which may be retained by the Party that received such Confidential Information subject to a continuing obligation of non-use and non-disclosure to confirm compliance with the non-use and non-disclosure provisions of this Agreement and/or to comply with document retention obligations under Applicable Laws), provided that each Party may retain and continue to use such Confidential Information of the other Party to the extent necessary to exercise any surviving rights or obligations under this Agreement;

(iii) KYE shall not, and shall cause its Affiliates and permitted sublicensees, not to, use or register any trademark, name, sign, logo, domain name, or social media presence consisting of or containing signs identical or confusingly similar, to the word “AGAMREE” or to other trademarked used in respect of the Product in the Territory with the approval of Catalyst per Section 11.6, or to Catalyst or its licensor’s other Trademarks previously used in relation to the Product or Compound. To the extent that KYE or its Affiliates own upon termination any trademark used in connection with the sale of the Product in the Territory, KYE agrees to transfer, and to cause its Affiliates, and permitted sublicensees, to transfer, such trademark to Catalyst upon Catalyst’s request and without any compensation, and to execute all documents and perform all acts necessary or useful to give effect to such transfer and to register Catalyst as the new trademark owner in the Territory.

(iv) Should Catalyst terminate this Agreement, Catalyst shall re-purchase all of KYE’s and its Affiliates’ and its permitted sublicensees’ inventory of the Products, provided that such Products have a minimum remaining shelf life of twelve (12) months, at a price equal to the Supply Price paid by KYE to Catalyst therefor. For all other terminations of this Agreement, Catalyst has the right, but not the obligation, to re-purchase all or part of KYE’s and its Affiliates’ and its permitted sublicensees' inventory of the Products, provided that such Products have a minimum remaining shelf life of twelve (12) months, at a price equal to the Supply Price paid by KYE to Catalyst therefor. For these purposes, KYE shall provide to Catalyst a list of the relevant Product(s) in the inventory of KYE, its Affiliates and permitted sublicensees, including information on the remaining quantities and the remaining shelf life of the relevant Products in the inventory at the effective date of the termination, as well as on the applicable re-purchase prices and the documents allowing to verify such repurchase prices. In case Catalyst did not exercise its re-purchase option, at the request of Catalyst, KYE shall, and shall instruct its Affiliates and permitted sublicensees to destroy, any remaining Products in the Territory, and shall send Catalyst written confirmation of such destruction.

(v) If this Agreement is terminated prior to KYE being issued a notice of compliance from Health Canada pursuant to section C.08.004 of the *Food and Drug Regulations* to market the Products in the Territory, a reasonable transition period will be implemented to transition any Studies (as defined in section 2.5 of this Agreement) from KYE back to Catalyst, or such other third party designated by Catalyst.

13.10 In the event that this Agreement is terminated as a result of a termination of the Santhera Agreement, Catalyst shall, at KYE’s request, provide KYE with reasonable assistance in initiating discussions with Santhera for KYE’s licensing of the Licensed Intellectual Property in the Territory; provided, however, that Catalyst makes no guarantees that Santhera will engage in licensing discussions with KYE or that Santhera will agree to license the Licensed Intellectual Property to KYE.

13.11 Nothing in this Article 13 (Term and Termination) shall limit any other remedy either Party may have for the other Party’s breach of this Agreement.

13.12 *Survival of Certain Obligations*. Expiration or termination of the Agreement shall neither relieve the Parties of any obligation accruing before such expiration or termination nor affect those obligations set forth in this Agreement which, from their context or meaning, are intended to survive termination or expiration of this Agreement.

ARTICLE 14 REPRESENTATIONS, WARRANTIES AND COVENANTS

14.1 Catalyst and KYE each represents and warrants to the other with respect to itself (or such other person as set forth below) that:

(i) it is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Agreement;

(ii) it is duly authorized by all requisite action to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby;

(iii) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter or operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or other Governmental Authority entered against it or by which any of its property is bound;

(iv) it has duly executed and delivered this Agreement;

(v) as of the Effective Date, each of its obligations under this Agreement is a legal, valid and binding obligation upon it, enforceable against it in accordance with the provisions of this Agreement except to the extent of the bankruptcy laws, laws of moratorium, and laws affecting the rights of creditors generally that might be applied with retroactive effect in any future proceeding;

(vi) it and its Affiliates have never been, are not currently, and during the Term of this Agreement will not become, a Debarred Entity and (ii) no debarred person or Debarred Entity has performed or rendered, or will perform or render, any services or assistance on its behalf relating to the Compound or the Product. If there exists a threat of debarment or any such debarment occurs, whether official or de facto, the effected Party shall promptly notify the other Party.

(vii) it and any of its Affiliates shall at all times comply with all Applicable Laws relating to its activities under this Agreement;

(viii) neither it, nor any of its Affiliates, nor to its knowledge any director, officer, agent, employee, or other person acting on behalf of the respective Party or any of its Affiliates is aware of or has taken any action, or will knowingly during the Term of this Agreement take any action, directly or indirectly, that would result in a violation by such persons or each Party of Applicable Laws, including the *Food and Drugs Act* and Food and Drug Regulations, or guidelines/policies promulgated by Health Canada, and all other Applicable Laws;

(ix) neither it, nor any of its Affiliates, nor to its knowledge any director, officer, agent, employee, or other person acting on behalf of the respective Party or any of its Affiliates is aware of or has taken any action, or will during the Term of this Agreement take any action, directly or indirectly, that would result in a violation by such persons or each Party of Applicable Laws on anti-corruption, anti-bribery, anti-money-laundering, sanctions or similar laws, including the *U.S. Foreign Corrupt Practices Act*, the *Canadian Corruption of Foreign Public Officials Act*, any sanctions, trade embargoes, or export controls implemented, administered, or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control, the U.S. Departments of State or Commerce, Canada's Competition Bureau or the Royal Canadian Military Police, or any anti-bribery, anti-corruption, anti-money-laundering or sanction laws or regulations applicable in the Territory or Switzerland (the "Anti-Corruption and Sanction Laws");

(x) the respective Party, its Affiliates, and, to its knowledge, any agent or other person acting on behalf of the respective Party or any of its Affiliates have conducted their businesses in compliance with such Anti-Corruption and Sanction Laws, and have instituted and will maintain during the Term of this Agreement policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith;

(xi) each Party represents and warrants that except in the case of its disclosure to the other Party in writing prior to the signing of this Agreement, (1) no significant shareholders (>25.0% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services, are currently or have been in the past two years a Government Official; (2) it is not aware of any immediate relatives (e.g., spouse, parents, children or siblings) of the persons listed in the previous subsection (1) having a public or private role which involves making decisions that could affect either Party's interests; (3) it does not have any other interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (4) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of it in performance of this Agreement. Each Party shall inform the other Party in writing at the earliest possible opportunity of any conflict of interest as described in this clause that arises during the performance of this Agreement;

(xii) each Party represents and warrants it will not make any payment or transfer of value, directly or indirectly, to a Government Official or to any other person while knowing that all or some portion of the payment will be offered to the person for purposes of influencing the person's action or having any other influence on any person to do or omit to do any act in violation of the person's lawful duties, influencing an act or decision of the person's in his or her official capacity, inducing the person to use his or her influence with the government, or influencing the person to assist the other Party in obtaining or retaining business or in securing any improper business advantage or benefit;

(xiii) it does not have in effect, and after the Effective Date it shall not enter into any oral or written agreement or arrangement that would conflict with its obligations under this Agreement;

(xiv) it shall not, and shall cause its Affiliates and permitted sublicensees not to, without the other Party's prior written consent, use any funding from any Governmental Authority to perform any activities under this Agreement in the Territory.

(xv) each Party covenants to the other, as of the Effective Date and during the Term of this Agreement, that it shall be solely responsible for, and shall ensure the payment of, any compensation or remuneration for its employees or contractors performing activities in connection with this Agreement that is legally sufficient under Applicable Laws to compensate, remunerate and award such employees or contractors for their contributions, as applicable.

14.2 Catalyst represents and warrants that, as of the Effective Date, (a) it is not in breach of the Santhera Agreement; and (b) to its knowledge, there have been no infringement claims in respect of the Licensed Intellectual Property in the Territory. Further Catalyst, shall promptly notify KYE of any event that is reasonably likely to create a material breach of the Santhera Agreement by Catalyst. For greater certainty, Catalyst does not represent and warrant that the Compound or Product or Licensed Patents or Licensed Know-How can be Developed or Commercialized for any particular indication, or that a Regulatory Authority will authorize the Product for marketing in the Territory or otherwise grant an approval with respect to the Product in the Territory.

14.3 KYE acknowledges and confirms (a) it has conducted its own investigation and analysis of (i) the Licensed Patents or Licensed Know-How and other proprietary rights of Third Parties as such rights relate to the Commercialization and Development of the Product in the Field in the Territory, and (ii) the potential infringement thereof, (b) understands the complexity and uncertainties associated with possible claims of infringement of Patent Rights or other proprietary rights of Third Parties, particularly those relating to pharmaceutical products, and (c) acknowledges and agrees that it is, subject to any claim it may have against Catalyst for a misrepresentation or breach of warranty or otherwise under this Agreement, solely responsible for the risks of such claims. KYE acknowledges and agrees that it has received access to all requested information relating to Licensed Patents, Licensed Know-How and the Product and all its questions in relation thereto have been answered to its satisfaction in the course of its due diligence related to the transactions contemplated by this Agreement.

14.4 *Disclaimers.* EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, CATALYST MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT, AND CATALYST SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES RELATING TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY WARRANTY OF VALIDITY OF LICENSED INTELLECTUAL PROPERTY, OR OF QUALITY, MERCHANTABILITY, OR FITNESS OF THE COMPOUND OR PRODUCT FOR A PARTICULAR USE. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY OR REPRESENTATION BY CATALYST THAT THE COMPOUND OR PRODUCT, OR THE PRACTICE OR USE OF THE LICENSED INTELLECTUAL PROPERTY WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

ARTICLE 15 CONFIDENTIALITY

15.1 "Confidential Information" means all information and data disclosed by or on behalf of one Party (the " Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") in connection with this Agreement, and/or learned by the Receiving Party hereunder, regardless of form, including a formula, pattern, compilation, program, method, technique, process, biological material, gene sequence, chemical structure or activity, design, source code, business plan, business opportunity, customer or personnel list, or financial statement proprietary to the Disclosing Party or its Affiliates, except any portion thereof which the Receiving Party can show by competent evidence:

(i) is known to the Receiving Party before receipt thereof under this Agreement or any other agreement between the Parties hereto providing for confidentiality;

(ii) is disclosed to the Receiving Party on a non-confidential basis by a Third Party, who is under no obligation of confidentiality to the Disclosing Party with respect to such information and who otherwise has a right to make such disclosure;

(iii) was, is or becomes published, as evidenced by a written version thereof, or generally known in the trade, scientific or medical community through no fault of the Receiving Party; or

(iv) is independently developed by the Receiving Party, without use of or reliance on the Disclosing Party's Confidential Information, by persons having no access thereto.

15.2 *Obligations of Confidentiality and Non-Use.* Each Receiving Party agrees that it shall keep confidential and shall not publish or otherwise disclose, and will take all reasonable steps to prevent disclosure of, Confidential Information of the Disclosing Party and will not use any Confidential Information of the Disclosing Party except to the extent permitted by this Agreement in connection with the performance of its obligations or exercise of its rights hereunder or otherwise agreed to in writing. Improvements shall be deemed Confidential Information of Catalyst. No provision of this Agreement shall be construed to preclude disclosure of Confidential Information to the extent required to be disclosed by Applicable Laws or by any rule or regulation of any court, stock exchanges or other Governmental Authority with competent jurisdiction; provided that the Receiving Party shall notify the Disclosing Party as soon as reasonably possible and whenever legally permissible and the Receiving Party shall, if requested by the Disclosing Party, use reasonable good faith

efforts, at the expense of the Disclosing Party, to assist in seeking a protective order (or equivalent) with respect to such disclosure or otherwise take reasonable steps to avoid making such disclosure, and the Receiving Party shall furnish only that portion of the Confidential Information which it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by the Disclosing Party. In addition, (a) the obligations of confidentiality set forth herein shall not be construed to prevent use or disclosure of, or reference to, such information as reasonably necessary to enforce the terms of this Agreement (whether in court, arbitration or otherwise), provided that the Party shall use reasonable good faith efforts to obtain confidential treatment in connection with any such disclosure of the Confidential Information of the other Party, and (b) either Party may disclose the Confidential Information of the other Party as reasonably necessary, under reasonable and customary written obligations of confidentiality, to actual or potential investors, acquirers (of the company or of assets related to this Agreement), permitted sublicensees, contractors and others on a need to know basis, (c) a Receiving Party may use and disclose the Confidential Information of the Disclosing Party as reasonably necessary to obtain or maintain any Regulatory Approval and to conduct Development and Commercialization activities, including to conduct non-clinical studies and clinical trials and for pricing approvals, provided, that such activities are otherwise consistent with the Receiving Party's rights and obligations under this Agreement and that the Receiving Party shall take all reasonable steps to limit disclosure of the Confidential Information outside such regulatory agency and to otherwise maintain the confidentiality of the Confidential Information.

15.3 Except as permitted by this Article 15 (Confidentiality), neither Party shall disclose any terms or conditions of this Agreement without the prior written consent of the other Party; provided, however, that Catalyst may disclose this Agreement and documents regarding reporting of Royalties, audit rights, and patent prosecution relating to this Agreement or regarding its performance (including reports on milestones and any payments) to Santhera and other Third Parties as required to the extent required for Catalyst to comply with its obligations under the Santhera Agreement. Notwithstanding the foregoing, either Party may disclose the terms of this Agreement to the extent required by applicable statute, rule or regulation of any court or other Governmental Authority with competent jurisdiction or by applicable rules of the U.S. Securities and Exchange Commission or similar regulatory agency in any country other than the U.S. or of any stock exchange or listing entity ("Securities Authority") as it determines, based on advice of counsel, to be reasonably necessary to comply with Applicable Laws, including laws or regulations of a Securities Authority, or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of such disclosures to the extent practicable and shall use reasonable efforts to submit to the other Party a draft of such public disclosure for review and comment by the other Party. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with a Securities Authority or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines to be necessary under Applicable Laws provided such Party shall use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that such other Party requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel is legally required to be disclosed. No such notice shall be required under this Section 15.3 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by the either Party hereunder or otherwise approved by the other Party.

15.4 *Publicity*. Neither Party shall issue any public announcement, press release, or other public disclosure regarding this Agreement or its subject matter, except (a) with the other Party's prior written consent, which shall not be unreasonably withheld, conditioned, or delayed, (b) for any such disclosure that is, in the opinion of the Disclosing Party's counsel, required by Applicable Laws or the rules of a stock exchange on which the securities of the Disclosing Party are listed, or (c) as provided in Section 15.2 (Obligations of Confidentiality and Non-Use). Moreover, neither Party shall have any right to use the name, trademark, trade name or logo of the other Party or its employees without the prior express written permission of the other Party, except as may be required by the Applicable Laws or stock exchange regulations.

15.5 *Scientific Publications*. Catalyst will have the right to review and comment on any scientific material proposed for publication or public oral or visual presentation by KYE that relates to the Compound or Products or includes Confidential Information of Catalyst. Before any such material is submitted for publication, KYE will deliver a complete copy to Catalyst at least forty-five (45) days prior to submitting the material to a publisher or initiating any other disclosure. KYE will comply with Catalyst's request to delete references to Catalyst's Confidential Information in any such material. In addition, if any such publication contains patentable subject matter of Catalyst, then at Catalyst's request, KYE will either delete the patentable subject matter from such publication or delay any submission for publication or other public disclosure for a period of up to an additional sixty (60) days so that appropriate patent applications may be prepared and filed.

15.6 *Equitable Relief*. Each Party acknowledges that its breach of this Article 15 (Confidentiality) would cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 15 (Confidentiality) by the other Party.

ARTICLE 16 INDEMNIFICATION; LIABILITY; INSURANCE

16.1 *KYE Indemnification*. KYE shall indemnify, defend and hold Catalyst, its Affiliates, and their respective officers, directors, employees and agents ("Catalyst Indemnitees") harmless from and against any and all harm, liability, damage, loss and expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") as a result of any Third Party claim, demand, action, or judgment, to the extent arising out of or relating to (a) the Development, Manufacture or Commercialization of the Product in the Territory by KYE, its Affiliates or Third Parties on behalf of KYE or its Affiliates; (b) any breach by KYE of this Agreement; or (c) the gross negligence or willful misconduct of any KYE Indemnitee (as hereinafter defined) relating to the Commercialization of the Product, provided, however, that the foregoing indemnity shall not apply to the extent that such Loss arose out of any of the matters for which Catalyst is obligated to indemnify the KYE Indemnitees pursuant to Section 16.2 (Catalyst Indemnification).

16.2 *Catalyst Indemnification*. Catalyst shall indemnify, defend and hold KYE, its Affiliates, and their respective officers, directors, employees and agents ("KYE Indemnitees") harmless from and against any and all Loss as a result of any Third Party claim, demand, action, or judgment, to the extent arising out of or relating to (a) the Development, Manufacture or supply or Commercialization of the Product by Catalyst, its Affiliates or Third Parties on behalf of Catalyst or its Affiliates; (b) any breach by Catalyst of this Agreement; or (c) the gross negligence or willful misconduct of any Catalyst Indemnitee; provided, however, that the foregoing indemnity shall not apply to the extent that such Loss arose out of any of the matters for which KYE is obligated to indemnify the Catalyst Indemnitees pursuant to Section 16.1 (KYE Indemnification).

16.3 LIMITATION ON LIABILITY. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER THIS AGREEMENT FOR ANY INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS AND LOST REVENUES.

16.4 *Claims Procedure*. A Party entitled to be indemnified by the other Party (an " Indemnified Party") pursuant to Section 16.1 (KYE Indemnification) or Section 16.2 (Catalyst Indemnification) hereof shall give written notice to the other Party (the "Indemnifying Party") promptly after such Indemnified Party has actual knowledge of any threatened or asserted claim as to which indemnity may be sought, and shall permit the Indemnifying Party to assume the defense of any such claim or any litigation resulting therefrom, provided that:

(i) the Indemnified Party may participate in such defense at such Indemnified Party's expense;

(ii) the failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Agreement to the extent that such failure to give notice did not result in prejudice to the Indemnifying Party or the Indemnifying Party's insurer;

(iii) the Indemnifying Party, in the defense of any such claim or litigation, shall not, except with the approval of the Indemnified Party (which approval shall not be unreasonably withheld or delayed), consent to entry of any judgment or enter into any settlement which, (i) would result in injunctive or other non-monetary relief being imposed against the Indemnified Party; or (ii) does not include the giving (as an unconditional term thereof) by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect to such claim or litigation; or (iii) includes an admission of liability; and

(iv) the Indemnified Party shall furnish such information regarding itself or the claim in question as the Indemnifying Party may reasonably request in writing, and shall be reasonably required in connection with the defense of such claim or litigation resulting therefrom.

16.5 *Insurance*. Each Party shall obtain and maintain comprehensive general liability insurance customary in the industry for companies of similar size conducting similar business.

ARTICLE 17 GOVERNING LAW; DISPUTE RESOLUTION

17.1 *Governing Law.* This Agreement shall be governed by and construed in accordance with the laws of the State of New York, U.S. without regard to its conflict of laws rules and to the Convention on the International Sale of Goods.

17.2 *Referral to Executives*. If a Dispute cannot be resolved by good faith negotiations, it shall be referred, by written notice from either Party to the other, to the Chief Executive Officers of the Parties for resolution. The Chief Executive Officers or their respective designees (with similar authority to resolve such Dispute) shall negotiate in good faith to resolve such dispute through discussions promptly following such written notice. If the Chief Executive Officers cannot resolve the Dispute within thirty (30) days of such written notice, or either Party concludes that the matter will not be so resolved, then the Dispute shall be resolved as provided in Section 17.3 (Arbitration).

17.3 *Arbitration.* Subject to Section 17.4 (Disputes Relating to Patents and Trademarks and Equitable Relief), any Dispute arising out of or in connection with this Agreement or the enforcement of any provision of this Agreement, if not resolved by the Chief Executive Officers pursuant to Section 17.2 (Referral to Executives), shall be finally resolved by binding arbitration administered by the ICC pursuant to the *Rules of Arbitration of the ICC* in force on the date on which a request for arbitration is submitted in accordance with those Rules. Judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration shall be conducted by a one or three arbitrators who shall have experience with respect to the matter(s) to be arbitrated. In case of three arbitrators, one shall be nominated by KYE, one shall be nominated by Catalyst, and the third arbitrator, who shall serve as a chair, shall be nominated by the two party-nominated arbitrators. The place of arbitration shall be New York (New York, U.S.A.). The language of the proceedings shall be English. Either Party may apply to the arbitrator(s) for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Nothing contained herein shall be construed to permit the arbitrator(s) to award punitive, exemplary or similar damages. Each Party shall bear an equal share of the arbitrators' fees and any administrative fees of arbitration. Except to the extent necessary to confirm, challenge, or enforce an award or as may be required by Applicable Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the Dispute shall be refunded if the arbitrator determines that such payments are not due.

17.4 *Disputes Relating to Patents and Trademarks and Equitable Relief.* Any Dispute relating to (a) either (i) the scope, validity, enforceability or infringement of any Patent Rights; or (ii) any Trademarks, shall in each case be submitted to a court of competent jurisdiction in the Territory, or (b) the need to seek urgent preliminary (including injunctive) relief (e.g., in the event of a potential or actual breach of the provisions in Section 2.8 (Non-Compete) or the confidentiality and non-use provisions in Article 15 (Confidentiality) need not be resolved through the procedure described in Section 17.3 (Arbitration), but may be immediately brought in any court of competent jurisdiction in order to preserve the status quo during the resolution of any Dispute under Section 17.3 (Arbitration).

17.5 *Attorneys' Fees.* If any action or proceeding relating to this Agreement or the enforcement of any provision of this Agreement is brought against any Party hereto, the prevailing Party shall be entitled to recover reasonable attorneys' fees, costs and disbursements (in addition to any other relief to which the prevailing Party may be entitled).

ARTICLE 18 GENERAL PROVISIONS

18.1 *Santhera Agreement*. KYE acknowledges and agrees that the terms of this Agreement are subject in all respects to the terms and conditions of the Santhera Agreement. KYE further agrees that (i) the licensor under the Santhera Agreement retained certain rights, which are not granted to KYE hereunder; (ii) such licensor shall be deemed to be a Third Party beneficiary of this Agreement; (iii) all Confidential Information provided to Catalyst hereunder may be shared with such licensor; and (iv) KYE shall fully cooperate with Catalyst to assist Catalyst in complying with its obligations (including but not limited to recordkeeping and information sharing) under the Santhera Agreement.

18.2 *Force Majeure*. Except with regard to obligations to pay money, neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by Force Majeure. The non-performing Party shall notify the other Party of such Force Majeure by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than necessary to resolve such Force Majeure event and the non-performing Party shall use diligent efforts to remedy its inability to perform. If a condition constituting Force Majeure exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory solution to the problem.

18.3 *Amendment and Waiver*. The terms and conditions of this Agreement may not be amended or modified, except in a writing signed by both Parties. No provision of or right under this Agreement shall be deemed to have been waived by any act or acquiescence on the part of any Party, its agents or employees, except by an instrument in writing signed by an authorized officer of such Party. No waiver by either Party of any breach of this Agreement by any other Party shall be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver.

18.4 *Independent Contractors*. Each Party represents that it is acting on its own behalf as an independent contractor and is not acting as an agent for or on behalf of any Third Party. This Agreement and the relations hereby established by and between Catalyst and KYE do not constitute a partnership, joint venture, agency or contract of employment between them. Neither Party shall be responsible for acts or omissions of the other Party or the other Party's agents or Affiliates or permitted sublicensees.

18.5 *Assignment.* No Party shall sell, assign or transfer its rights or obligations under this Agreement to any Third Party or to an Affiliate without the prior written consent of the other Party, except that (a) Catalyst is entitled to assign the right to receive any payments under this Agreement from KYE (including milestone and other payments) to a Third Party without KYE's consent, and (b) Catalyst may sell, assign or transfer its rights and obligations under this Agreement without KYE's consent to (i) a Third Party successor to substantially all of Catalyst's business or assets relating to the Compound or Products (whether by merger, sale of stock, sale of assets or other transaction), or (ii) an Affiliate. Any purported assignment of this Agreement in breach of this Section 18.5 (Assignment) shall be null and void. Subject to the foregoing, this Agreement will be binding on and inure to the benefit of the Parties and their respective successors and permitted assigns.

18.6 *No Set-Off*. Unless otherwise provided herein or agreed in writing, payments to be made under this Agreement shall be made in full without any set-off or other similar rights.

18.7 *Notices*. All communications hereunder shall be in writing, in English and shall be deemed to have been duly given upon receipt by the addressee at the addresses set forth below, or such other address as either Party may specify by notice sent in accordance with this Section 18.7 (Notices). Receipt may be sufficiently established by confirmation of delivery by an internationally recognized courier service, such as Federal Express, DHL or UPS.

If to Catalyst:

[***]

with a copy to:

[***]

If to KYE:

[***]

with a copy to:

[***]

A copy of any notice under this Agreement shall be sent to the Receiving Party by email, however, such email is neither a requirement for a proper notice, nor is it a sufficient notice. However, for communications at a day-to-day, operational level, correspondence by email shall be sufficient.

18.8 *Severability.* In the event any provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof. The Parties agree that they will negotiate in good faith or will permit a court or arbitrator to replace any provision hereof so held invalid, illegal or unenforceable with a valid provision which is as similar as possible in substance to the invalid, illegal or unenforceable provision.

18.9 *No Presumption*. In construing the terms of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms.

Word Meanings. The captions and headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Words such as herein, hereinafter, hereof and hereunder refer to this Agreement as a whole and not merely to a Section or paragraph in which such words appear, unless the context otherwise requires. The singular shall include the plural, and each masculine, feminine and neuter reference shall include and refer also to the others, unless the context otherwise requires. The word “or” is used in the inclusive sense typically associated with the phrase “and/or.” The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation” and shall not be construed to limit any general statement which it follows to the specific or similar items or matters immediately following it. The word “will” shall be construed to have the same meaning and effect as the word “shall.” All references herein to Sections or Exhibits shall be construed to refer to Sections and Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto.

18.10 *Expenses.* Each Party bears its own costs and expenses in connection with negotiating and drafting this Agreements.

18.11 *Entire Agreement.* This Agreement and the Exhibits attached hereto contain the entire understanding of each of the Parties hereto with respect to the transactions and matters contemplated hereby supersedes all prior agreements and understandings relating to the subject matter hereof; and no representations, inducements, promises or agreements, whether oral or otherwise, between such Parties not contained herein or incorporated herein by reference shall be of any force or effect.

18.12 *Further Assurances.* Each Party shall and shall use all reasonable endeavors to procure that any necessary Third Party shall promptly execute and deliver such further documents and do such further acts as may be required for the purpose of giving full effect to this Agreement.

18.13 *No Third Party Beneficiaries*. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other persons except as otherwise expressly provided in this Agreement.

18.14 *Counterparts.* This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Agreement in Portable Document Format (PDF) sent by electronic mail or by any other electronic means. PDF or electronic signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding on the Parties, and, upon delivery, will constitute due execution of this Agreement.

[remainder of page intentionally left blank]

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

KYE PHARMACEUTICALS INC.

By: /s/ John McKendry
Name: John McKendry
Title: President & CEO
I have authority to bind the corporation

CATALYST PHARMACEUTICALS INC.

By: /s/ Richard Daly
Name: Richard Daly
Title: President & CEO
I have authority to bind the corporation

List of Exhibits:

Exhibit A - Licensed Patents

Exhibit A – Licensed Patents

[***]

Exhibit 31.1

Certification of Principal Executive Officer

I, Richard J. Daly, certify that:

1.I have reviewed this quarterly report on Form 10-Q of Catalyst Pharmaceuticals, Inc.;

2.Based on my knowledge, this quarterly 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 15(d)-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 subsidiary, 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 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 registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 7, 2024

/s/ Richard J. Daly
Richard J. Daly
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Michael W. Kalb, certify that:

1.I have reviewed this quarterly report on Form 10-Q of Catalyst Pharmaceuticals, Inc.;

2.Based on my knowledge, this quarterly 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 15(d)-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 subsidiary, 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 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 registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 7, 2024

/s/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Required by 18 U.S.C. Section 1350
(as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)

I, Richard J. Daly as Principal Executive Officer of Catalyst Pharmaceuticals, Inc. (the Company), certify, pursuant to 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002), that to my knowledge:

1.the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2024 (the Report), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 7, 2024

/s/ Richard J. Daly
Richard J. Daly
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification Required by 18 U.S.C. Section 1350
(as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)

I, Michael W. Kalb as Principal Financial Officer of Catalyst Pharmaceuticals, Inc. (the Company), certify, pursuant to 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002), that to my knowledge:

1.the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2024 (the Report), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 7, 2024

/s/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)