REFINITIV

DELTA REPORT

10-Q

RYTM - RHYTHM PHARMACEUTICALS, I

10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	4106
CHANGES	230
DELETIONS	3223
ADDITIONS	653

REFINITIV

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, June 30, 2024

OR

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

For the transition period from to

Commission file number 001-38223

RHYTHM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-2159271**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

222 Berkeley Street

12th Floor

Boston, MA 02116

(Address of Principal Executive Offices)

(Zip Code)

(857) 264-4280

(Registrant's Telephone Number, Including Area Code)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	RYTM	The Nasdaq Stock Market LLC (Nasdaq Global Market)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "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 provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of shares outstanding of the registrant's Common Stock as of May 1, 2024 August 1, 2024 was 60,972,909. 61,133,765.

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RHYTHM PHARMACEUTICALS, INC.

FORM 10-Q

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Rhythm Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)

(Unaudited)

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	$ 53,428	$ 60,081	$ 161,669	$ 60,081
Short-term investments	147,771	215,765	157,461	215,765
Accounts receivable, net	14,695	14,867	17,598	14,867
Inventory	8,507	8,624	11,994	8,624
Prepaid expenses and other current assets	11,352	8,931	8,644	8,931
Total current assets	235,753	308,268	357,366	308,268
Property and equipment, net	1,149	1,341	973	1,341
Right-of-use asset	670	781	3,696	781
Intangible assets, net	6,815	7,028	6,601	7,028
Restricted cash	460	328	460	328
Other long-term assets	13,804	14,999	12,750	14,999
Total assets	$ 258,651	$ 332,745	$ 381,846	$ 332,745
Liabilities and stockholders' equity				
Liabilities, Convertible Preferred Stock and Stockholders' equity				
Current liabilities:				
Accounts payable	$ 7,550	$ 4,885	$ 4,543	$ 4,885
Accrued expenses and other current liabilities	44,531	48,262	48,077	48,262
Deferred revenue	1,286	1,286	1,286	1,286
Lease liability	793	770	816	770
Total current liabilities	54,160	55,203	54,722	55,203
Long-term liabilities:				
Deferred royalty obligation	107,368	106,143	108,372	106,143
Lease liability, non-current	284	490	3,301	490
Derivative liability	660	1,150	360	1,150
Other long-term liabilities	34,598	—	35,596	—
Total liabilities	197,070	162,986	202,351	162,986
Commitments and contingencies (Note 14)				
Commitments and contingencies (Note 15)				
Series A convertible preferred stock, $0.001 par value: 150,000 shares authorized; 150,000 and 0 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively. Liquidation preference of $150,000 as of June 30, 2024.			140,152	—
Stockholders' equity:				
Preferred Stock, $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—		

Common stock, $0.001 par value: 120,000,000 shares authorized; 60,964,468 and 59,426,559 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	60	59		
Preferred Stock, $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2024 and December 31, 2023			—	—
Common stock, $0.001 par value: 120,000,000 shares authorized; 61,095,949 and 59,426,559 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively			60	59
Additional paid-in capital	1,097,810	1,064,302	1,108,269	1,064,302
Accumulated other comprehensive income (loss)	(181)	134		
Accumulated other comprehensive (loss) income			(617)	134
Accumulated deficit	(1,036,108)	(894,736)	(1,068,369)	(894,736)
Total stockholders' equity	61,581	169,759	39,343	169,759
Total liabilities and stockholders' equity	$ 258,651	$ 332,745		
Total liabilities, convertible preferred stock and stockholders' equity			$ 381,846	$ 332,745

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

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Rhythm Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three months ended March 31,	
	2024	2023
Revenues:		
Product revenue, net	$ 25,967	$ 11,469
Total revenues	25,967	11,469
Costs and expenses:		
Cost of sales	2,807	1,421
Research and development	128,665	37,945
Selling, general, and administrative	34,382	24,634
Total costs and expenses	165,854	64,000
Loss from operations	(139,887)	(52,531)
Other (expense) income:		
Other income (expense), net	524	(27)
Interest expense	(4,755)	(3,061)
Interest income	3,046	3,440
Total other (expense) income, net	(1,185)	352
Loss before income taxes	(141,072)	(52,179)

Provision for income taxes	300	—
Net loss	$ (141,372)	$ (52,179)
Net loss per share, basic and diluted	$ (2.35)	$ (0.92)
Weighted-average common shares outstanding, basic and diluted	60,143,558	56,708,975
Other comprehensive loss:		
Net loss	$ (141,372)	$ (52,179)
Foreign currency translation adjustment	(71)	21
Unrealized gain (loss), net on marketable securities	(244)	65
Comprehensive loss	$ (141,687)	$ (52,093)

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 29,078	$ 19,221	$ 55,045	$ 30,691
Total revenues	29,078	19,221	55,045	30,691
Costs and expenses:				
Cost of sales	2,947	2,236	5,753	3,657
Research and development	30,194	33,543	158,858	71,487
Selling, general, and administrative	36,415	30,046	70,797	54,674
Total costs and expenses	69,556	65,825	235,408	129,818
Loss from operations	(40,478)	(46,604)	(180,363)	(99,127)
Other income (expense):				
Other income (expense), net	302	(17)	824	34
Gain on settlement of forward contract	8,900	—	8,900	—
Interest expense	(4,603)	(3,303)	(9,358)	(6,449)
Interest income	4,097	3,221	7,143	6,660
Total other income (expense), net	8,696	(99)	7,509	245
Loss before income taxes	(31,782)	(46,703)	(172,854)	(98,882)
Provision for income taxes	479	—	779	—
Net loss	$ (32,261)	$ (46,703)	$ (173,633)	$ (98,882)
Accrued dividends on convertible preferred stock	(1,302)	—	(1,302)	—
Net loss attributable to common stockholders	$ (33,563)	$ (46,703)	$ (174,935)	$ (98,882)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.55)	$ (0.82)	$ (2.89)	$ (1.74)
Weighted-average common shares outstanding, basic and diluted	61,011,824	56,867,662	60,577,691	56,788,757
Other comprehensive loss:				
Net loss attributable to common stockholders	$ (33,563)	$ (46,703)	$ (174,935)	$ (98,882)
Foreign currency translation adjustment	(302)	(48)	(373)	(27)
Unrealized (loss) gain, net on marketable securities, net of tax	(134)	40	(378)	105
Comprehensive loss	$ (33,999)	$ (46,711)	$ (175,686)	$ (98,804)

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

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Rhythm Pharmaceuticals, Inc.

Condensed Consolidated Statements of Convertible Preferred Stock & Stockholders' Equity

(in thousands, except share data)

(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	59,426,559	$ 59	$ 1,064,302	$ 134	$ (894,736)	$ 169,759
Stock-based compensation expense	—	—	7,767	—	—	7,767
Issuance of common stock in connection with ESPP	28,495	—	673	—	—	673
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	1,077,271	1	6,352	—	—	6,353
Issuance of common stock as consideration for LGC license	432,143	—	18,716	—	—	18,716
Foreign currency translation adjustment	—	—	—	(71)	—	(71)
Unrealized loss on marketable securities	—	—	—	(244)	—	(244)
Net loss	—	—	—	—	(141,372)	(141,372)
Balance at March 31, 2024	60,964,468	$ 60	$ 1,097,810	$ (181)	$ (1,036,108)	$ 61,581
Balance at December 31, 2022	56,612,429	$ 56	$ 974,356	$ (92)	$ (710,058)	$ 264,262
Stock-based compensation expense	—	—	6,376	—	—	6,376
Issuance of common stock in connection with ESPP	32,169	—	665	—	—	665
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	207,806	—	553	—	—	553
Foreign currency translation adjustment	—	—	—	21	—	21
Net unrealized gains on short-term investments	—	—	—	65	—	65
Net loss	—	—	—	—	(52,179)	(52,179)
Balance at March 31, 2023	56,852,404	$ 56	$ 981,950	$ (6)	$ (762,237)	$ 219,763

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	—	—	59,426,559	$ 59	$ 1,064,302	$ 134	$ (894,736)	$ 169,759
Stock-based compensation expense	—	—	—	—	7,767	—	—	7,767
Issuance of common stock in connection with ESPP	—	—	28,495	—	673	—	—	673
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	—	—	1,077,271	1	6,352	—	—	6,353
Issuance of common stock as consideration for LGC license	—	—	432,143	—	18,716	—	—	18,716
Foreign currency translation adjustment	—	—	—	—	—	(71)	—	(71)
Unrealized loss on marketable securities	—	—	—	—	—	(244)	—	(244)
Net loss	—	—	—	—	—	—	(141,372)	(141,372)
Balance at March 31, 2024	—	$ —	60,964,468	$ 60	$ 1,097,810	$ (181)	$ (1,036,108)	$ 61,581
Issuance of Series A Preferred Stock, net of $2,250 of issuance costs	150,000	138,850	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	10,358	—	—	10,358
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	—	—	131,481	—	1,403	—	—	1,403
Accretion of preferred stock dividends	—	1,302	—	—	(1,302)	—	—	(1,302)
Foreign currency translation adjustment	—	—	—	—	—	(302)	—	(302)

Unrealized loss on marketable securities	—	—	—	—	—	(134)	—	(134)
Net loss	—	—	—	—	—	—	(32,261)	(32,261)
Balance at June 30, 2024	150,000	$ 140,152	61,095,949	$ 60	$ 1,108,269	$ (617)	$ (1,068,369)	$ 39,343
Balance at December 31, 2022	—	—	56,612,429	56	974,356	(92)	(710,058)	264,262
Stock-based compensation expense	—	—	—	—	6,376	—	—	6,376
Issuance of common stock in connection with ESPP	—	—	32,169	—	665	—	—	665
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	—	—	207,806	—	553	—	—	553
Foreign currency translation adjustment	—	—	—	—	—	21	—	21
Net unrealized gains on short-term investments	—	—	—	—	—	65	—	65
Net loss	—	—	—	—	—	—	(52,179)	(52,179)
Balance at March 31, 2023	—	$ —	56,852,404	$ 56	$ 981,950	$ (6)	$ (762,237)	$ 219,763
Stock-based compensation expense	—	—	—	—	8,891	—	—	8,891
Issuance of common stock in connection with ESPP	—	—		—	—	—	—	—
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	—	—	43,664	1	341	—	—	342
Issuance of common stock upon completion of public offering, net of offering costs	—	—						—
Foreign currency translation adjustment	—	—	—	—	—	(48)	—	(48)
Net unrealized gains on short-term investments	—	—	—	—	—	40	—	40
Net loss	—	—	—	—	—	—	(46,703)	(46,703)
Balance at June 30, 2023	—	$ —	56,896,068	$ 57	$ 991,182	$ (14)	$ (808,940)	$ 182,285

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

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Rhythm Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Three months ended March 31,	
	2024	2023
Operating activities		
Net loss	$ (141,372)	$ (52,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,767	6,376
Depreciation and amortization	405	457
Non-cash interest expense and amortization of debt issuance costs	4,009	3,061
Non-cash accretion & amortization of short-term investments	(2,055)	(2,341)
Unrealized loss on short-term investments	(244)	—
Non-cash accretion of non-current liability	929	—
Non-cash rent expense	111	94

Change in fair value of embedded derivative liability	(490)	(50)
Acquired IPR&D assets classified as investing activities	92,385	5,395
Changes in operating assets and liabilities:		
Accounts receivable	172	(1,893)
Inventory	117	(2,570)
Prepaid expenses and other current assets	(2,421)	2,155
Deferred revenue	—	(6)
Other long-term assets, net	1,195	(99)
Accounts payable, accrued expenses and other liabilities	(1,251)	5,167
Net cash used in operating activities	(40,743)	(36,433)
Investing activities		
Purchases of short-term investments	—	(69,644)
Maturities of short-term investments	70,050	92,675
Acquisition of IPR&D assets	(40,000)	(4,520)
Purchases of property and equipment	—	(47)
Net cash provided by investing activities	30,050	18,464
Financing activities		
Repayment of deferred royalty obligation	(2,783)	(1,351)
Proceeds from the exercise of stock options	6,353	553
Proceeds from issuance of common stock from ESPP	673	665
Net cash provided by (used in) financing activities	4,243	(133)
Effect of exchange rates on cash	(71)	86
Net decrease in cash, cash equivalents and restricted cash	(6,521)	(18,016)
Cash, cash equivalents and restricted cash at beginning of period	60,409	128,005
Cash, cash equivalents and restricted cash at end of period	$ 53,888	$ 109,989
Supplemental disclosure of non-cash investing activities:		
Non-current liability issued in exchange for the acquisition of IPR&D	$ 33,669	$ —
Issuance of common stock in exchange for IPR&D	$ 18,716	$ —

	Six months ended June 30,	
	2024	2023
Operating activities		
Net loss	$ (173,633)	$ (98,882)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	18,125	15,267
Depreciation and amortization	795	899
Non-cash interest expense	7,987	6,194
Non-cash accretion & amortization of short-term investments	(3,562)	(4,299)
Non-cash accretion of non-current liability	1,927	—
Non-cash rent expense	181	192
Change in fair value of embedded derivative liability	(790)	(20)
Gain on settlement of forward contract	(8,900)	—
Acquired IPR&D assets classified as investing activities	92,385	5,650
Changes in operating assets and liabilities:		
Accounts receivable	(2,731)	(7,607)
Inventory	(3,370)	(3,260)
Prepaid expenses and other current assets	287	1,540
Deferred revenue	—	(148)
Other long-term assets, net	2,249	1,123
Accounts payable, accrued expenses and other liabilities	(769)	5,828
Net cash used in operating activities	(69,819)	(77,523)
Investing activities		
Purchases of short-term investments	(66,312)	(145,078)
Maturities of short-term investments	127,800	217,175

Acquisition of IPR&D assets	(40,000)	(5,395)
Purchases of property and equipment	—	(47)
Net cash provided by investing activities	21,488	66,655
Financing activities		
Repayment of deferred royalty obligation	(5,756)	(2,657)
Proceeds from the exercise of stock options	7,755	894
Proceeds from issuance of common stock from ESPP	673	665
Gain on settlement of forward contract	8,900	—
Proceeds from Series A Preferred Stock, net of issuance costs	138,850	—
Net cash provided by (used in) financing activities	150,422	(1,098)
Effect of exchange rates on cash	(372)	(27)
Net increase (decrease) in cash, cash equivalents and restricted cash	101,719	(11,993)
Cash, cash equivalents and restricted cash at beginning of period	60,409	128,005
Cash, cash equivalents and restricted cash at end of period	$ 162,128	$ 116,012
Supplemental disclosure of non-cash investing and financing activities:		
Non-current liability issued in exchange for the acquisition of IPR&D	$ 33,669	$ —
Issuance of common stock in exchange for IPR&D	$ 18,716	$ —
Accretion of preferred stock dividends	$ 1,302	$ —
Holdback payable associated with acquisition of IPR&D assets, in accrued expenses	$ —	$ 500
Transaction costs associated with acquisition of IPR&D assets, in accounts payable	$ —	$ 255

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

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Rhythm Pharmaceuticals, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

(In thousands, except share and per share information)

1. Nature of Business

Rhythm Pharmaceuticals, Inc. (the “Company” or “we”) is a global, commercial-stage biopharmaceutical company dedicated to transforming the lives of patients and their families living with rare neuroendocrine diseases. We are focused on advancing our melanocortin-4 receptor agonists, including our lead asset, IMCIVREE® (setmelanotide), as a precision medicine designed to treat hyperphagia and severe obesity caused by rare MC4R pathway diseases. While obesity affects hundreds of millions of people worldwide, we are developing therapies for a subset of individuals who have hyperphagia, a pathological hunger that leads to abnormal food-seeking behaviors, and severe obesity due to an impaired MC4R pathway, which may be caused by traumatic injury or genetic variants. The MC4R pathway is an endocrine pathway in the brain that is responsible for regulating hunger, caloric intake and energy expenditure, which consequently affect body weight. IMCIVREE, an MC4R agonist for which we hold worldwide rights, is the first-ever therapy developed for patients with certain rare diseases that is approved or authorized in the United States, European Union, and Great Britain, Canada, and other countries and regions.

The Company is a Delaware corporation organized in February 2013 under the name Rhythm Metabolic, Inc., and as of October 2015, under the name Rhythm Pharmaceuticals, Inc. The Company has wholly owned subsidiaries in the US, Ireland, the United Kingdom, the Netherlands, France, Germany, Italy, Spain and Canada.

The Company is subject to risks and uncertainties common to commercial-stage companies in the biotechnology industry, including but not limited to, risks associated with the commercialization of approved products, completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Commercialization of approved products will require significant resources and in order to market IMCIVREE, the Company must continue to build its sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even though the Company has an approved product, and even if the Company's further product development efforts are successful, it is uncertain when, if ever, the Company will realize sufficient revenue from product sales to fund operations.

Liquidity

The Company has incurred operating losses and negative cash flows from operations since inception. As of March 31, 2024 June 30, 2024, the Company had an accumulated deficit of $1,036,108. $1,068,369. The Company has primarily funded these losses through the proceeds from the sales of common and preferred stock, asset sales, royalty financing, out-license arrangements, as well as capital contributions received from the former parent company, Rhythm Holdings LLC. While the Company is generating product revenue, management expects operating losses to continue for the foreseeable future. The Company has devoted substantially all of its resources to its drug development efforts, comprising comprised of research and development, the acquisition of in process research and development assets, manufacturing, conducting clinical trials for its product candidates, protecting its intellectual property, commercialization activities and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations.

At March 31, 2024 June 30, 2024, the Company had $201,199 $319,130 of cash and cash equivalents and short-term investments on hand. On April 1, 2024, the Company entered into an Investment Agreement (the "Investment Agreement") with certain affiliates of Perceptive Advisors LLC ("Perceptive") and certain other investors a life sciences focused institutional investor (each, an "Investor" and collectively, the

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"Investors" collectively, the "Investors"), relating to the issuance and sale of 150,000 shares of a new series of the Company's Series A Convertible Preferred Stock, par value $0.001 per share, titled the "Series A Convertible Preferred Stock" (the "Convertible Preferred Stock"), for an aggregate purchase price of $150,000, $147,750, net of issuance costs of $2,250, or $1,000 per share (the "Issuance"). The Issuance closed on April 15, 2024.

In the future, the Company will be dependent on obtaining funding from third parties, such as proceeds from the issuance of debt, sale of equity, proceeds from out license arrangements, product sales and funded research and development programs to maintain the Company's operations and meet the Company's obligations. There is no guarantee that additional equity or other financings will be available to the Company on acceptable terms, or at all. If the Company fails to obtain additional funding when needed, the Company would be forced to scale back, terminate its operations or seek to merge with or be acquired by another company. Management believes that the Company's existing cash resources together with the proceeds received from the sale of preferred stock in April 2024, will be sufficient to fund the Company's operations through at least the next twelve months from the filing of this Quarterly Report on Form 10-Q with the SEC.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP, and the applicable rules and regulations of the Securities and Exchange Commission, or SEC, regarding interim financial reporting. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification, or ASC, and Accounting Standards

Updates, or ASU, of the Financial Accounting Standards Board, or FASB. As permitted under these rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted.

The accompanying condensed consolidated balance sheet as of March 31, 2024 June 30, 2024, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended March 31, 2024 June 30, 2024 and 2023, the condensed consolidated statements of convertible preferred stock and stockholders' equity for the three and six months ended March 31, 2024 June 30, 2024 and 2023 and the condensed consolidated statements of cash flows for the three six months ended March 31, 2024 June 30, 2024 and 2023 and the related footnote disclosures are unaudited. In management's opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2023 and include all adjustments, which are all normal recurring adjustments, necessary for the fair presentation of the interim financial statements. The results for the three six months ended March 31, 2024 June 30, 2024 are not necessarily indicative of the results expected for the full fiscal year, any other interim periods, or any future year or period.

The accompanying unaudited condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the unaudited condensed consolidated financial statements. As of March 31, 2024 June 30, 2024, there have been no material changes in the Company's significant accounting policies from those that were disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. Significant estimates relied upon in preparing these financial statements include estimates related to determining our net product revenue, license revenue, accruals related to research and development expenses, assumptions used to record stock-based compensation

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expense, interest expense on our deferred royalty obligation, and the valuation allowance on the Company's

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deferred tax assets. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of Rhythm Pharmaceuticals, Inc. and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Reclassification of Prior Year Balances

Certain prior year amounts have been reclassified to conform to the current period presentation. These reclassifications had no effect on the reported results of operations or cash flows. In Specifically, in the condensed consolidated statements of cash flows, the Company reclassified $2,341 $4,299 to non-cash accretion and & amortization of short-term investments from prepaid expenses and other current assets for the three six months ended March 31, 2023 June 30, 2023. The reason for the reclassification was to conform with the current year's presentation.

Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company currently operates in one business segment, which is the development and commercialization of therapies for patients with rare diseases. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. The Company does not operate separate lines of business with respect to its product or product candidates. Accordingly, the Company has one reportable segment.

Off-Balance Sheet Risk and Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents and short-term investments, which are maintained at two federally insured financial institutions. The deposits held at these two institutions are in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

The Company is exposed to risks associated with extending credit to customers related to the sale of products. The Company does not require collateral to secure amounts due from its customers. For the three months ended March 31, 2024 June 30, 2024 and 2023, approximately 74% and 84% of all of the Company's revenue was generated from a single customer in the United States. For the six months ended June 30, 2024 and 2023, approximately 75% and 83%, respectively, of all of the Company's revenue was generated from a single customer in the United States. As of March 31, 2024 June 30, 2024 and December 31, 2023, approximately 72% 66% and 67%, respectively, of the Company's accounts receivable was outstanding from a single customer in the United States.

The Company relies on third-party manufacturers and suppliers for the manufacture and supply of its product. The inability of the suppliers or manufacturers to fulfill supply requirements of the Company could materially impact future operating results. A change in the relationship with the suppliers or manufacturer, or an adverse change in their business, could materially impact future operating results.

The Company relies on separate third parties to perform genetic testing in the United States and Europe, respectively. The inability of the vendor vendors to fulfill testing services for the Company could materially impact future operating results and adversely impact our ability to further develop setmelanotide. A change in the relationship with the genetic testing service providers, or an adverse change in their business, could materially impact future operating results.

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Accounts Receivable, net

Accounts receivable consists of amounts due from customers, net of customer allowances for cash discounts and any estimated expected credit losses. The Company's measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. To date, the Company has not experienced any credit losses. The Company's contracts with its customers have customary payment terms that generally require payment within 90 days. The Company analyzes amounts that are past due for collectability, and periodically evaluates the creditworthiness of its customers. As of March 31, 2024 June 30, 2024 and December 31, 2023, the Company determined an allowance for doubtful accounts was not required based upon our review of contractual payments and our customers' circumstances.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

Product Revenue, net

In the United States (the "U.S."), which accounts for the largest portion of our total revenues, the Company sells its product to a limited number of one specialty pharmacies. pharmacy. The product is distributed through third-party logistics, or 3PL, distribution agent that does not take title to the product. Once the product is delivered to the Company's specialty pharmacy provider, our customer in the U.S., the customer (or "wholesaler") takes title to the product. The wholesaler then distributes the product to patients. In our distribution agreement with the 3PL company, the Company acts as principal because we retain control of the product. Internationally, we make sales primarily to specialty distributors and retail pharmacy chains, as well as hospitals, many of which are government-owned or supported. The Company offers returns of product sold to the customer on a limited basis. basis, however, no material returns have been recognized to date.

Revenue from product sales is recognized when the customer obtains control of our product, which occurs at a point in time, upon transfer of title to the customer because at that point in time we have no ongoing obligations to the customer. There are no other performance obligations besides the sale of product. We classify payments to our customers or other parties in the distribution channel for services that are distinct and priced at fair value as selling, general and administrative expenses in our consolidated statements of operations and comprehensive loss. Otherwise, payments to a customer or other parties in the distribution channel that do not meet those criteria are classified as a reduction of revenue, as discussed further below. Taxes collected from the customer relating to product sales and remitted to governmental authorities are excluded from revenue. Because our payment terms are generally ninety days or less, the Company concluded there is not a significant financing component because the period between the transfer of a promised good or service to the customer and when the customer pays for that good or service will be one year or less. The Company expenses incremental costs of obtaining a contract as and when incurred since the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, or the transaction price, which includes estimates of variable consideration for which reserves are established and which result from discounts, rebates, and co-pay assistance that are offered within contracts between us and our customers, health care providers and other indirect customers relating to the sale of IMCIVREE. These reserves 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 the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is considered probable that a significant reversal

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in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following are the components of variable consideration related to product revenue:

Chargebacks: The Company estimates obligations resulting from contractual commitments with the government and other entities to sell products to qualified healthcare providers and patients at prices lower than the list prices charged to our customers. The government and other entities charge us for the difference between what they pay for the product and the selling price to our customers.

Government rebates: The Company is subject to discount obligations under government programs, including Medicaid programs, Medicare and Tricare in the United States as well as certain government rebates and pricing adjustments in certain international markets that we operate. We estimate Medicaid, Medicare and Tricare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payer mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability that is included in accrued expenses and other current liabilities on our condensed consolidated balance sheets. On a quarterly basis, we update our estimates and record any adjustments in the period that we identify the adjustments.

Trade discounts and allowances: The Company provides customary invoice discounts on IMCIVREE sales to certain of our customers for prompt payment that are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we receive and pay for various distribution services from our customers in the distribution channel. For services that are not distinct from the sale of our product, such fees are classified as a reduction of product revenue.

Product returns: Our customers have limited return rights related to the product's damage or defect. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of revenue and a refund liability in the period the related product revenue is recognized. Based on the distribution model for IMCIVREE, the Company believes there will be minimal returns.

Other incentives: Other incentives include co-payment assistance the Company provides to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue. The estimate is recorded as a reduction of revenue in the same period the related revenue is recognized.

Provisions for cash trade discounts, chargebacks and allowances are recorded as reductions of to accounts receivable, and fees, returns, government rebates, and other incentives are recorded as a component of accrued expenses.

License Agreements

LG Chem

In January 2024, we entered into a license agreement and share issuance agreement with LG Chem, Ltd. ("LGC"). Under the terms of the license agreement, we obtained worldwide rights to develop LGC's proprietary compound LB54640 and will assume assumed sponsorship of two ongoing LGC Phase 2 studies designed to evaluate safety, tolerability, pharmacokinetics and weight loss efficacy of LB54640. The SIGNAL trial is a randomized, placebo-controlled, double-blind study designed to enroll and evaluate approximately 28 patients with acquired hypothalamic obesity. Participants On July 23, 2024, the Company announced that the first patients have been dosed and participants in the SIGNAL trial will receive one of three doses of LB54640 or placebo by oral administration once daily for 14 weeks (patients may continue on open-label therapy for up to 52 weeks, weeks), and the primary endpoint of the study is the change from baseline in body mass index after 14 weeks of treatment. The open-label, single-arm, 16-week ROUTE trial is designed to enroll five patients with POMC or LEPR deficiency obesity.

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We paid LGC $40.0 million in cash and issued shares of our common stock with an aggregate fair value of $18.7 million. The shares were issued at a per share price equal to the ten-day volume weighted-average closing price for our

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common stock, calculated as of the trading day immediately prior to January 4, 2024. We also agreed to make a an additional $40.0 million payment in cash 18 months after the effective date of the license agreement. This payment has been recorded at its present value and reflected in other long-term liabilities on our unaudited condensed consolidated balance sheet.

In addition, under the terms of the license agreement, we agreed to pay LGC up to $205 million in cash upon achieving various regulatory and subject sales milestones based on net sales of LB54640. Subject to the completion of Phase 2 development of LB54640, the Company also has agreed to pay LGC royalties of between low-to-mid single digit percent of net revenues from its MC4R portfolio, including LB54640, commencing in 2029 and dependent upon achievement of various regulatory and indication approvals, and subject to customary deductions and anti-stacking. Royalties may further increase to a low double digit percent royalty, though such royalty would only be applicable on net sales of LB54640 in a region if LB54640 is covered by a composition of matter or method of use patent controlled by LGC in such region and the Company's MC4R portfolio is not covered by any composition of matter or method of use patents controlled by the Company in such region. Such increased rate would only apply on net sales of LB54640 for the limited remainder of the royalty term in the relevant region.

RareStone Group Ltd.

In December 2021, the Company entered into an Exclusive License Agreement with RareStone Group Ltd., or the RareStone License. Pursuant to the RareStone License, we granted to RareStone an exclusive, sublicensable, royalty-bearing license under certain patent rights and know-how to develop, manufacture, commercialize and otherwise exploit any pharmaceutical product that contains setmelanotide in the diagnosis, treatment or prevention of conditions and diseases in humans in China, including mainland China, Hong Kong and Macao. RareStone has a right of first negotiation in the event that the Company chooses to grant a license to develop or commercialize the licensed product in Taiwan. The arrangement includes a license and an additional performance obligation to supply product upon the request of RareStone.

According to the terms of the RareStone License, RareStone has agreed to seek local approvals to commercialize IMCIVREE for the treatment of obesity and hyperphagia due to biallelic POMC, PCSK1 or LEPR deficiency, as well as Bardet-Biedl and Alström syndromes. Additionally, RareStone has agreed to fund efforts to identify and enroll patients from China in the Company's global EMANATE trial, a Phase 3, randomized, double-blind, placebo-controlled trial to evaluate setmelanotide in four independent sub-studies in patients with obesity due to a heterozygous variant of POMC/PCSK1 or LEPR; certain variants of the SRCI gene, and certain variants of the SH2B1 gene. In accordance with the terms of the RareStone License, RareStone made an upfront payment to Rhythm of $7,000 and issued Rhythm 1,077,586 ordinary shares. The Company is eligible to receive development and commercialization milestones of up to $62,500, as well as tiered royalty payments on annual net sales of IMCIVREE.

The Company initially estimated the fair value of the RareStone equity to be $2,440 based on a preliminary valuation during the first quarter of 2022. Upon completion of the valuation procedures during the second quarter of 2022, the Company concluded the initial fair value of the RareStone equity to be $1,040. During the third quarter of 2022, the Company estimated the fair value of the RareStone equity to be de minimis based upon the results of an updated valuation and recorded an other-than-temporary impairment of $1,040 related to the decline in fair value as a component of other expense in our consolidated statements of operations and other comprehensive loss for the year ended December 31, 2022. The other-than-temporary impairment of $1,040 included the reclassification of a $300 unrealized loss previously recorded as a component of accumulated other comprehensive income (loss) in our condensed consolidated statement of stockholders' equity during the second quarter of 2022.

The Company received total upfront consideration of $8,040 comprised of an upfront payment of $7,000, and the estimated fair value of the RareStone equity of $1,040. The Company determined that the RareStone License contains two performance obligations, the delivery of the license and the supply of clinical and commercial product. The Company further determined the supply of commercial product to RareStone contains a significant future discount and estimates the discount to be $1,286, which is recorded as a component of deferred revenue on the consolidated balance sheet at June 30, 2024 and December 31, 2023.

Based on a relative fair-value allocation between the license and the manufacture of clinical and commercial product, the Company recognized $6,754 of license revenue in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2022. The discount related to commercial manufacturing supply

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will be deferred and recognized over the commercial supply period or upon termination of the agreement.No license revenue was recognized during the years three and six months ended December 31, 2023 or 2021. June 30, 2024 and 2023, respectively.

On October 28, 2022, we delivered written notice, or the October Notice, to RareStone that we have terminated the RareStone License for cause. In accordance with the Notice, we maintain that RareStone has materially breached its obligations under the RareStone License to fund, perform or seek certain key clinical studies and waivers, including with respect to our global EMANATE trial, among other obligations. On December 21, 2022, RareStone provided written notice to us that it objects to the claims in the Notice, including our termination of the RareStone License for cause. On March 16, 2023, we provided written notice, or the March Notice, to RareStone reaffirming our position that RareStone has materially breached its obligations under the RareStone License and that we have terminated the RareStone License for cause, and also requested documentation supporting RareStone's purported dispute notice objecting to the claims in the Notice.

On May 10, 2023, RareStone provided written notice to the Company reaffirming its objections to the claims in our October Notice and March Notice, including to the Company's termination of the RareStone License for cause. On November 29, 2023, RareStone wrote to us seeking to negotiate and execute a commercial supply agreement as contemplated under the Exclusive License Agreement, and on January 19, 2024, we responded in writing again reaffirming our position that RareStone has materially breached its obligations under the RareStone License and that we have terminated the RareStone License for cause.

Deferred Royalty Obligation

The Company treats the debt obligation to HealthCare Royalty Management, LLC as discussed further in Note 12, 13, "Long-Term Obligations", as a deferred royalty obligation, amortized using the effective interest rate method over the estimated life of the revenue streams. The Company recognizes interest expense thereon using the effective rate, which is based on our current estimates of future revenues over the life of the arrangement. In connection therewith, the Company periodically assesses its expected revenues using internal projections, imputes interest on the carrying value of the deferred royalty obligation, and records interest expense using the imputed effective interest rate. To the extent the Company's estimates of future revenues are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will account for any such changes by adjusting the effective interest rate on a prospective basis, with a corresponding impact to the reclassification of our deferred royalty obligation. The assumptions used in determining the expected repayment term of the deferred royalty obligation and amortization period of the issuance costs requires the Company to make estimates that could impact the classification of such costs, as well as the period over which such costs will be amortized.

Inventory

Prior to receiving approval from the FDA in November 2020 to sell IMCIVREE in the United States, the Company expensed all costs incurred related to the manufacture of IMCIVREE as research and development expense because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and the lack of history for the Company of regulatory approval of drug candidates. The Company values inventories at the lower of cost or estimated net realizable value. The Company determines the cost of inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. Raw materials and work in process includes all inventory costs prior to packaging and labelling, including raw materials, active pharmaceutical ingredient, and drug product. Finished goods include packaged and labelled products. Raw materials and work in process that may be used for either research and development or commercial sale are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is intended to be used for research and development, it is expensed as research and development once that determination is made.

Cost of Product Sales

Cost of product sales consists of manufacturing costs, transportation and freight, amortization of capitalized intangibles, royalty payments and indirect overhead costs associated with the manufacturing and distribution of IMCIVREE. Cost of product sales may also include periodic costs related to certain manufacturing services and inventory

adjustment charges. Finally, cost of sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Intangible Assets, Net

Definite-lived intangible assets related to capitalized milestones under license agreements are amortized on a straight-line basis over their remaining useful lives, which are estimated to be the remaining patent life. If our estimate of the product's useful life is shorter than the remaining patent life, then a shorter period is used. Amortization expense is recorded as a component of cost of sales on the consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment and finite lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. The Company measures recoverability of assets to be held and used by comparing the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the Company measures the impairment to be recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset, less the cost to sell. No events or changes in circumstances existed to require an impairment assessment during the three and six months ended March 31, 2024 June 30, 2024 and 2023, respectively.

Acquired IPR&D and Milestone Expenses

In an asset acquisition, payments incurred prior to regulatory approval to acquire rights to in-process research and development projects are expensed as acquired IPR&D and recorded as a component of research and development expense in the condensed consolidated statements of operations and comprehensive net loss unless the project has an alternative future use. These costs include upfront and development milestone payments related to licensing arrangements, or other asset acquisitions that provide rights to develop, manufacture and/or sell pharmaceutical products. Where contingent development milestone payments are due to third parties, prior to regulatory approval, the payment obligations are expensed when the achievement of the underlying milestone becomes probable. Regulatory and commercial milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized to cost of products sold over the remaining useful life of the related product.

Foreign Currency Translation

The majority of the Company's operations occurs in subsidiaries that have the U.S. dollar denominated as its functional currency. The assets and liabilities of the Company's subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Revenue and expense amounts for these subsidiaries are translated using the average exchange rates for the period. Changes resulting from foreign currency translation are included in accumulated other comprehensive income (loss) on the Company's consolidated statement of stockholders' equity. Net foreign currency exchange transaction gains (losses), which are included in other (expense) income, net on our consolidated statements of operations, were immaterial for the three and six months ended March 31, 2024 June 30, 2024 and 2023.

Fair Value Measurements

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

Level 1 — Quoted market prices in active markets for identical assets or liabilities.

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Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's cash equivalents and marketable securities and derivative liability at March 31, 2024 June 30, 2024 and December 31, 2023 were carried at fair value, determined according to the fair value hierarchy. See Note 6 for further discussion.

The carrying amounts reflected in the condensed consolidated balance sheets for accounts payable and accrued expenses and other current liabilities approximate their fair values due to their short-term maturities at March 31, 2024 June 30, 2024 and December 31, 2023, respectively.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common shareholders by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per common share is computed by adjusting the weighted average shares outstanding for the potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. For purposes of the diluted net loss per share calculation, stock options, performance stock units and restricted stock units are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share is the same for all periods presented.

The following table includes the potential common shares that were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive for the periods indicated:

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Stock options	7,029,546	6,973,369	7,044,823	6,992,200	7,044,823	6,992,200
Restricted stock units	1,775,146	1,046,232	2,036,409	1,131,632	2,036,409	1,131,632
Performance stock units	—	613,191	—	599,720	—	599,720
Common stock reserved for the conversion of Series A convertible preferred stock			3,125,000	—	3,125,000	—
Potential common shares	8,804,692	8,632,792	12,206,232	8,723,552	12,206,232	8,723,552

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

Application of New or Revised Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. The standard requires disclosure of incremental segment information on an annual and interim basis and allows for multiple measures of a segment's profit or loss provided that one of those measures is

consistent with GAAP. The amendments in this update do not change how a public company identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine its reportable segments,

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but rather requires public entities to provide in interim periods all disclosures about a reporting segment's profit or loss and assets that are currently required annually. ASU 2023-07 becomes effective for the annual period starting on January 1, 2024, and for interim periods starting on January 1, 2025. Early adoption is permitted. The Company is currently evaluating the disclosure requirements related to the new standard but does not anticipate a material impact to its net financial position.

3. Asset Acquisitions

LG Chem, Ltd.

On January 4, 2024, the Company entered into a license agreement and share issuance agreement with LG Chem, Ltd. ("LGC"). Under the terms of the license agreement, the Company obtained worldwide rights to LGC's proprietary compound LB54640 and will assume assumed sponsorship of two ongoing LGC Phase 2 studies designed to evaluate safety, tolerability, pharmacokinetics and weight loss efficacy of LB54640.

The total purchase consideration of $92.4 million was composed of $40.0 million of cash paid at closing and issued shares of the Company's common stock with an aggregate value of $20.0 million. The shares were issued at a per share price equal to the ten-day volume weighted average closing price for our common stock, calculated as of the trading day immediately prior to January 4, 2024. As of January 4, 2024, the fair value of common stock issued was $18.7 million. The total purchase consideration also includes a an additional $40.0 million license fee payable in 18 months, whose present value at closing was $33.7 million, and $0.8 million of transaction costs which are recorded as selling, general and administrative expenses.

In addition, under the terms of the license agreement, we agreed to pay LGC up to $205 million in cash upon achieving various regulatory and sales milestones based on net sales of LB54640. In addition and subject to the completion of Phase 2 development of LB54640, the Company has agreed to pay LGC royalties of between low-to-mid single digit percent of net revenues from its MC4R portfolio, including LB54640, commencing in 2029 and dependent upon achievement of various regulatory and indication approvals, and subject to customary deductions and anti-stacking. Royalties may further increase to a low double digit percent royalty, though such royalty would only be applicable on net sales of LB54640 in a region if LB54640 is covered by a composition of matter or method of use patent controlled by LGC in such region and the Company's MC4R portfolio is not covered by any composition of matter or method of use patents controlled by the Company in such region. Such increased rate would only apply on net sales of LB54640 for the limited remainder of the royalty term in the relevant region.

The assets acquired were In-Process Research and Development (IPR&D) ("IPR&D") assets. However, since the IPR&D assets were determined to have no alternative future use, the Company recognized the $92.4 million of purchase consideration as research and development expense in the three six months ended March 31, 2024 June 30, 2024.

The Company determined that the additional contingent consideration did not meet the definition of a derivative as of the acquisition date. Therefore, the Company did not record a contingent consideration liability on the acquisition date. The Company will recognize any future contingent consideration payments related to the LG Chem LGC transaction in the period in which the achievement of the underlying milestones becomes probable.

Xinvento B.V.

On February 27, 2023, the Company, through its wholly-owned Dutch subsidiary, Rhythm Pharmaceuticals Netherlands B.V., a Dutch private limited liability company ("Rhythm BV"), entered into a Share Purchase Agreement (the "Purchase Agreement") with Xinvento B.V., a Dutch private limited liability company based in the Netherlands ("Xinvento"), and the other parties named therein, pursuant to which, and concurrently with the execution thereof, Rhythm BV acquired all of the issued and outstanding shares of Xinvento. The aggregate consideration at closing was approximately $5,667, inclusive of transaction costs, as adjusted pursuant to the terms of the Purchase Agreement and subject to the distribution and payment terms set forth therein (the "Closing Purchase Price").

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In addition to the Closing Purchase Price, the Purchase Agreement provides for the payment of additional contingent consideration totaling up to $206,000 upon achievement of certain development, regulatory and commercial milestones by Xinvento, as follows: (i) up to an aggregate of $6,000 in clinical development milestones; (ii) up to an aggregate of $125,000 in regulatory approval and commercial milestones; and (iii) up to an aggregate of $75,000 in sales milestones in the event a second molecule is selected, developed and approved.

The total purchase consideration of $5,667 was composed of $4,520 of cash paid at closing, a $500 holdback, paid in the three months ended March 31, 2024, and $647 of acquisition-related costs. The Company determined that substantially all of the value as of acquisition date related to Xinvento's In-Process Research and Development. IPR&D. As a result, the Company determined this transaction should be accounted for as an asset acquisition.

The assets acquired were In-Process Research and Development (IPR&D) IPR&D assets. However, since the IPR&D assets were determined to have no alternative future use, the Company recognized the $5,667 of purchase consideration as research and development expense in the year ended December 31, 2023.

The Company determined that the additional contingent consideration did not meet the definition of a derivative as of the acquisition date. Therefore, the Company did not record a contingent consideration liability on the acquisition date. The Company will recognize any future contingent consideration payments related to the Xinvento transaction in the period in which the achievement of the underlying milestones becomes probable.

Xinvento's results of operations are included in the condensed consolidated financial statements from the date of acquisition. For the three months ended March 31, 2024, the net loss associated with the operations of Xinvento was de minimis in the Company's condensed consolidated statements of operations.

4. Inventory

Inventory consists of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Raw Materials	$ 3,226	$ 4,625	$ 4,145	$ 4,625
WIP	2,541	1,104	1,986	1,104
Finished Goods	2,740	2,895	5,863	2,895
Total Inventory	$ 8,507	$ 8,624	$ 11,994	$ 8,624

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Research and development costs	$ 13,193	$ 12,925	$12,443	$12,925
Professional fees	3,960	3,833	3,945	3,833
Payroll related	7,754	15,439	11,497	15,439
Royalties	1,278	1,180	1,454	1,180
Sales Allowances	10,144	9,475	12,962	9,475
Other	8,202	5,410	5,776	5,410
Accrued expenses and other current liabilities	$ 44,531	$ 48,262	$48,077	$48,262

6. Fair Value of Financial Assets and Liabilities

As of March 31, 2024 June 30, 2024 and December 31, 2023, the carrying amount of cash and cash equivalents and short-term investments was $201,199 $319,130 and $275,846 respectively, which approximates fair value. Cash and cash equivalents and short-term investments includes investments in U.S. treasury securities and money market funds that invest in U.S. government securities that are valued using quoted market prices. Accordingly, money market funds and government funds are categorized as Level 1. The financial assets valued based on Level 2 inputs consist of corporate debt securities and commercial paper, which consist of investments in highly-rated investment-grade corporations.

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short-term investments includes investments in U.S. treasury securities and money market funds that invest in U.S. government securities that are valued using quoted market prices. Accordingly, money market funds and government funds are categorized as Level 1. The financial assets valued based on Level 2 inputs consist of corporate debt securities and commercial paper, which consist of investments in highly-rated investment-grade corporations.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2024 using:				Fair Value Measurements as of June 30, 2024 using:			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents:								
Commercial Paper					$ —	$ 51,230	$ —	$ 51,230
Money market funds	$ 43,028	$ —	$ —	$ 43,028	$98,254	$ —	$ —	$ 98,254
Marketable securities:								
Corporate debt securities and commercial paper	—	147,771	—	147,771	—	157,461	—	157,461
Total	$ 43,028	$ 147,771	$ —	$ 190,799	$98,254	$208,691	$ —	$306,945
Liabilities:								
Derivative liability	$ —	$ —	$ 660	$ 660	$ —	$ —	$ 360	$ 360
Total	$ —	$ —	$ 660	$ 660	$ —	$ —	$ 360	$ 360

	Fair Value Measurements as of December 31, 2023 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Commercial paper	$ —	$ —	$ —	$ —
Money market funds	40,868	4,979	—	45,847
Marketable securities:				
Corporate debt securities and commercial paper	—	215,765	—	215,765
Total	$ 40,868	$ 220,744	$ —	$ 261,612
Liabilities:				
Derivative liability	$ —	$ —	$ 1,150	$ 1,150
Total	$ —	$ —	$ 1,150	$ 1,150

The estimated fair value of the derivative liability related relates to our Royalty Interest Financing Agreement (RIFA) with HealthCare Royalty Partners was determined using Level 3 inputs. The fair value measurement of the derivative liability is sensitive to changes in the unobservable inputs used to value the financial instrument. Changes in the inputs could result in changes to the fair value of each financial instrument.

The embedded derivative liability associated with our deferred royalty obligation, as discussed further in Note 12, 13, "Long-Term Obligations", is measured at fair value using an option pricing Monte Carlo simulation model and is included as a component of the deferred royalty obligation on the condensed consolidated balance sheets. The embedded derivative liability is subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of other (expense) income, net. The assumptions used in the option pricing Monte Carlo simulation model include: (1) our estimates of the probability and timing of related events; (2) the probability-weighted net sales of IMCIVREE, including worldwide net product sales, upfront payments, milestones and royalties; (3) our risk-adjusted discount rate that includes a company specific risk premium; (4) our cost of debt; (5) volatility; and (6) the probability of a change in control occurring during the term of the instrument.

The forward contract associated with our Series A Convertible Preferred Stock, as discussed further in Note 10, "Series A Preferred Stock", is measured at fair value. In order to value the forward contract, a binomial lattice model was used to determine the fair value of the Series A Preferred Stock. The fair value of the forward contract was measured as the difference between the consideration payable of $150,000 and the fair value of the Series A Preferred Stock. The fair value of the forward contract was determined to be $0 at initial issuance and the change in the fair value from initial issuance to settlement of $8,900 was recognized as other income in the condensed consolidated statements of operation for the three and six months ended June 30, 2024. The assumptions used in the binomial lattice model include: (1) the Company's common stock price on the issuance and settlement dates; (2) the Conversion Price as of $48.00 as per the

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	Three months ended March 31,	
	2024	2023
Beginning aggregate estimated fair value of Level 3 liabilities	$ 1,150	$ 1,340
Initial recording of embedded derivative	—	—
Change in fair value of embedded derivative	(490)	(50)
Ending aggregate estimated fair value of Level 3 liabilities	$ 660	$ 1,290

Agreement; (3) a 20-year term to maturity; (4) an estimate of the Company's credit risk-adjusted discount rate; and (5) volatility.

	Six months ended June 30,	
	2024	2023
Beginning aggregate estimated fair value of Level 3 liabilities	$ 1,150	$ 1,340
Change in fair value of embedded derivative	(790)	(20)
Fair value of forward contract - Series A Convertible Preferred Stock	8,900	—
Settlement of forward contract	(8,900)	—
Ending aggregate estimated fair value of Level 3 liabilities	$ 360	$ 1,320

Marketable Securities

The following tables summarize the Company's marketable securities:

	March 31, 2024				June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets								
Corporate debt securities and commercial paper (due within 1 year)	$ 147,742	$ 51	$ (22)	$ 147,771	$157,565	$ 10	$ (115)	$157,460
	$ 147,742	$ 51	$ (22)	$ 147,771	$157,565	$ 10	$ (115)	$157,460

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Assets				
Corporate debt securities and commercial paper (due within 1 year)	$ 215,490	$ 282	$ (7)	$ 215,765
	$ 215,490	$ 282	$ (7)	$ 215,765

7. Right of Use Asset and Lease Liability

The Company has a material operating lease for its head office facility located in Boston, Massachusetts and other immaterial operating leases for certain equipment. On May 2, 2024, the Company entered into an agreement to amend the current operating lease agreement for its head office facility. Under the amendment, the current lease was extended for five years through July 31, 2030, with $5,694 committed to future lease payments. The Company's office lease has a remaining lease term Company acquired Right of 1.3 years. Use Assets of $3.1 million under the amended operating lease.

The Company measured the lease liability associated with the office lease modification using a discount an incremental borrowing rate ("IBR") of 10% at inception. 13%. The Company estimated the incremental borrowing rate IBR for the leased asset based on a range of comparable interest rates the Company would incur to borrow an amount equal to the lease payments on a collateralized basis over a similar term in a similar economic environment. As of March 31, 2024 June 30, 2024, the Company has not entered into any lease arrangements classified as a finance lease.

The Company's corporate headquarters is located in Boston, Massachusetts. This facility houses Rent expense, or operating lease costs, was $272, $606, $291 and $587, for the three and six month periods ended June 30, 2024 and 2023.

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Supplemental cash flow information related to the Company's research, clinical, regulatory, commercial lease for the six months ended June 30, 2024 and administrative personnel. The 2023, includes cash payments of $421 and $413, respectively, used in the measurement of its operating lease liability. As of June 30, 2024, the Company's operating lease agreement commenced May 2019 and liability has a weighted average remaining lease term of six years with a five-year renewal option to extend the lease. The Company has not included the five-year renewal option to extend the lease in its measurement of the right-of-use asset or lease liability. approximately five years.

The following table presents the maturities of the Company's operating lease liability related to office space as of March 31, 2024 June 30, 2024, all of which is under a non-cancellable operating lease:

	Operating Lease	Operating Lease
2024	640	$ 429
2025	502	456
2026		1,103
2027		1,125
2028		1,148
2029		1,171
2030		691
Total operating lease payments	1,142	6,123
Add: imputed interest	(65)	
Less: imputed interest		(2,006)
Total operating lease liability	$ 1,077	$ 4,117

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8. Intangible Assets

	As of March 31, 2024				As of December 31, 2023				As of June 30, 2024			
	Estimated life (years)	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net	Estimated life (years)	Cost	Accumulated Amortization	Net
Capitalized Milestones	11	$9,000	$ (2,185)	$6,815	$9,000	$ (1,972)	$7,028	11	$9,000	$ (2,399)	$6,601

As of March 31, 2024 June 30, 2024, the Company's finite-lived net intangible assets, which totaled $6,815 $6,601 resulted from the capitalization of certain milestone payments made to Ipsen Pharma, S.A.S., or Ipsen, in accordance with the terms of the Company's license

agreement with Ipsen, in connection with the Company's first commercial sale of IMCIVREE in the U.S. in March 2021 and in France in March 2022.

As of March 31, 2024 June 30, 2024, amortization expense for the next five years and beyond is summarized as follows:

2024	$ 641	$ 427
2025	855	855
2026	855	855
2027	855	855
2028	855	855
Thereafter	2,754	2,754
Total	$ 6,815	$6,601

Amortization expense totaled $214, $427, $214, and $214 $428 for the three and six months ended March 31, 2024 June 30, 2024 and 2023, respectively. Amortization expense is included in cost of sales in the condensed consolidated statements of operations and comprehensive loss.

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9. Income Taxes

The Company recorded an income tax provision of approximately $300 $479 and $779 for the three and six months ended March 31, 2024 June 30, 2024. The income tax provision is a result of taxable income from the Company's foreign jurisdictions. The Company did not record an income tax provision for the three or six months ended March 31, 2023 June 30, 2023, as it generated sufficient tax losses during the period. The Company expects to maintain a full valuation allowance against its net deferred tax assets for the year. year ended December 31, 2024.

10. Series A Convertible Preferred Stock

On April 1, 2024, the Company entered into an Investment Agreement (the "Investment Agreement") with certain affiliates of Perceptive Advisors LLC ("Perceptive") and certain other investors (each, an "Investor" and collectively, the "Investors"), relating to the issuance and sale of 150,000 shares of a new series of the Company's Series A Convertible Preferred Stock, par value $0.001 per share, titled the "Series A Convertible Preferred Stock" (the "Convertible Preferred Stock"), for an aggregate purchase price of $147,750, net of $2,250 of issuance costs, or $1,000 per share (the "Issuance"). The Issuance closed on April 15, 2024.

The Company determined the obligation to issue 150,000 shares of Convertible Preferred Stock to Perceptive and Investors in the future at a set price represented a forward contract which was required to be accounted for at fair value. The fair value of the forward contract was measured as the difference between the fair value of the Series A Preferred Stock, as determined using a binomial lattice valuation model, and the consideration payable to the Company. The assumptions used in the binomial lattice model include: (1) the Company's common stock price on the issuance and settlement dates; (2) the Conversion Price as of $48.00 as per the Agreement; (3) a 20-year term to maturity; (4) an estimate of the Company's credit risk-adjusted discount rate; and (5) volatility. The fair value of the forward contract upon issuance was determined to be $0. Upon closing, the value of the forward contract was determined to be $8,900 and the fair value of the Convertible Preferred Stock was determined to be $141,100. The Convertible Preferred Stock was recorded at its fair value on the Issuance and the change in fair value of the forward contract was recorded as other income in its consolidated statement of operations for the three months ended June 30, 2024. Issuance costs of $2,250 were incurred and recorded as a reduction in the carrying value of the Convertible Preferred Stock in the three months ended June 30, 2024.

The Company classifies its Series A Convertible Preferred Stock outside of stockholders' equity as the redemption of such shares is outside the Company's control. The Company did not adjust the carrying values of the Series A Convertible Preferred Stock to redemption value as the shares are not probable of becoming redeemable as of June 30, 2024.

The Convertible Preferred Stock has the following rights and privileges:

Liquidation:

The Series A Preferred Stock will rank senior to the Company's common stock with respect to the distribution of assets upon the Company's liquidation, dissolution or winding up.

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary ("Liquidation"), each holder of Convertible Preferred Stock shall be entitled to receive payment for the greater of (i) 1.75 multiplied by the sum of the Liquidation Preference (i.e., Initial Liquidation Preference of $1,000 per share plus Paid-in-Kind ("PIK") Dividends) plus unpaid Regular Dividends (to the extent such accumulated and unpaid Regular Dividends are not included in such Liquidation Preference) or (ii) the amount such holder would have received if the Series A Preferred Stock were fully converted to common stock. If the assets available for distribution are not sufficient to pay the holders of the Convertible Preferred Stock pursuant to the preceding sentence, the assets will be distributed ratably to the holders of the Convertible Preferred Stock.

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Voting:

Holders of the Convertible Preferred Stock have the right to vote with the holders of common stock on each matter submitted for a vote on an as-converted basis, subject to the terms of the Convertible Preferred Stock as specified in the Amended and Restated Certificate of Designations.

The holders of the Convertible Preferred Stock shall also have certain protective voting rights. Specifically, as long as the Series A Preferred Stock are outstanding, each of the following events require at least a two thirds affirmative vote of the Series A Preferred Stock holders: (a) any amendment or modification of the Certificate of Incorporation to authorize or create, or to increase the authorized number of shares of, any class or series of Dividend Parity Stock, Liquidation Parity Stock, Dividend Senior Stock or Liquidation Senior Stock, (b) any amendment, modification, repeal or waiver of any provision of the Certificate of Incorporation or the Amended and Restated Certificate of Designations that adversely affects the rights, preferences, privileges or powers of the Convertible Preferred Stock, (c) increase or decrease the number of authorized shares of Convertible Preferred Stock or issue additional shares of Convertible Preferred Stock, (d) the Company's consolidation or combination with, or merger with or into, another Person, or any binding or statutory share exchange or involving the Convertible Preferred Stock, in each case unless: (i) the Convertible Preferred Stock either (x) remains outstanding after such consolidation, combination, merger, share exchange or reclassification; or (y) is converted or reclassified into, or is exchanged for, or represents solely the right to receive, preference securities of the continuing, resulting or surviving Person of such consolidation, combination, merger, share exchange or reclassification, or the parent thereof; (ii) the Convertible Preferred Stock that remains outstanding or such preference securities, as applicable, have rights, preferences and voting powers that, taken as a whole, are not materially less favorable to the Holders or the holders thereof, as applicable, than the rights, preferences and voting powers, taken as a whole, of the Convertible Preferred Stock immediately before the consummation of such consolidation, combination, merger, share exchange or reclassification; and (iii) the issuer of the Convertible Preferred Stock that remains outstanding or such preference securities, as applicable, is a corporation duly organized and existing under the laws of the United States of America, any State thereof or the District of Columbia that, if not the Company, will succeed to the Company under the Amended and Restated Certificate of Designations and the Convertible Preferred Stock.

Redemption:

The Company has the right to redeem all Convertible Preferred Stock after the Redemption Trigger Date, which is the fifth anniversary of the Initial Issue Date of April 15, 2024. The amount payable on the redemption date is equal to the Liquidation Preference (i.e., Initial Liquidation Preference of $1,000 per share plus PIK Dividends) plus any unpaid Regular Dividends (to the extent such accumulated and unpaid Regular Dividends are not included in such Liquidation Preference).

If a change of control occurs, each holder shall have the right to require the Company to repurchase all, or any whole number of shares that is less than all, of the holder's Series A Preferred Stock at an amount equal to 1.75 multiplied by the sum of the Liquidation Preference (i.e., Initial Liquidation Preference of $1,000 per share plus PIK Dividends) plus any unpaid Regular Dividends (to the extent such accumulated and unpaid Regular Dividends are not included in such Liquidation Preference). As of June 30, 2024, the Company did not adjust the carrying value of the Series A Preferred Stock to its redemption value, since a change of control was determined to not be probable.

Dividends:

After the second anniversary, dividends on the Convertible Preferred Stock accrue quarterly, at a 6% annual rate, and if not paid out in cash before the quarter end, will become PIK Dividends and added to the liquidation preference, or original issue price plus PIK Dividends. Since dividends do not commence until the second anniversary of the Issuance, the Convertible Preferred Stock is considered increasing rate preferred stock. Accordingly, the Company accretes the dividends, using the effective interest method, from Issuance to the first contractual call date, April 15, 2029. The Company accrued dividends of $1,302 for the three months ended June 30, 2024, as a reduction to Additional Paid-In Capital and an increase to the carrying value of Convertible Preferred Stock. The carrying value of Convertible Preferred Stock as of June 30, 2024 is $140,152.

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Conversions:

Holders of Convertible Preferred Stockhave the option to convert any number of whole shares at any time. The conversion is based on the sum of the Liquidation Preference plus unpaid Dividends divided by the $48.00 Conversion Price. Given the Initial Liquidation Preference of $1,000, each share of Convertible Preferred Stock would be convertible into 20.8333 shares of common stock, prior to any adjustments such as PIK Dividends, unpaid Dividends, stock splits, or voluntary conversion rate increases. Upon conversion, cash will be paid in lieu of any fractional share of common stock. However, based on certain restrictions on the conversion of the Convertible Preferred Stock specified in the Amended and Restated Certificate of Designations, a holder of Convertible Preferred Stock is not entitled to effect a conversion of any portion of its shares of Convertible Preferred Stock, or to vote in its capacity as a holder of shares of Convertible Preferred Stock with respect to matters submitted to holders of the common stock if, after giving effect to such conversion, that holder would beneficially own in excess of 4.99%, in the case of one holder, or 9.99%, in the case of the other holder, of the number of shares of common stock outstanding immediately after giving effect to such exercise.

On May 7, 2024, the Company filed an Amended and Restated Certificate of Designations in respect of the Convertible Preferred Stock containing certain technical amendments to the terms of the Convertible Preferred Stock. The amendments contained in the Amended and Restated Certificate of Designations (x) limited the voting rights of the Convertible Preferred Stock to 24.9438 shares of the Company's common stock per $1,000 liquidation preference of Convertible Preferred Stock and (y) eliminated a 1% step up in the interest rate that otherwise would have applied in the unlikely event that the Company was required to obtain and failed to obtain stockholder approval for certain conversion shares underlying the Convertible Preferred Stock.

On July 10, 2024, the Company filed with the Securities Exchange Commission (the "SEC") a prospectus supplement to the prospectus included in the Company's registration statement on Form S-3ASR filed with the SEC on March 2, 2023, covering the resale from time to time by the Investors of up to an aggregate of 3,124,995 shares of common stock, to satisfy registration rights that the Company granted to such stockholders in connection with the Issuance.

11. Common Stock

As of March 31, 2024 June 30, 2024, an aggregate of 15,285,096 15,747,881 shares of common stock was were reserved for future issuance under the Company's stock plans, including outstanding which number includes stock options, restricted stock units, and performance stock units that have been issued totaling 8,804,692 granted covering 9,081,232 shares of common stock, 150,000 shares of Convertible Preferred Stock potentially convertible into 3,125,000 shares of common stock, and 1,294,531 1,888,797 shares of common stock that remain available for future grants under the Company's 2017 Equity Incentive Plan (the "2017 Plan"), 2017 Employee Stock Purchase Plan. Plan and 2022 Employment Inducement Plan (the "Inducement Plan").

On November 2, 2021, the Company entered into a Sales Agreement with Cowen and Company, LLC ("Cowen"), pursuant to which the Company may issue and sell shares of its common stock, having an aggregate offering price of up to $100.0 million, from time to time through an "at the market" equity offering program under which Cowen acts as sales agent (the "ATM Program"). Between August 10, 2023 and August 21, 2023, the Company sold approximately two million shares of its common stock in the ATM Program for net proceeds of approximately $48.9 million. The Company intends to use the net proceeds from the ATM Program to support its global commercialization efforts for IMCIVREE® (setmelanotide) and clinical development programs in hypothalamic obesity and other rare MC4R pathway diseases.

On February 29, 2024, the Company and Cowen entered into Amendment No. 1 to Sales Agreement (the "Amendment") to increase the aggregate offering price of the shares of Common Stock common stock that may be issued and sold pursuant to the Sales Agreement to $200,000,000 (excluding the aggregate offering price of shares of Common Stock

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common stock issued and sold pursuant to the Sales Agreement prior to February 29, 2024). In connection with the Amendment, on February 29, 2024, the Company filed with the SEC a prospectus supplement, dated February 29, 2024, which, combined with the Base Prospectus (together, the "New Prospectus"), amended the Prior Prospectus in its entirety. The issuances and sales under the Sales Agreement, as amended by the Amendment, will be made pursuant to the Registration Statement and the New Prospectus.

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On January 4, 2024, the Company issued 432,143 shares of common stock as partial consideration for its acquisition of the worldwide rights to LGC's proprietary compound LB54640.

On February 9, 2022, the Company's board of directors adopted the Rhythm Pharmaceuticals, Inc. 2022 Employment Inducement Plan or the Inducement Plan, without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules or Rule 5635(c)(4). In accordance with Rule 5635(c)(4), awards under the Inducement Plan may only be made to a newly hired employee who has not previously been a member of the Company's board of directors, or an employee who is being rehired following a bona fide period of non-employment by the Company or a subsidiary, as a material inducement to the employee's entering into employment with the Company or its subsidiary. An aggregate of 1,000,000 shares of the Company's common stock have been reserved for issuance under the Inducement Plan. The Company will continue continues to grant awards under the 2017 Plan pursuant to the terms thereof.

The exercise price of stock options granted under the Inducement Plan will is not be less than the fair market value of a share of the Company's common stock on the grant date. Other terms of awards, including vesting requirements, are determined by the Company's board of directors and are subject to the provisions of the Inducement Plan. Stock options granted to employees generally vest over a four-year period but may be granted with different vesting terms. Certain options may provide for accelerated vesting in the event of a change in control. Stock options granted under the Inducement Plan expire no more than 10 years from the date of grant. As of the three months ended March

31, 2024 June 30, 2024, 553,889 574,353 stock option awards have been issued under the Inducement Plan. As of March 31, 2024, 281,196 and 344,154 restricted stock unit awards have been granted under the Inducement Plan. As of March 31, 2024 June 30, 2024, 164,915 81,493 shares of common stock are available for future grant under the Inducement Plan.

On January 4, 2024, the Company issued 432,143 shares of common stock as partial consideration for its acquisition of the worldwide rights to LGC's proprietary compound LB54640.

11. 12. Related-Party Transactions

Expenses paid directly to related parties for the three and six months ended March 31, 2024 June 30, 2024 and 2023, were $135 and $322, respectively. immaterial. Outstanding payments due to related parties as of March 31, 2024 June 30, 2024 and December 31, 2023 were $5 and $1, respectively. See also Note 13, "Subsequent Events" for disclosure regarding transactions after March 31, 2024. immaterial.

12. 13. Long-Term Obligations

On June 16, 2022, we entered into a RIFA with entities managed by HealthCare Royalty Management, LLC, collectively referred to as the Investors. Pursuant to the RIFA and subject to customary closing conditions, the Investors have agreed to pay the Company an aggregate investment amount of up to $100,000, or the Investment Amount. Under the terms of the RIFA, we received $37,500 on June 29, 2022 upon FDA approval of IMCIVREE in BBS, referred to as the Initial Investment Amount, and we received an additional $37,500 on September 29, 2022 of the Investment Amount upon EMA approval for BBS. On September 12, 2023, we received the remaining $24,370 of the Investment Amount, net of debt issuance costs, following the achievement of a specified amount of cumulative net sales of IMCIVREE between July 1, 2022 and September 30, 2023.

As consideration for the Investment Amount and pursuant to the RIFA, we agreed to pay the Investors a tiered royalty on our annual net revenues, or Revenue Interest, including worldwide net product sales and upfront payments and milestones. The applicable tiered percentage will initially be 11.5% on annual net revenues up to $125,000, 7.5% on annual net revenues of between $125,000 and $300,000 and 2.5% on annual net revenues exceeding $300,000. If the Investors have not received cumulative minimum payments equal to 60% of the amount funded by the Investors to date by March 31, 2027, or 120% of the amount funded by the Investors to date by March 31, 2029, we must make a cash payment immediately following each applicable date to the Investors sufficient to gross the Investors up to such minimum amounts after giving full consideration of the cumulative amounts paid by us to the Investors through each date, referred to as the Under Performance Payment. As the repayment of the funded amount is contingent upon worldwide net product sales and upfront payments, milestones, and royalties, the repayment term may be shortened or extended depending on actual

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worldwide net product sales and upfront payments, milestones, and royalties. We made repayments of $2,783 $5,758 in the three six months ended March 31, 2024 June 30, 2024. As of March 31, 2024 June 30, 2024 we have made cumulative payments of $10,313. $13,288.

The Investors' rights to receive the Revenue Interests will terminate on the date on which the Investors have received payments equal to a certain percentage of the funded portion of the Investment Amount including the aggregate of all payments made to the Investors as of such date, each percentage tier referred to as the Hard Cap, unless the RIFA is earlier terminated. The total Revenue Interests payable by us to the Investors is capped between 185% and 250% of the Investment Amount paid, dependent on the aggregate royalty paid between 2028 and 2032. If a change of control of occurs,

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the Investors may accelerate payments due under the RIFA up to the Hard Cap plus any other obligations payable under the RIFA.

The repayment period commenced on July 8, 2022 for the Initial Investment Amount, and expires on the earlier of (i) the date at which the Investors received cash payments totaling an aggregate of a Hard Cap ranging from 185% to 250% of the Initial Investment Amount or (ii) the legal maturity date of July 8, 2034. If the Investors have not received payments equal to 250% of the Investment Amount by the twelve-year anniversary of the initial closing date, we will be required to pay an amount equal to the Investment Amount plus a specific annual rate of return less payments previously received by Investors. In the event of a change of control, we are obligated to pay Investors an amount equal to the Hard Cap in effect at the time, ranging from 185% to 250% plus any Under Performance Payment of the Investment Amount less payments previously received by Investors. In addition, upon the occurrence of an event of default, including, among others, our failure to pay any amounts due to Investors under the deferred royalty obligation, insolvency, our failure to pay indebtedness when due, the revocation of regulatory approval of IMCIVREE in the U.S. or our breach of any covenant contained in the RIFA and our failure to cure the breach within the prescribed time frame, we are obligated to pay Investors an amount equal to the Hard Cap in effect at the time of default ranging from 185% to 250% plus any Under Performance Payment of the Investment Amount less payments previously received by Investors. In addition, upon an event of default, Investors may exercise all other rights and remedies available under the RIFA, including foreclosing on the collateral that was pledged to Investors, which consists of all of our present and future assets relating to IMCIVREE.

We have evaluated the terms of the RIFA and concluded that the features are similar to those of a debt instrument. Accordingly, we have accounted for the transaction as long-term debt and presented it as a deferred royalty obligation on our condensed consolidated balance sheets. We have further evaluated the terms of the RIFA and determined that the repayment of the Hard Cap in effect at the time which ranges from 185% to 250% of the Investment Amount, less any payments made to date, upon a change of control is an embedded derivative that requires bifurcation from the debt instrument and fair value recognition. We determined the fair value of the derivative using an option pricing Monte Carlo simulation model taking into account the probability of change of control occurring and potential repayment amounts and timing of such payments that would result under various scenarios, as further described in Note 2, “Summary of Significant Accounting Policies” to our condensed consolidated financial statements. The aggregate fair value of the embedded derivative liability was $660 $360 and $1,150 as of March 31, 2024 June 30, 2024 and December 31, 2023, respectively. We will remeasure the embedded derivative to fair value each reporting period until the time the features lapse and/or termination of the deferred royalty obligation. For the three and six months ended March 31, 2024 June 30, 2024 and 2023, we recognized other income of $490 and $50, respectively, due to the remeasurement of the embedded derivative liability.

The carrying value of the deferred royalty obligation as of March 31, 2024 June 30, 2024 was $107,368 $108,372 based on $100,000 of proceeds, net of the fair value of the bifurcated embedded derivative liability upon execution of the RIFA, and debt issuance costs incurred. The carrying value of the deferred royalty obligation approximated fair value as of March 31, 2024 June 30, 2024 and December 31, 2023. The effective interest rate as of March 31, 2024 June 30, 2024 was 15.15% 14.93%. In connection with the deferred royalty obligation, we incurred debt issuance costs totaling $3,287. Debt issuance costs have been netted against the debt and are being amortized over the estimated term of the debt using the effective interest method, adjusted on a prospective basis for changes in the underlying assumptions and inputs. The assumptions used in determining the expected repayment term of the debt and amortization period of the issuance costs requires that we make estimates that could impact the short and long-term classification of these costs, as well as the period over which these costs will be amortized.

13. Subsequent Events

On April 1, 2024, the Company entered into an Investment Agreement (the “Investment Agreement”) with certain affiliates of Perceptive Advisors LLC (“Perceptive”) and certain other investors (each, an “Investor” and collectively, the

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“Investors”), relating **14. Subsequent Events**

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance and sale of 150,000 shares of a new series of the Company’s Series A Convertible Preferred Stock, par value $0.001 per share, titled the “Series A Convertible Preferred Stock” (the “Convertible Preferred Stock”), financial statements to provide additional evidence for an aggregate purchase price of

$150,000, certain estimates or $1,000 per share (the “Issuance”). The Issuance closed on April 15, 2024. Prior to identify matters that require additional disclosure. Subsequent events have been evaluated as required. No events or transactions occurred subsequent to the closing of the Issuance, certain of the investors and certain of their affiliated entities held over 5% of the Company’s common stock, par value $0.001 per share (the “Common Stock”). balance sheet date that require disclosure.

On May 7, 2024, the Company filed an Amended and Restated Certificate of Designations in respect of the Convertible Preferred Stock containing certain technical amendments to the terms of the Convertible Preferred Stock. The amendments contained in the Amended and Restated Certificate of Designations (x) limited the voting rights of the Convertible Preferred Stock to 24.9438 shares of the Company’s common stock per $1,000 liquidation preference of Convertible Preferred Stock and (y) eliminated a 1% step up in the interest rate that otherwise would have applied in the unlikely event that the Company was required to obtain and failed to obtain stockholder approval for certain conversion shares underlying the Convertible Preferred Stock.

On May 2, 2024, the Company entered into an agreement to amend the current material operating lease agreement for its head office facility located at 222 Berkeley Street in Boston, Massachusetts. Under the amendment, the current lease has been extended for five years through July 31, 2030, with $5,694 committed to future lease payments.

14. 15. Commitments and Contingencies

Legal Proceedings

The Company, from time to time, may be party to various litigation arising in the ordinary course of business. The Company is not presently subject to any pending or threatened litigation that it believes, if determined adversely to the Company, individually, or taken together, would reasonably be expected to have a material adverse effect on its business or financial results.

Other

The Company is party to various agreements, principally relating to licensed technology, that require future payments relating to milestones whose achievement may become probable in subsequent periods, or royalties on future sales of specified products. Additionally, the Company is party to various contracts with CROs and CMOs that generally provide for termination on notice, with the exact amounts in the event of termination to be based on the timing of the termination and the terms of the agreement.

Based on the Company’s current development plans as of March 31, 2024 June 30, 2024, the Company does not expect to make milestone payments due to third parties during the next 12 months from the filing of this Annual Report on Form 10-K, in connection with our license agreements. These milestones are generally recognized in the period in which the achievement of the underlying milestones becomes probable. When the achievement of these milestones or sales have not occurred, such contingencies are not recorded in the Company’s consolidated financial statements.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the “safe harbor” created by those sections. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including without limitation statements regarding: the promise or potential of any of our products or product candidates; the marketing, commercialization, and commercialization sales of IMCIVREE (setmelanotide), and the timing of commercialization; the design, success, cost and timing of our product development activities and clinical trials for setmelanotide and our other product candidates; our ability to obtain regulatory approval for setmelanotide in further indications, as well as for our other product candidates; our financial performance, including

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our expectations regarding our existing cash, operating losses, expenses and sources of future financing; the sufficiency of our cash, cash equivalents and short-term investments to fund our operations; our ability to hire and retain necessary personnel; patient enrollments and the timing thereof; the timing of announcements regarding results of clinical trials; our ability to protect our intellectual property; ongoing activities under and our ability to negotiate our collaboration and license agreements, if needed, and the impact of termination; our marketing, commercial sales, revenue generation, and revenue generation; cost of revenue; expectations surrounding our manufacturing arrangements; the potential financial impact and, the ongoing integration process of Xinvento B.V.; the impact of the current or future economic slowdown conditions on our business and operations and our future financial results; and other statements identified by words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "likely," "plans," "potential," "predicts," "projects," "seeks," "should," "target," "will," "would," or similar expressions and the negatives of those terms are forward-looking statements. These forward-looking statements are neither promises nor guarantees of future performance, and

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are subject to a variety of known and unknown risks, uncertainties, and other important factors, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including but not limited to those set forth in Part II, Item 1A under the heading "Risk Factors" of this Quarterly Report on Form 10-Q. Except as may be required by law, we have no plans to update our forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.

Overview

We are a global, commercial-stage biopharmaceutical company dedicated to transforming the lives of patients and their families living with rare neuroendocrine diseases. We are focused on advancing our melanocortin-4 recptor receptor (MC4R) agonists, including our lead asset, IMCIVREE® (setmelanotide), as a precision medicine designed to treat hyperphagia and severe obesity caused by rare MC4R pathway diseases. While obesity affects hundreds of millions of people worldwide, we are advancing developing therapies for a subset of individuals who have hyperphagia, a pathological hunger that leads to abnormal food-seeking behaviors, and severe obesity due to an impaired MC4R pathway, which may be caused by genetic variants or traumatic injury or genetic variants. injury. The MC4R pathway is an endocrine pathway in the brain that is responsible for regulating hunger, caloric intake and energy expenditure, which consequently affect body weight. IMCIVREE, an MC4R agonist for which we hold worldwide rights, is the first-ever therapy developed for patients with certain rare diseases that is approved or authorized in the United States, European Union (EU), Great Britain, Canada and other countries and regions. IMCIVREE is approved by the U.S. Food and Drug Administration (FDA) for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to: (i) proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1) or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); or (ii) Bardet-Biedl syndrome (BBS). The European Commission (EC) has authorized IMCIVREE for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 2 years of age and above. Great Britain's Medicines & Healthcare Products Regulatory Agency (MHRA) have has authorized IMCIVREE for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. In addition to the United States and Canada, we We have achieved market access for or named patient sales of IMCIVREE for BBS or POMC and LEPR deficiencies, or both, in 14 countries outside the United States, and we continue to collaborate with authorities to achieve access in additional markets.

In addition to initial commercial efforts, we are advancing what we believe is the most comprehensive clinical research program ever initiated in MC4R pathway diseases, with multiple ongoing and planned clinical trials. Our MC4R pathway program is designed to expand the total number of patients who would benefit from setmelanotide therapy or our one of our new drug candidates, RM-718, which is designed to be a more selective MC4R agonist with weekly administration, or LB54640, an investigational oral small molecule MC4R agonist in Phase 2 clinical trials. With setmelanotide, we have completed enrollment in our Phase 3 trial in patients with hypothalamic obesity. Our Phase 3 EMANATE trial, comprised of four independent substudies evaluating setmelanotide in genetically caused MC4R pathway diseases, and our Phase 2 DAYBREAK trial evaluating setmelanotide in additional genetic indications, are ongoing. With RM-718, in March 2024 we initiated a

Phase 1 in-human trials, including a multiple-ascending dose study in patients with hypothalamic obesity, and in July 2024, we announced that we had dosed the first patients in our Phase 2 trial evaluating LB54640 in patients with hypothalamic obesity, and in July 2024, we announced that we had dosed the first patients in our Phase 2 trial evaluating LB54640 in patients with hypothalamic obesity. In our recently completed Phase 3 pediatrics trial in 12 patients between the ages of 2 and younger than 6 with BBS or POMC or LEPR deficiency obesities, setmelanotide achieved the primary endpoint

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with a 3.04 mean reduction in BMI-Z score (a measure of body mass index deviations from what is considered normal) and 18.4 percent mean reduction in BMI. We are seeking regulatory approval in the United States and Europe to expand the label for IMCIVREE to treat patients as young as 2 years of age with these diseases based on these data.

We are leveraging what we believe is the largest known DNA database focused on obesity - with almost 80,000 sequencing samples as of December 31, 2023 - to improve the understanding, diagnosis and care of people living with severe obesity due to certain variants in genes associated with the MC4R pathway. Our sequencing-based epidemiology

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estimates show that each of these genetically-defined MC4R pathway deficiencies are considered rare diseases, according to established definitions based on patient populations. Our epidemiology estimates are approximately 4,600 to 7,500 for U.S. patients in initial FDA-approved indications, including obesity due to biallelic POMC, PCSK1 or LEPR deficiencies,
and BBS. We estimate the epidemiology for patients with hypothalamic obesity to be between 5,000 and 10,000 in the United States, based on our analysis of published literature. Our epidemiology estimates for the indications being studied in our Phase 3 EMANATE trial suggest that approximately 53,000 U.S. patients with one of these genetically driven obesities have the potential to respond well to setmelanotide. Similarly, our epidemiology estimates for patients with genetic indications who demonstrated an initial response in our Phase 2 DAYBREAK trial is approximately 65,300. We believe that all these patients face similar challenges as other patients with rare diseases, namely lack of awareness, resources, tests, tools and, especially, therapeutic options.

We are developing setmelanotide to address additional patients with acquired hypothalamic obesity. In our Phase 2 trial evaluating setmelanotide as a treatment for hypothalamic obesity, as announced in November 2022, 16 of 18 patients achieved the primary endpoint with a body mass index (BMI) decrease greater than 5 percent on setmelanotide therapy, and we observed a 14.5 mean percent reduction in BMI across all patients. Fourteen of these patients transitioned from this Phase 2 trial into our open-label, long-term extension trial and they remain on therapy, as of April 2024. Twelve of these 14 patients had achieved a 25.5% reduction in mean BMI from baseline at one year on setmelanotide therapy. We completed enrollment in the pivotal 120-patient cohort in our Phase 3 clinical trial. Patients with acquired hypothalamic obesity aged 4 years or older were randomized 2:1 to setmelanotide therapy or placebo for a total of 60 weeks, including up to eight weeks for dose titration. The primary endpoint is the percent change in BMI after approximately 52 weeks on a therapeutic regimen of setmelanotide versus placebo. Key secondary endpoints include the proportion of patients who achieve ≥5% reduction in BMI from baseline in adults (≥18) or BMI Z-score reduction of ≥0.2 from baseline in pediatrics after approximately 52 weeks on a therapeutic regimen of compared with placebo, and mean change in the weekly average of the daily most hunger score in patients ≥12 years from baseline after approximately 52 weeks on a therapeutic regimen of setmelanotide versus placebo.

In collaboration with Camurus AB, or Camurus, we had been developing a once-weekly, long-acting formulation of setmelanotide using Camurus' FluidCrystal® technology. As announced in December 2023, we have paused development in favor of advancing RM-718. In March 2024, we communicated results from a Phase 3 switch study of weekly setmelanotide and daily setmelanotide formulations to Camurus. The results showed that pharmacokinetic data were supportive of the feasibility of a weekly formulation of setmelanotide, and data showed that the weekly setmelanotide formulation had similar efficacy and safety profile as the approved formulation for daily injection.

Additional recent clinical, regulatory, corporate and commercial updates include:

On May 7, 2024 August 6, 2024, we announced that approximately 100 new prescriptions for IMCIVREE for Bardet-Biedl syndrome (BBS) BBS were written by U.S. prescribers and that we have had received payor approval for reimbursement for approximately 70 prescriptions during the first quarter of 2024.

On May 3, 2024 we delivered one oral presentation and two posters at The Pediatric Endocrine Society's (PES) Annual Meeting May 2-5, 2024 in Chicago, IL, which highlighted previously disclosed data that showed setmelanotide achieved clinically meaningful weight reduction in pediatric patients with hypothalamic obesity, BBS or POMC and LEPR deficiency obesities.

On April 29, 2024 August 6, 2024, we announced that we dosed the publication of results from our Phase 2 study of setmelanotide for the treatment of hypothalamic obesity first patients in the peer-reviewed journal *The Lancet Diabetes & Endocrinology*. The publication

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highlighted that our global Phase 3 trial evaluating setmelanotide achieved a mean percent reduction in BMI of 15% from baseline (N=18) at 16 weeks of therapy, and preliminary data from Rhythm's long-term extension study showing patients with hypothalamic obesity (n=12) achieved mean BMI reduction of approximately 26% at one year on setmelanotide treatment. obesity.

On March 25, 2024 August 6, 2024, we announced that we completed submission of our supplemental New Drug Application (sNDA) to the U.S. FDA to expand the label of IMCIVREE® (setmelanotide) to treat pediatric patients between the ages of 2 and younger than 6 years old in approved indications.

On July 31, 2024, we announced that the EC expanded the marketing authorization for IMCIVREE to include children as young as 2 years old with obesity due to BBS or POMC, PCSK1, or LEPR deficiency.

On July 23, 2024, we announced that we dosed the first patients had been dosed in our Phase 1 2 clinical trial evaluating LB54640 in hypothalamic obesity.

Effective July 1, 2024, we appointed Alastair "Al" Garfield, Ph.D. to serve as Chief Scientific Officer.

On June 3, 2024, we presented the first patient and caregiver reported experiences from qualitative interviews following the completion of RM-718, our Phase 2 trial that evaluated treatment with setmelanotide in hypothalamic obesity during the Endocrine Society Annual Meeting & Expo (ENDO 2024).

On May 22, 2024, the National Institute for Health and Care Excellence (NICE) in Great Britain issued guidance that recommends IMCIVREE as an investigational, weekly melanocortin-4 receptor (MC4R)-specific agonist designed to be MC1R-sparing option for treating obesity and to potentially avoid hyperpigmentation. the control of hunger (hyperphagia) in patients between 6 years old and younger than 18 with BBS.

We also expect to achieve the following near-term milestones:

- Complete submission of Announce DAYBREAK Stage 2 data during a supplementary New Drug Application (sNDA) to the FDA seeking a label expansion to treat pediatric patients between 2 and younger than 6 years old in approved indications medical meeting in the second quarter half of 2024, and potentially receive EMEA approval in the fourth quarter of 2024;

- Begin dosing patients in the Japanese, 12-patient supplemental cohort of the Phase 3 trial evaluating setmelanotide in hypothalamic obesity in the second quarter of 2024;

- Announce data from stage 2 of the exploratory Phase 2 DAYBREAK study evaluating setmelanotide in certain genetically-caused MC4R pathway diseases in the third quarter of 2024;

- Begin dosing the first patients in the Phase 2 SIGNAL trial evaluating LB54640, an investigational oral small molecule MC4R agonist, in patients with hypothalamic obesity, in the third quarter of 2024. The 28-patient SIGNAL trial is a randomized, placebo-controlled, double-blind study designed to evaluate three dose levels of LB54640. The primary endpoint of the study is the change from baseline in body mass index after 14 weeks of treatment, and patients may continue on therapy for up to 52 weeks;

- Complete enrollment in two or more substudies in the Phase 3 EMANATE trial evaluating setmelanotide in genetically caused MC4R pathway diseases in the second half of 2024;

- Complete the Company's Phase 1 clinical trial of RM-718, an investigational, weekly melanocortin-4 receptor (MC4R)-specific agonist, and announce data from this trial – including data from a planned cohort of patients with hypothalamic obesity - in the first half of 2024; and
- Announce top-line data in the Phase 3 trial evaluating setmelanotide in hypothalamic obesity in the first half of 2025. 2025;

Up until recently, our operations have been limited primarily to conducting research and development activities for setmelanotide. To date, we have not generated sufficient cash flow from product sales and have financed our operations primarily through the proceeds received from the sales of common and preferred stock, royalty interest financing, asset sales, as well as capital contributions from the former parent company, Rhythm Holdings LLC. From August 2015 through August 2017, we raised aggregate net proceeds of $80.8 million through our issuance of series A

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preferred stock. Since our initial public offering, or IPO, on October 10, 2017 and our underwritten follow-on offerings through October 2022, we have raised aggregate net proceeds of approximately $791.5 million through the issuance of our common stock after deducting underwriting discounts, commissions and offering related transaction costs. We also received $100.0 million from the sale of our Rare Pediatric Disease Priority Review Voucher, or PRV, to Alexion Pharmaceuticals, Inc. in February 2021. In June 2022, we entered into the Revenue Interest Financing Agreement ("RIFA"), with entities managed by HealthCare Royalty Partners, collectively referred to as the Investors, and through December 31, 2023 have received cumulative proceeds of $96.7 million, net of certain transaction costs.

IMCIVREE became commercially available to patients 6 years of age and older with obesity due to POMC, PCSK1 or LEPR deficiency in the U.S. in the first quarter of 2021 and patients 6 years of age and older with obesity due to BBS during June 2022. Following marketing authorizations in the EU, and Great Britain and Canada, we are pursuing a country-by-country strategy to establish market access and reimbursement for IMCIVREE in several additional countries. During March 2022, we treated the first patients with IMCIVREE in France under the paid early access program and we treated the first patients with IMCIVREE in Germany during June 2022. We expect to continue to fund our operations through the sale of equity,

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debt financings or other sources. We have built our own marketing and commercial sales infrastructure in the United States and are in the process of building a similar infrastructure in several European markets and the United Kingdom. We may enter into collaborations arrangements with other parties for certain markets outside the United States. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such other arrangements as, and when, needed, we may have to significantly delay, scale back or discontinue the development or commercialization of setmelanotide.

As of March 31, 2024 June 30, 2024 we had an accumulated deficit of $1,036.1 million. $1,068.4 million. Our net loss was $141.4 million $32.3 million and $52.2 million $173.6 million for the three and six months ended March 31, 2024 June 30, 2024 and 2023, respectively. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our expenses may increase in connection with our ongoing activities, as we:

- continue to conduct clinical trials for setmelanotide and our other product candidates;
- engage contract manufacturing organizations, or CMOs, for the manufacture of clinical and commercial-grade setmelanotide;
- seek regulatory approval for setmelanotide for future indications, and for our other product candidates;
- expand our clinical and financial operations and build a marketing and commercialization infrastructure;
- engage in the sales and marketing efforts necessary to support the continued commercial efforts of IMCIVREE globally;
- take into account the levels, timing and collection of revenue earned from sales of IMCIVREE and other products approved in the future, if any; and
- continue to operate as a public company.

As of March 31, 2024 June 30, 2024, our existing cash and cash equivalents and short-term investments were approximately $201.2 $319.1 million. On April 1, 2024 April 15, 2024, we entered into an Investment Agreement with certain investors resulting in the issuance of convertible preferred stock to the certain investors and proceeds to the Company of $150.0 million, as disclosed in Note 13, “Subsequent Events” 10, “Series A Preferred Stock”, to the unaudited condensed consolidated financial statements included under Part I, Item 1 of this Quarterly Report on Form 10-Q.

We expect that our existing cash and cash equivalents and short-term investments as of March 31, 2024, combined with the proceeds received from the April 2024 issuance of convertible preferred stock, June 30, 2024 will be sufficient to fund our operations into 2026.

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Corporate Background

We are a Delaware corporation organized in February 2013 under the name Rhythm Metabolic, Inc., and as of October 2015, under the name Rhythm Pharmaceuticals, Inc.

Financial Operations Overview

Revenue

To date, we have generated approximately $123.4 million $152.5 million in product revenue. Our lead product candidate, IMCIVREE, was approved by the FDA in November 2020 for chronic weight management in adult and pediatric patients six years of age and older with obesity due to POMC, PCSK1 or LEPR deficiency confirmed by genetic testing. IMCIVREE became commercially available in the United States in the first quarter of 2021. We recorded our first sales of IMCIVREE in the United States in March 2021 and we made our first sales in France during March 2022 under the

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paid early access program. IMCIVREE was approval by the FDA and the EC in adult and pediatric patients six years of age and older with obesity due to BBS in June and September 2022, respectively. Following these approvals for BBS, we expect our sales of IMCIVREE will continue to grow as we identify and treat more patients with this disease and obtain reimbursement throughout the international markets in which we operate.

Cost of sales

All of our inventory of IMCIVREE produced prior to FDA approval is available for commercial or clinical use. Most of the manufacturing costs have been recorded as research and development expenses in prior periods. Accordingly, the product cost component related to IMCIVREE included in cost of sales for the three months ended March 31, 2024 and 2023 was insignificant. We expect cost of sales to increase in 2024 as we continue to sell inventory that is produced after we began capitalizing manufacturing costs for IMCIVREE commercial inventory. We expect cost of sales to increase in 2023 as we continue to sell inventory that is produced after we began capitalizing manufacturing costs for IMCIVREE commercial inventory.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery and genetic sequencing efforts, and the clinical development of setmelanotide, which include:

- expenses incurred under agreements with third parties, including CROs that conduct research and development and preclinical activities on our behalf, and the cost of consultants and CMOs that manufacture drug products for use in our preclinical studies and clinical trials;
- employee-related expenses including salaries, benefits and stock-based compensation expense;
- the cost of lab supplies and acquiring, developing and manufacturing preclinical and clinical study materials;
- the cost of genetic sequencing of potential patients in clinical studies;
- facilities, depreciation, and other expenses, which include rent and maintenance of facilities, insurance and other operating costs;
- acquired in process research and development costs associated with the acquisition of Xinvento B.V., or Xinvento in the three months ended March 31, 2023; and
- acquired in process research and development costs associated with the acquisition of LG Chem's Chem, Ltd.'s, or LGC's proprietary compound LB54640 in the three months ended March 31, 2024.

We expense research and development costs to operations as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

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The following table summarizes our current research and development expenses:

Research and development summary	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Research and development expense	$ 128,665	$ 37,945	$30,194	$33,543	$158,858	$71,487

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We are unable to predict the duration and costs of the current or future clinical trials of our product candidates. The duration, costs, and timing of clinical trials and development of setmelanotide, RM-718, LB54640, and a potential therapeutic product candidate for CHI congenital hyperinsulinism (CHI) will depend on a variety of factors, including:

- the scope, rate of progress, and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- the rate of enrollment in clinical trials;
- the safety and efficacy demonstrated by setmelanotide and other product candidates in future clinical trials;
- changes in regulatory requirements;
- changes in clinical trial design; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of our product candidates would significantly change the costs and timing associated with its development and potential commercialization.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our setmelanotide and other development programs progress. However, we do not believe that it is possible at this time to accurately project total program-specific expenses to commercialization and there can be no guarantee that we can meet the funding needs associated with these expenses.

Selling, general and administrative expenses

Selling expenses consist of professional fees related to preparation for the commercialization of setmelanotide, as well as salaries and related benefits for commercial employees, including stock-based compensation. As we further implement and execute our commercialization plans to market setmelanotide in new territories and as we explore new collaborations to develop and commercialize setmelanotide, we anticipate that these expenses will materially increase.

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, relating to our full-time employees not involved in R&D or commercial activities. Other significant costs include rent, legal fees relating to patent and corporate matters and fees for accounting and consulting services.

The following table summarizes our current selling, general and administrative expenses:

Selling, general and administrative summary	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Selling, general and administrative expense	$ 34,382	$ 24,634	$36,415	$30,046	$70,797	$54,674

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We anticipate that our selling, general and administrative expenses will increase in the future to support our continued and expanding commercialization efforts for IMCIVREE in the United States and the European Union as well as increased costs of operating as a global commercial stage biopharmaceutical public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, compliance with local rules and regulations in the United States and foreign jurisdictions, exchange listing and Securities and Exchange Commission, or SEC, expenses, insurance and investor relations costs, among other expenses.

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Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make 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 financial statements, as well as the reported amounts of revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances on an ongoing basis, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the 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 under different assumptions or conditions.

There were no significant changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Results of Operations

Comparison of the three months ended March 31, 2024 June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 June 30, 2024 and 2023, together with the changes in those items in dollars and as a percentage:

Three Months Ended March 31,		Change		Three Months Ended June 30,		Change	
2024	2023	$	%	2024	2023	$	%

	(in thousands)				(in thousands)			
Statement of Operations Data:								
Product revenue, net	$ 25,967	$ 11,469	$ 14,498	126 %	$ 29,078	$ 19,221	$ 9,857	51 %
Costs and expenses:								
Cost of sales	2,807	1,421	1,386	98 %	2,947	2,236	711	32 %
Research and development	128,665	37,945	90,720	239 %	30,194	33,543	(3,349)	(10)%
Selling, general, and administrative	34,382	24,634	9,748	40 %	36,415	30,046	6,369	21 %
Total costs and expenses	165,854	64,000	101,854	159 %	69,556	65,825	3,731	6 %
Loss from operations	(139,887)	(52,531)	(87,356)	166 %	(40,478)	(46,604)	6,126	(13)%
Other income (expense), net	(1,185)	352	(1,537)	(437)%	8,696	(99)	8,795	(8,884)%
Loss before income taxes	(141,072)	(52,179)	(88,893)	170 %	(31,782)	(46,703)	14,921	(32)%
Provision for income taxes	300	—	300	100 %	479	—	479	100 %
Net loss	$ (141,372)	$ (52,179)	$ (89,193)	171 %	$(32,261)	$(46,703)	$14,442	(31)%

Product revenue, net. Product revenue, net increased by $14.5 $9.9 million to $26.0 $29.1 million for the three months ended March 31, 2024 June 30, 2024 from $11.5 $19.2 million for the three months ended March 31, 2023 June 30, 2023, an increase of 126% 51%. We expect our sales of IMCIVREE to continue to increase following the FDA approval for the treatment of patients with BBS in the United States in June 2022 and ten other countries since then. 2022. For the three months ended March 31, 2024 June 30, 2024 and 2023, a substantial amount of our product revenue, or 74% and 83% 84%, respectively, was generated from sales of our product to patients in the United States.

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Cost of sales. Cost of sales increased by $1.4 million $0.7 million to $2.8 million $2.9 million for the three months ended March 31, 2024 June 30, 2024 from $1.4 $2.2 million for the three months ended March 31, 2023 June 30, 2023, an increase of 98% 32%, which was driven by a corresponding increase in revenue in the three months ended March 31, 2024 June 30, 2024. Cost of sales is composed of royalty expense due to Ipsen Pharma S.A.S., or Ipsen, on our net product revenue, amortization of our capitalized sales-based milestone payment made to Ipsen, upon our first commercial sale in the United States and European Union, the cost of product, as well as costs associated with our patient assistance programs. Specifically, the $1.4 million $0.7 million increase in cost of sales in the three months ended March 31, 2024 June 30, 2024 from the same period in 2023 was due to $0.7 million $0.5 million of additional royalties due to our growth in

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sales and $0.7 million $0.2 million attributed to increased product cost associated with higher sales volume. We expect cost of sales as a percentage of product revenue, net to continue to be in a range of 10% to 12% in the foreseeable future.

Research and development expense. Research and development expense increased decreased by $90.7 $3.3 million to $128.7 $30.2 million for the three months ended March 31, 2024 June 30, 2024 from $37.9 $33.5 million for the three months ended March 31, 2023 June 30, 2023, an increase a decrease of 239% 10%. The net increase decrease was primarily due to the following:

- acquired a decrease in process research and development our clinical trial costs associated with the acquisition decreased activity in our long-term extension trial for setmelanotide therapy of LG Chem's proprietary compound LB54640 approximately $1.9 million, decreased activity in our weekly switch trial of $92.4 million $1.1 million, and decreased activity in the three months ended March 31, 2024 our Pathway Phase II trial of $2.0 million; and

- a decrease in our clinical trial costs associated with our Phase 3 EMANATE trial and our Phase 2 DAYBREAK trial, totaling $3.6 million.

The above decreases were partially offset by:

- an increase of $2.3 million $2.0 million in our clinical trial costs associated with increased activity in our Phase 3 hypothalamic obesity trial and $1.9 million associated with our Phase 3 EMANATE trial, as well as RM-718 clinical trial costs for the two clinical trials inherited from LGC in the three months ended March 31, 2024; trial; and

- an increase of $1.1 million due to increased preclinical research costs related to RM-718; and
- an increase of $1.2 million in salaries, benefits and stock-based compensation related to the hiring of additional full-time employees in order to support the growth of our research and development program.

The above increases were partially offset by:

- the purchase of in-process research and development assets of $5.7 million from Xinvento, BV in the three months ended March 31, 2023, which did not recur in the three months ended March 31, 2024.

Selling, general and administrative expense. Selling, general and administrative expense increased by $9.7 million $6.4 million to $34.4 million $36.4 million for the three months ended March 31, 2024 June 30, 2024 from $24.6 million $30.0 million for the three months ended March 31, 2023 June 30, 2023, an increase of 40% 21%. The increase was primarily due to the following:

- an increase of $5.2 million $5.4 million due to increased compensation and benefits related costs associated with additional headcount to support our expanding business operations as well as to establish commercial operations in international regions; and

- an increase of $2.2 million $0.8 million related to professional services costs, including legal, consulting and tax services; and
- an increase of $2.1 million related to costs associated with ongoing sales and marketing activities for IMCIVREE's expansion in the US and international markets. services.

Other income (expense), net. Other income (expense), net decreased increased by $1.6 million $8.8 million to ($1.2) million $8.7 million for the three months ended March 31, 2024 June 30, 2024 from $0.4 million $0.1 million for the three months ended March 31, 2023 June 30, 2023. The decrease increase was primarily due to the following:

- a decrease gain of $8.9 million recognized for the change in fair value of a forward contract recorded with the issuance of convertible preferred stock; and

- an increase in interest income of $0.4 million $0.9 million earned on our short-term investments, based on lower average higher investment balances; balances from the proceeds of $150.0 million from the convertible preferred stock issuance.

The above amounts were partially offset by:

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- recognition of $1.0 million of non-cash interest expense in the three months ended June 30, 2024 associated with accretion of the non-current liability payable to LGC in July, 2025; and

- an increase in non-cash interest expense of $0.8 million $0.7 million related to amortization of debt discount and deferred financing fees associated with our higher deferred royalty obligation balance; balance, based on the receipt of our final $25.0 million sales milestone in the three months ended September 30, 2023.

Comparison of the six months ended June 30, 2024 and 2023

	Six Months Ended June 30,		Change	
	2024	2023	$	%
	(in thousands)			
Statement of Operations Data:				
Product revenue, net	$ 55,045	$ 30,691	$ 24,354	79 %
Total revenues	55,045	30,691	24,354	79 %
Costs and expenses:				
Cost of sales	5,753	3,657	2,096	57 %
Research and development	158,858	71,487	87,371	122 %
Selling, general, and administrative	70,797	54,674	16,123	29 %
Total costs and expenses	235,408	129,818	105,590	81 %
Loss from operations	(180,363)	(99,127)	(81,236)	82 %
Other income (expense), net	7,509	245	7,264	2,965 %
Loss before income taxes	(172,854)	(98,882)	(73,972)	75 %
Provision for income taxes	779	—	779	100 %
Net loss	$ (173,633)	$ (98,882)	$ (74,751)	76 %

Product revenue, net. Product revenue, net increased by $24.3 million to $55.0 million for the six months ended June 30, 2024 from $30.7 million for the six months ended June 30, 2023, an increase of 80%. We expect our sales of IMCIVREE to continue to increase following the FDA approval for the treatment of patients with BBS in the United States in June 2022. During the six months ended June 30, 2024 and 2023, a substantial amount of our product revenue, or 75% and 85%, respectively, has been generated in the United States.

Cost of sales. Cost of sales increased by $2.1 million to $5.8 million for the six months ended June 30, 2024, an increase of 57%. Cost of sales primarily reflects a royalty due to Ipsen, on our net product sales and the amortization of our capitalized sales-based milestone payment made to Ipsen, upon our first commercial sale in the U.S. and EU, the cost of product as well as costs associated with our patient assistance programs. Specifically, the $2.1 million increase in cost of sales for the six months ended June 30, 2024 was due to $1.2 million of additional royalties due to our growth in net product revenue and $0.9 million due to higher product costs from higher net product revenue. We expect cost of sales as a percentage of product revenue, net to be in a range of 10% to 12% in the foreseeable future.

Research and development expense. Research and development expense increased by $87.4 million to $158.9 million for the six months ended June 30, 2024 from $71.5 million for the six months ended June 30, 2023, an increase of 122%. The net increase was primarily due to the following:

- acquired in process research and development costs associated with the acquisition of LGC's proprietary compound LB54640 of $92.4 million in the six months ended June 30, 2024;
- recognition an increase of $0.9 million $2.3 million in salaries, benefits and stock-based compensation related to the hiring of non-cash interest expense additional full-time employees in order to support the three months ended March 31, 2024 growth of our research and development programs;
- an increase of $2.0 million in our clinical trial costs associated with accretion of the non-current liability payable to LGC increased activity in July, 2025. our Phase 3 hypothalamic obesity trial and $1.9 million associated with our RM-718 clinical trial; and

The above amounts were partially offset by:

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- an increase of $1.3 million due to increased gene sequencing costs to support our expanded clinical programs.

The above increases were partially offset by:

- the purchase of in-process research and development assets of $5.7 million from Xinvento in other income the six months ended June 30, 2023, which did not recur in the six months ended June 30, 2024;
- a decrease in our clinical trial costs associated with our Phase 3 EMANATE trial and our Phase 2 DAYBREAK trial, totaling $3.6 million; and
- a decrease of $0.9 million in costs associated with the manufacturing of clinical material.

Selling, general and administrative expense. Selling, general and administrative expense increased by $16.1 million to $70.8 million for the six months ended June 30, 2024 from $54.7 million for the six months ended June 30, 2023, an increase of 29%. The increase was primarily due to the following:

- an increase of $9.3 million due to increased salaries, benefits and stock-based compensation related costs associated with additional headcount to support our expanding business operations as well as to build out our commercial operations in the United States and internationally;
- an increase of $3.0 million related to professional services costs;
- an increase of $2.5 million due to increased costs associated with marketing, data analytics, website and sponsorships; and
- an increase of $1.2 million due to increased costs associated with information technology, international office space, and general corporate travel related expenses for our expanding workforce.

Other income (expense), net. Other (income) expense, net was $7.5 million for the six months ended June 30, 2024 as compared to $0.2 million for the six months ended June 30, 2023.

The increase was primarily due to the following:

- a gain of $8.9 million recognized for the change in fair value of our RIFA a forward contract recorded with the issuance of convertible preferred stock;
- a change in fair value of the embedded derivative in our debt royalty obligation of $0.7 million and realized foreign currency gains of $0.3 million; and
- an increase in interest income of $0.5 million earned on our short-term investments, based on lower higher investment balances from the proceeds of $150.0 million from the convertible preferred stock issuance;

The above amounts were partially offset by:

- recognition of $1.9 million of non-cash interest expense in the six months ended June 30, 2024 associated with accretion of the non-current liability payable to LGC in July, 2025; and
- an increase in non-cash interest expense of $1.5 million related to amortization of debt discount and deferred financing fees associated with our higher deferred royalty obligation balance, based on the receipt of our final $25.0 million sales milestone in the three months ended September 30, 2023.

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Liquidity and Capital Resources

As of March 31, 2024 June 30, 2024, our cash and cash equivalents and short-term investments were approximately $201.2 $319.1 million.

Cash flows

The following table provides information regarding our cash flows for the three six months ended March 31, 2024 June 30, 2024 and 2023:

	Three Months Ended March 31,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Net cash (used in) provided by:				
Operating activities	$ (40,743)	$ (36,433)	$ (69,819)	$(77,628)
Investing activities	30,050	18,464	21,488	66,655
Financing activities	4,243	(133)	150,422	(1,098)
Effect of exchange rates on cash	(71)	86	(372)	(27)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (6,521)	(18,016)	$101,719	(12,098)

Net cash used in operating activities

The use of cash in all periods resulted primarily from our net loss adjusted for non-cash charges and changes in components of operating assets and liabilities.

Net cash used in operating activities was $40.7 $69.8 million for the three six months ended March 31, 2024 June 30, 2024 and consisted primarily of a net loss of $141.4 million $173.6 million adjusted for non-cash items of $102.8 million $108.1 million, which consisted of non-cash stock-based compensation, depreciation and amortization, rent expense and the change in the fair value of our embedded derivative liability, totaling $10.4 million $18.3 million. Our net loss adjusted for non-cash items also includes $92.4 million of acquired In Process Research and Development (IPR&D) assets, which are classified as investing activities. The change in operating assets and liabilities used net cash of approximately $4.3 million, primarily driven by net increases in accounts receivable and inventory of $6.1 million, net decreases in accounts payable and accrued expenses of $0.8 million, offset by net decreases in long-term assets of $2.2 million and net decreases in prepaid expenses of $0.3 million.

Net cash used in operating activities was $77.6 million for the six months ended June 30, 2023 and consisted primarily of a net loss of $98.9 million adjusted for non-cash items of $22.6 million, which consisted of non-cash stock-based compensation, depreciation and amortization, rent expense and the change in the fair value of our embedded derivative liability. Our net loss also includes $5.7 million of acquired IPR&D assets, which are classified as investing activities. The change in operating assets and liabilities used net cash of approximately $2.2 million $6.9 million, primarily driven by net increases in prepaid expenses and other assets of $2.4 million and net decreases in accounts payable and accrued expenses of $1.3 million, offset by a net increase in long-term assets of $1.2 million and decreases in accounts receivable and inventory of $0.3 million.

Net cash used in operating activities was $36.4 million for the three months ended March 31, 2023 and consisted primarily of a net loss of $52.2 million adjusted for non-cash items of $15.3 million, which consisted of non-cash stock-based compensation, depreciation and amortization and rent expense, totaling $9.9 million. Our net loss also included $5.4 million of acquired IPR&D assets, which are classified as investing activities. The change in operating assets and liabilities reflected a total net source of cash of approximately $0.4 million from an increase in accounts payable and accrued expenses of $5.2 million, $5.8 million due to the timing of payments, offset by increases to in accounts receivable and inventory of $4.8 million $10.9 million and a net increase in prepaid expenses and other assets of $1.9 million.

Net cash provided by investing activities

Net cash provided by investing activities was $30.1 million $21.5 million for the three six months ended March 31, 2024 June 30, 2024 and relates to gross maturities of short-term investments of $70.1 million $127.8 million, offset by purchases of short term investments for $66.3 million and cash used for the purchase of LGC's proprietary compound LB54640 for $40.0 million in January 2024.

Net cash provided by investing activities was $18.5 million $66.7 million for the three six months ended March 31, 2023 June 30, 2023 and relates to $92.7 million $217.2 million of maturities of short-term investments, partially offset by $69.6 million $145.1 million of purchases of short-term investments, investments. We also used approximately $5.4 million to acquire Xinvento's IPR&D assets and cash used in $0.1 million to the acquisition purchase of Xinvento, BV of $4.5 million. property plant and equipment.

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Net cash provided by (used in) financing activities

Net cash provided by financing activities was $4.2 million $150.4 million for the three six months ended March 31, 2024 June 30, 2024, and consisted of net proceeds of $7.0 million $147.8 million from the issuance of Series A Preferred Stock as well as proceeds of $8.4 million from the exercise of stock options and the issuance of common stock from our Employee Stock Purchase Plan. These proceeds were offset by $2.8 million $5.8 million of repayments on of our deferred royalty obligation.

Net cash used in financing activities was $0.1 million $1.1 million for the three six months ended March 31, 2023 June 30, 2023, and consisted which comprised of $1.4 million $2.7 million of repayments on of our deferred royalty obligation, partially offset by proceeds $1.6 million of $1.3 million cash proceeds from the exercise of stock options and the issuance of common stock under the from our Employee Stock Purchase Plan.

Funding requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical development of and seek marketing approval for setmelanotide for future indications, continue the clinical development of our other product candidates and build out our global organization. In addition, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. We also expect to incur additional costs associated with operating as a public company.

On April 1, 2024, we entered into an Investment Agreement with certain investors resulting in the issuance of convertible preferred stock to the investors and proceeds to the Company of $150.0 million, as disclosed in Note 13, "Subsequent Events", to the unaudited condensed consolidated financial statements included under Part I, Item 1 of this Quarterly Report on Form 10-Q. 10, "Series A Preferred Stock". We expect that our existing cash and cash equivalents and short-term investments as of the end of March 31, 2024 June 30, 2024, combined with the proceeds received from the April 2024 issuance of convertible preferred stock, will be sufficient to fund our operations into 2026. Our cash and cash equivalents are maintained at financial institutions in amounts that exceed federally-insured limits. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

We may need to obtain substantial additional funding in connection with our research and development activities and any continuing operations thereafter. If we are unable to raise capital when needed or on favorable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Our future capital requirements will depend on many factors, including:

- the cost to continue to commercialize setmelanotide, by building an growing our internal sales force or entering into collaborations with third parties and providing support services for patients;
- the scope, progress, results and costs of clinical trials for our setmelanotide program as well as for RM-718 and LB54640, and in connection with a therapeutic product candidate for CHI;

- the costs, timing and outcome of regulatory review of our setmelanotide program as well as for RM-718 and LB54640, and in connection with a therapeutic product candidate for CHI;
- the costs related to the acquisition, integration, research and development and commercialization efforts related to the acquisition of Xinvento B.V. and any related therapeutic product candidates;
- the obligations owed to Ipsen, Camurus and Takeda Pharmaceutical Company Limited, or Takeda, and LG Chem LGC pursuant to our license agreements;
- the extent to which we acquire or in-license other product candidates and technologies;

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- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain additional collaborations on favorable terms, if at all; and

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- the costs of operating as a public company

Although IMCIVREE has been approved by the FDA in certain indications, and became commercially available in the first quarter of 2021, IMCIVREE may not achieve commercial success. In addition, developing our setmelanotide program is a time-consuming, expensive and uncertain process that may take years to complete, and we may never generate the necessary data or results required to obtain future marketing approvals and achieve product sales. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Further, the global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. All of these factors could impact our liquidity and future funding requirements, including but not limited to our ability to raise additional capital when needed on acceptable terms, if at all. The duration of this economic slowdown is uncertain and the impact on our business is difficult to predict. See “Risk Factors— Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations.”

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, involves agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our setmelanotide program on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future

commercialization efforts or grant rights to develop and market our setmelanotide program that we would otherwise prefer to develop and market ourselves.

ATM program

On November 2, 2021, we entered into a Sales Agreement with Cowen and Company, LLC ("Cowen"), pursuant to which we may issue and sell shares of its our common stock, having an aggregate offering price of up to $100.0 million, from time to time through an "at the market" equity offering program under which Cowen acts as sales agent (the "ATM Program"). Between August 10, 2023 and August 21, 2023, we sold approximately two million shares of our common stock in the ATM Program for net proceeds of approximately $48.9 million.

On February 29, 2024, the Company and Cowen entered into Amendment No. 1 to Sales Agreement (the "Amendment") to increase the aggregate offering price of the shares of Common Stock common stock that may be issued and sold pursuant to the Sales Agreement to $200,000,000 (excluding the aggregate offering price of shares of Common Stock common stock issued and sold pursuant to the Sales Agreement prior to February 29, 2024). In connection with the Amendment, on February 29, 2024, the Company filed with the SEC Securities Exchange Commission a prospectus supplement, dated February 29, 2024, which, combined with the Base Prospectus (together, the "New Prospectus"), amended the Prior Prospectus in its entirety. The issuances and sales under the Sales Agreement, as amended by the Amendment, will be made pursuant to the Registration Statement and the New Prospectus.

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On September 19, 2022, we completed a public offering of 4,800,000 shares of common stock at a price to the public of $26.00 per share. We received $116.9 million in net proceeds after deducting underwriting discounts, commissions and offering expenses. In addition, we granted the underwriters a 30-day option to purchase up to an additional 720,000 shares of its common stock at the price to the public, less underwriting discounts and commissions. On October 18, 2022, we completed the sale of an additional 580,000 shares of common stock at a price to the public of $26.00 per share pursuant to the partial exercise of the underwriters' option to purchase additional shares, for aggregate net proceeds of approximately $14.2 million after deducting underwriting discounts, commissions and offering expenses.

Contractual obligations

As of March 31, 2024 June 30, 2024, apart from additional contractual obligations under our acquisition of Xinvento and LG Chem's LGC's LB54640 as disclosed in Note 3, "Asset Acquisitions", to the unaudited condensed consolidated financial statements included under Part I, Item 1 of this Quarterly Report on Form 10-Q, there were no other material changes to our principal

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contractual obligations and commitments as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As of March 31, 2024 June 30, 2024, there were no material changes to our quantitative and qualitative disclosures about market risks as reported in Part II, Item 7A "Quantitative and Qualitative Disclosures About Market Risks" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

We maintain disclosure controls and procedures (as that term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their cost.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Exchange Act, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2024 June 30, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weakness described below.

Material Weakness in Internal Control

As previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, we identified a material weakness in internal control related to ineffective information technology general controls, or ITGCs, in the areas of user access and program change management over our key accounting and reporting information technology, or IT, system. As a result, the related business process controls (IT application controls and IT-dependent manual controls) that are dependent on the ineffective ITGCs, or that use data produced from the system impacted by the ineffective ITGCs, were also ineffective.

The material weakness identified above did not result in any material misstatements in our financial statements or disclosures, and there were no changes to previously released financial results. Our management concluded that the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, present fairly, in

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all material respects, our financial position, results of operations, and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Remediation of Material Weakness

Our management is committed to maintaining a strong internal control environment. In response to the identified material weakness above, management has taken we have implemented, and intends are continuing to continue implement, measures designed to take comprehensive actions to remediate the material weakness in improve internal control over financial reporting. reporting to remediate the control deficiencies that led to our material weakness.

The Our ongoing remediation actions include: (i) developing and implementing additional training and awareness programs addressing ITGCs and policies, including educating control owners concerning the principles and requirements of each control, with a focus on user access; (ii) increasing the extent of oversight and verification checks included in the operation of user access and program change management controls and processes; (iii) deploying additional tools to

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support administration of user access and program change management; and (iv) enhancing quarterly management reporting on the remediation measures to the Audit Committee of the Board of Directors.

We believe that these actions, when fully implemented, will remediate the material weakness. The weakness will not be considered remediated, however, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We may also conclude that additional measures may be required to remediate the material weakness in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weakness expeditiously.

Changes in Internal Control Over Financial Reporting

During the three months ended June 30, 2024, we continued to implement certain internal controls in connection with remediation efforts related to the material weakness identified in our Annual Report on Form 10-K for the year ended December 31, 2023.

Except as described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described below, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common stock. Additional risks and uncertainties that we currently do not know about or that we currently believe to be immaterial may also impair our business. You should carefully consider the risks described below and the other information in this Quarterly Report on Form 10-Q for the period ended March 31, 2024 June 30, 2024 (the "Quarterly Report"), including our unaudited condensed consolidated financial statements and the related notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Risks Related to Our Financial Position and Need for Capital

We are a commercial stage biopharmaceutical company with a limited operating history and have not generated significant revenue from product sales. We have incurred significant operating losses since our inception, anticipate that we will incur continued losses for the foreseeable future and may never achieve profitability.

We are a commercial stage biopharmaceutical company with a limited operating history on which to base your investment decision. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in February 2013. Our operations to date have been primarily focused on developing and commercializing IMCIVREE® (setmelanotide) to treat patients living with hyperphagia and severe obesity caused by rare MC4R pathway diseases. Our business activities have included acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and conducting research and development activities, including clinical trials, for setmelanotide. To date we have generated approximately $123.0 million $152.5 million of revenue from product sales. In the United States, IMCIVREE is approved for chronic

weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to POMC, PCSK1 or LEPR deficiency as determined by an FDA approved test demonstrating variants in POMC, PCSK1 or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance, or BBS. The EC has authorized IMCIVREE for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. The MHRA authorized setmelanotide for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. Health Canada has approved IMCIVREE for weight management in adult and pediatric patients 6 years of age and older with obesity due to BBS or genetically-confirmed POMC, PCSK1, or LEPR deficiency due to variants interpreted as pathogenic, likely pathogenic, or of uncertain significance. In total, to date we have achieved market access for or named patient sales of IMCIVREE for BBS or POMC and LEPR deficiencies, or both, in 14 countries, and we continue to collaborate with authorities to achieve access in additional markets.

We have not obtained any other regulatory approvals for setmelanotide. We first commercialized IMCIVREE in the U.S. in the first quarter of 2021 and therefore do not have a long history operating as a commercial company. We are continuing to transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not be successful in such transition. We are still at the early stages of demonstrating our ability to manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Since our inception, we have focused substantially all of our efforts and financial resources on the research and development of setmelanotide, which is approved by the FDA and Health Canada and authorized by the EC and the

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MHRA, as noted above, and is in development to address patients affected by several other indications. We have funded our operations to date primarily through the proceeds from the sales of common stock and preferred stock, asset sales, royalty interest financing, as well as capital contributions from our former parent, Rhythm Holdings LLC, and have incurred losses in each year since our inception.

Our net losses were $141.4 million $173.6 million and $52.2 million $98.9 million for the years six months ended March 31, 2024 June 30, 2024 and 2023, respectively. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of $1,036 million $1,068.4 million. Substantially all of our operating losses have resulted from costs incurred in connection with our development programs and from commercial and general and administrative costs associated with our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with our additional clinical trials of setmelanotide, with clinical trials of our product candidates (RM-718, which is designed to be a more selective MC4R agonist with weekly administration, and LB54640, an investigational oral small molecule MC4R agonist now in Phase 2 clinical trials), and with the development of any other product candidates we may choose to pursue, including a product candidate for CHI. In addition, since we have market access for IMCIVREE for BBS or POMC and LEPR deficiencies, or both, in 14 countries, we expect to continue to incur significant sales, marketing and outsourced manufacturing expenses. Nevertheless, setmelanotide may not be a commercially successful drug. We have and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have generated approximately $123.0 million $152.5 million of revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- continue to commercialize setmelanotide by building a commercial organization and/or entering into collaborations with third parties;

- ensure IMCIVREE is available to patients;
- continue to achieve market acceptance of setmelanotide in the medical community and with third-party payors;
- continue to initiate and successfully complete later-stage clinical trials for setmelanotide, RM-718, LB54640, or other product candidates that meet their clinical endpoints;
- continue to initiate and successfully complete all studies required to obtain U.S. and foreign marketing approvals for setmelanotide as a treatment to address patients with deficiencies affecting the MC4R pathway; and
- successfully manufacture or contract with others to manufacture setmelanotide, or RM-718 and LB54640 if approved.

As described above, absent our entering into collaboration or partnership agreements, we have and expect to continue to incur significant sales and marketing, commercialization, and research and development costs. Additionally, as a result of the acquisition of Xinvento B.V., we also expect to devote substantial financial resources to the research and development and potential commercialization of a product candidate for CHI. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate significant product revenue, we will not become profitable and will be unable to continue operations without continued funding.

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We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We are currently in the early stages of commercializing IMCIVREE for chronic weight management in patients with obesity due to BBS, POMC, PCSK1 or LEPR deficiencies in the U.S., Canada, the EU and Great Britain and advancing setmelanotide through clinical development for additional indications in the United States and for potential approvals in other countries. Developing peptide therapeutic products is expensive and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance setmelanotide in additional clinical trials, as well as in connection with research and development activities for setmelanotide, RM-718, and LB54640, and in connection with a product candidate for CHI as a result of the acquisition of Xinvento B.V. We intend to use our available cash resources to advance the clinical development of setmelanotide, for disease-education and community-building activities, patient identification, and commercialization activities related to IMCIVREE. Depending on the status of additional regulatory approvals and commercialization of setmelanotide, as well as the progress we make in sales of IMCIVREE, we may still require significant additional capital to fund the continued development of setmelanotide and our operating needs thereafter, as well as research and development activities for setmelanotide, RM-718, LB54640, and a product candidate for CHI. We may also need to raise additional funds if we choose to pursue additional indications and/or geographies for setmelanotide or otherwise expand more rapidly than we presently anticipate.

From August 2015 through August 2017, we raised aggregate net proceeds of $80.8 million through our issuance of series A preferred stock. In connection with our initial public offering, or IPO, in October 2017 and our underwritten follow-on offerings through December 2023, we raised aggregate net proceeds of approximately $791.5 million through the issuance of our common stock after deducting underwriting discounts, commissions and offering related transaction costs. We received a further $100.0 million from asset sales, specifically in connection with the sale of our Rare Pediatric Disease Priority Review Voucher, or PRV, to Alexion Pharmaceuticals, Inc. In June 2022, we entered into a Revenue Interest Financing Agreement, or RIFA, with HealthCare Royalty Partners for a total investment amount of up to $100.0 million, conditioned upon our achievement of certain clinical development and sales milestones. As of March 31, 2024, we have received $96.7 million of aggregate proceeds, net of debt issuance costs, under the RIFA. We also received $150.0 million $147.8 million in net proceeds under an investment agreement, or the Investment Agreement, with certain affiliates of Perceptive Advisors LLC, or Perceptive, and certain other investors, relating to the issuance and sale of 150,000 shares of a new series of the Company's Series A Convertible Preferred Stock, par value $0.001 per share, titled the "Series A Convertible Preferred Stock", or the Convertible Preferred Stock, for an aggregate purchase price of $150.0 million, or $1,000 per share. As of March 31, 2024 June 30, 2024, our cash and cash equivalents and short-term investments were approximately $201.2 million $319.1 million. We expect that our existing cash and cash equivalents and short-term investments will be sufficient to fund our operations into 2026. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party

funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. We will also require additional capital to obtain additional regulatory approvals for, and to continue to commercialize, setmelanotide, as well as for research and development activities for setmelanotide, RM-718, LB54640, and a product candidate for CHI. Raising funds in the current economic and geopolitical environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to commercialize IMCIVREE and develop setmelanotide, RM-718, LB54640, and a product candidate for CHI. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on

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terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or other third parties at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to setmelanotide or technologies or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of setmelanotide or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially adversely affect our business, financial condition and results of operations.

Our Revenue Interest Financing Agreement with Healthcare Royalty Partners could restrict our ability to commercialize IMCIVREE, limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.

On June 16, 2022, we entered into the RIFA, with entities managed by HealthCare Royalty Management, collectively referred to as the Investors. Pursuant to the RIFA and subject to customary closing conditions, the Investors agreed to pay us an aggregate investment amount of up to $100.0 million, or the Investment Amount. Under the terms of the RIFA, we received $37.5 million on June 29, 2022 upon FDA approval of IMCIVREE in BBS, and an additional $37.5 million on September 29, 2022, following EC marketing authorization for BBS on September 6, 2022. On September 12, 2023, we received the remaining $24.4 million of the Investment Amount, net of debt issuance costs, following the achievement of a specified amount of cumulative net sales of IMCIVREE between July 1, 2022 and September 30, 2023.

As consideration for the Investment Amount and pursuant to the RIFA, we agreed to pay the Investors a tiered royalty on our annual net revenues, or Revenue Interest, including worldwide net product sales and upfront payments and milestones. The applicable tiered percentage will initially be 11.5% on annual net revenues up to $125 million, 7.5% on annual net revenues of between $125 million and $300 million and 2.5% on annual net revenues exceeding $300 million. If the Investors have not received cumulative minimum payments equal to 60% of the amount funded by the Investors to date by March 31, 2027 or 120% of the amount funded by the Investors to date by March 31, 2029, we must make a cash payment immediately following each applicable date to the Investors sufficient to gross the Investors up to such minimum amounts after giving full consideration of the cumulative amounts paid by us to the Investors through each date, referred to as the

Under Performance Payment. As the repayment of the funded amount is contingent upon worldwide net product sales and upfront payments, milestones, and royalties, the repayment term may be shortened or extended depending on actual worldwide net product sales and upfront payments, milestones, and royalties. As of March 31, 2024 June 30, 2024 we have made $10,313 $13,288 of payments, including $2,783 $5,758 in the three six months ended March 31, 2024 June 30, 2024.

The Investors' rights to receive the Revenue Interests will terminate on the date on which the Investors have received payments equal to a certain percentage of the funded portion of the Investment Amount including the aggregate of all payments made to the Investors as of such date, each percentage tier referred to as the Hard Cap, unless the RIFA is earlier terminated. The total Revenue Interests payable by us to the Investors is capped between 185% and 250% of the Investment Amount paid to us, dependent on the aggregate royalty paid between 2028 and 2032. If a change of control of occurs, the Investors may accelerate payments due under the RIFA up to the Hard Cap plus any other obligations payable under the RIFA.

Our obligations under the RIFA could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;

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- limiting our ability to obtain additional financing or enter into IMCIVREE partnership agreements;
- requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital; and
- if we fail to comply with the terms of the RIFA, resulting in an event of default that is not cured or waived, Investors could seek to enforce their security interest in our cash and cash equivalents and all assets relating to IMCIVREE that secures such indebtedness.

To the extent we incur additional debt (including without limitation additional amounts under the RIFA), the risks described above could increase.

Risks Related to the Development of Setmelanotide and Other Product Candidates

Positive results from earlier clinical trials of setmelanotide may not be predictive of the results of later clinical trials of setmelanotide. If we cannot generate positive results in our later clinical trials of setmelanotide, we may be unable to successfully develop, obtain regulatory approval for, and commercialize additional indications for setmelanotide.

Positive results from any of our Phase 1, Phase 2, or Phase 3 clinical trials of setmelanotide, or initial results from other clinical trials of setmelanotide, may not be predictive of the results of later clinical trials. The duration of effect of setmelanotide tested in our Phase 1 and Phase 2 clinical trials was often for shorter periods than in our pivotal Phase 3 clinical trials. The duration of effect of setmelanotide has only been studied in long-term durations for a small number of patients in our Phase 2 and Phase 3 clinical trials and safety or efficacy issues may arise when more patients are studied in longer trials and on commercial drug. It is possible that the effects seen in short-term clinical trials will not be replicated in long-term or larger clinical trials. In addition, not all of our trials demonstrated statistically significant weight loss and there can be no guarantee that future trials will do so.

Positive results observed in one patient population are not necessarily predictive of positive results for other populations. We have demonstrated statistically significant and clinically meaningful reductions in weight and hunger in Phase 3 clinical trials in obesity due to POMC, PCSK1 or LEPR deficiencies and BBS, and believe we have demonstrated proof of concept in Phase 2 clinical trials in impairments due to a variant in one of the two alleles in the *POMC, PCSK1,* or *LEPR* genes (HET obesity), as well as the SRC1 and SH2B1 genes, all genetic

diseases of extreme and unrelenting appetite and obesity. We hypothesize that patients with other upstream genetic variants in the MC4R pathway may also respond with reductions in weight and hunger after treatment with setmelanotide. However, patients with other upstream genetic variants may not have a similar response to setmelanotide, and until we obtain more clinical data in other genetic variants, we will not be sure that we can achieve proof of concept in such populations.

We are actively working to advance additional genetic variants related to the MC4R pathway through our clinical development programs. Our continued development efforts are focused on obesity related to several single gene related, or monogenic, MC4R pathway impairments: BBS; obesity due to a genetic variant in one of the two alleles of the *POMC*, *PCSK1* or *LEPR* gene, or HETs; obesity due to steroid receptor coactivator 1, or SRC1, variants; obesity due to SH2B adapter protein 1, or SH2B1; hypothalamic obesity; and MC4R deficiency obesity. For example, in April 2022 we enrolled the first patient in our pivotal Phase 3 EMANATE clinical trial of setmelanotide. The trial is a randomized, double-blind, placebo-controlled study with four independent sub-studies evaluating setmelanotide in patients with: heterozygous POMC/PCSK1 obesity; heterozygous LEPR obesity; certain variants of the SRC1; or certain variants of SH2B1 genes. Each of the four sub-studies will be entirely independent of the others and, if successful, is designed to support separate regulatory submissions to the FDA and EMA in each studied population. However, the FDA and EMA may not view

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positive results in one sub-study, even if such results are statistically significant and clinically meaningful, as being sufficient for approval for any given indication.

Success in a basket trial, or any trial in one cohort, may not predict success in another cohort. In contrast, in the event of an adverse safety issue, clinical hold, or other adverse finding in one or more cohorts being tested, such event could adversely affect our trials in the other cohorts and may delay or prevent completion of such clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway.

Additionally, setbacks may be caused by new safety or efficacy observations made in clinical trials, including previously unreported adverse events, or AEs. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval or a marketing authorization from the EC or foreign regulatory authorities. If we fail to obtain positive results in our Phase 3 clinical trials of setmelanotide, the development timeline and regulatory approval and commercialization prospects for setmelanotide and, correspondingly, our business and financial prospects, would be materially adversely affected.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published or reported. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and

more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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The exclusive license agreement with LGC is important to our business. If we or LGC fail to adequately perform under the agreement, the development of LB54640 could be delayed, or if we or LGC terminate the agreement, we would lose our rights to develop and commercialize LB54640.

In January 2024, we entered into a license agreement and share issuance agreement with LGC. Pursuant to the terms of the license agreement, we obtained exclusive worldwide rights to develop LGC's proprietary compound LB54640 and assumed sponsorship of two ongoing LGC Phase 2 studies designed to evaluate safety, tolerability, pharmacokinetics and weight loss efficacy of LB54640. In addition and subject to the completion of Phase 2 development of LB54640, we have agreed to pay LGC royalties of between low-to-mid single digit percent of net revenues from our MC4R portfolio, including LB54640, commencing in 2029 and dependent upon achievement of various regulatory and indication approvals, and subject to customary deductions and anti-stacking. Royalties may further increase to a low double digit percent royalty, though such royalty would only be applicable on net sales of LB54640 in a region if LB54640 is covered by a composition of matter or method of use patent controlled by LGC in such region and the Company's MC4R portfolio is not covered by any composition of matter or method of use patents controlled by the Company in such region. Such increased rate would only apply on net sales of LB54640 for the limited remainder of the royalty term in the relevant region. The license agreement will continue until the expiration of the obligation to pay royalties in all countries or regions, unless terminated earlier. We or LGC can terminate the license agreement in certain circumstances, including for the other party's material uncured breach. If the license agreement is terminated, we would lose our rights to develop and commercialize LB54640, and, under some circumstances, we could be subject to certain ongoing payments, penalties and fees, all of which in turn would have a material adverse effect on our business.

The number of patients suffering from each of the MC4R pathway variants we are targeting is small and has not been established with precision. If the actual number of patients is smaller than we estimate, our revenue and ability to achieve profitability may be materially adversely affected.

Due to the rarity of our target indications, there is no comprehensive patient registry or other method of establishing with precision the actual number of patients with MC4R pathway deficiencies. As a result, we have had to rely on other available sources to derive clinical prevalence estimates for our target indications. In addition, we have internal genetic sequencing results from individuals with severe obesity that provide another approach to estimating prevalence. As of March 31, 2024June 30, 2024, our database had approximately 80,000 sequencing samples. Since the published epidemiology studies for these genetic variants are based on relatively small population samples, and are not amenable to robust statistical analyses, it is possible that these projections may significantly exceed the addressable population, particularly given the need to genotype patients to definitively confirm a diagnosis.

Based on multiple epidemiological methods, we have estimated the potential addressable patient populations with these MC4R pathway deficiencies based on the following sources and assumptions:

- *POMC Deficiency Obesity*. POMC Deficiency Obesity is defined by the presence of biallelic variants in the *POMC* or *PCSK1* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance. Our addressable patient population estimate for POMC deficiency obesity is approximately 100 to 500 patients in the United States, with a comparable addressable patient population in Europe. Our estimates are based on:
    - approximately 50 patients with POMC deficiency obesity noted in a series of published case reports, each mostly reporting a single or small number of patients. However, we believe our addressable patient population for this deficiency may be approximately 100 to 500 patients in the United States, and a comparable addressable patient population in Europe, as most of the reported cases are from a small number of academic research centers, and because genetic testing for POMC deficiency obesity is often unavailable and currently is rarely performed;
    - our belief, based on discussions with experts in rare diseases, that the number of diagnosed cases could increase several-fold with increased awareness of this deficiency and the availability of new treatments;

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- U.S. Census Bureau figures for adults and children, and Centers for Disease Control and Prevention, or CDC, prevalence numbers for adults with severe obesity (body mass index, or BMI, greater than 40 kg/m$_2$) and for children with severe early-onset obesity (99th percentile at ages two to 17 years old); and
- our internal sequencing yield for POMC deficiency obesity patients (including both *POMC* and *PCSK1* gene diseases), defined as patients having biallelic variants in the *POMC* or *PCSK1* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance, of approximately 0.05%.

- *LEPR Deficiency Obesity*. LEPR Deficiency Obesity is defined by the presence of biallelic variants in the *LEPR* gene that are interpreted as pathogenic, likely pathogenic, or of uncertain significance. Our addressable patient population estimate for LEPR deficiency obesity is approximately 500 to 2,000 patients in the United States, with a comparable addressable patient population in Europe. Our estimates are based on:
    - epidemiology studies on LEPR deficiency obesity in small cohorts of patients comprised of children with severe obesity and adults with severe obesity who have a history of early onset obesity;
    - U.S. Census Bureau figures for adults and children and CDC prevalence numbers for adults with severe obesity (BMI, greater than 40 kg/m$_2$) and for children with severe early-onset obesity (99th percentile at ages two to 17 years old);
    - with wider availability of genetic testing expected for LEPR deficiency obesity and increased awareness of new treatments, our belief that up to 40% of patients with these diseases may eventually be diagnosed; and
    - our internal sequencing yield for LEPR deficiency obesity patients, defined as patients having biallelic variants in the *LEPR* gene that are interpreted as pathogenic, likely pathogenic, or of uncertain significance, of approximately 0.09%.
- *Bardet-Biedl Syndrome*. Our addressable patient population estimate for BBS is approximately 4,000 to 5,000 patients in the United States based on:
    - published prevalence estimates of one in 100,000 in North America, which projects to approximately 3,250 people in the United States. We believe the majority of these patients are addressable patients;
    - comparisons to our patient identification efforts in Europe where we believe there are approximately 1,500 patients diagnosed and being cared for at academic centers in Europe;
    - our patient identification efforts to date in the United States;
    - our internal sequencing yield for biallelic pathogenic or likely pathogenic variants in BBS genes of approximately 0.3%; and
    - our belief that with wider availability of genetic testing expected for BBS and increased awareness of new treatments, the number of patients diagnosed with this disorder will increase.

- *POMC, PCSK1, or LEPR Heterozygous Obesities; SRC1 and SH2B1 Obesities*. Our potential setmelanotide-responsive patient population estimate for POMC, PCSK1, or LEPR heterozygous, SRC1 and SH2B1 obesity patients with at least one variant interpreted as pathogenic, likely pathogenic, or of uncertain significance suspected pathogenic is approximately 53,000 patients in the United States. Our estimates are based on:
    - U.S. Census Bureau population data and CDC prevalence numbers for early onset obesity (120% the 95th percentile between the ages of 2-5 years);
    - our internal sequencing yield of patients with POMC, PCSK1, or LEPR heterozygous, SRC1 or SH2B1 variants interpreted as pathogenic, likely pathogenic, or of uncertain significance of approximately 10-15%; and
    - a clinical response rate of 40% for patients carrying pathogenic or likely pathogenic variants, and 20% for patients carrying a variant of uncertain significance.

The clinical response rate used in this calculation is based on the clinical data currently available to us from our trials and may change as more data become available.

- *MC4R Deficiency Obesity*. Our addressable patient population estimate for MC4R-rescuable deficiency obesity is approximately 10,000 patients in the United States. This estimate is based on:
    - U.S. Census Bureau population data and CDC prevalence numbers for early onset obesity (120% the 95th percentile between the ages of 2-5 years);
    - a comprehensive ongoing biochemical screening study indicating there may be a defined subset of individuals who carry MC4R variants that may be rescued by an MC4R agonist; and
    - our internal sequencing yield for MC4R deficiency obesity patients of approximately 2.0% prior to application of functional filters.
- *Hypothalamic obesity*. Our addressable patient population estimate for hypothalamic obesity (HO) is 5,000 to 10,000 patients in the United States. This estimate is based on:
    - diagnosis of an underlying HO etiology such as craniopharyngioma (CP), astrocytoma, or other brain tumors with CP accounting for approximately 50% of HO etiologies;
    - an annual incidence of CP of approximately 1.3 to 2.2 per million per year in the United States, which projects to approximately 600 cases of CP per year based on a United States population of approximately 329 million;
    - approximately 50% (based on a published range of 6% to 91%) of CP patients develop HO;
    - published estimates of overall survival (OS) after CP diagnosis, with a 20-year OS of 84%;
    - allowing for patients that develop HO due to other factors besides CP, results in an estimated HO prevalence after CP diagnosis in the United States exceeding 2,500-7,500 patients; and
    - internal Company estimate is based on reported incidence of hypothalamic obesity following CP and long-term survival rates.

- Obesity due to a deficiency in the MC4R pathway caused by variants in the SEMA3 family, PHIP, TBX3 or PLXNA family. Our addressable patient population estimate for obesity patient with variants in these genes is approximately 63,500 patients in the United States. This estimate is based on:

- results from our URO genetic testing program with samples from more than 36,000 participants, classification of variants for pathogenic, likely pathogenic and 20% of with a variant of uncertain significance and applied to established estimate of approximately 5 million people in the US with early-onset obesity.

We believe that the patient populations in the EU are similar to those in the United States. However, we do not have comparable epidemiological data from the EU and these estimates are therefore based solely on applying relative population percentages to the Company-derived estimates described above.

Defining the exact genetic variants that result in MC4R pathway diseases is complex, so if any approval that we obtain is based on a narrower definition of these patient populations than we had anticipated, then the potential market for setmelanotide for these indications will be smaller than we originally believed. In either case, a smaller patient population in our target indications would have a materially adverse effect on our ability to achieve commercialization and generate revenues.

If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of additional marketing approvals could be delayed or prevented.

We may not be able to initiate or continue our planned clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, including general obesity, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there are limited patient pools from which to draw for clinical studies. In addition to the rarity of genetic diseases of obesity, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or future product candidates being investigated for the indications we are investigating;

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- clinicians' willingness to screen their patients for genetic markers to indicate which patients may be eligible for enrollment in our clinical trials;
- delays in or temporary suspension of the enrollment of patients in our planned clinical trial due to public health emergencies;
- ability to obtain and maintain patient consents;
- patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion, including as a result of health conditions or being forced to quarantine, or, because they may be late-stage cancer patients or for other reasons, will not survive the full terms of the clinical trials.

In addition, the pediatric population is an important patient population for setmelanotide, RM-718, and LB54640, and our addressable patient population estimates include pediatric populations. However, it may be more challenging to conduct studies in younger participants, and to locate and enroll pediatric patients. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may also result in increased development costs for setmelanotide and any future product candidates and jeopardize our ability to obtain additional marketing approvals for the sale of setmelanotide. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

Failures or delays in the commencement or completion of our planned clinical trials of setmelanotide, RM-718, or LB54640 could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

Successful completion of our ongoing and planned clinical trials is a prerequisite to submitting an NDA or NDA supplement to the FDA, an MAA to the EMA, and other applications for marketing authorization to equivalent competent authorities in foreign jurisdictions, and consequently, successful completion of such trials, at a minimum, will be required for regulatory approvals and the commercial marketing of setmelanotide for additional indications as well as RM-718 and LB54640.

We do not know whether our planned clinical trials will begin or whether any of our clinical trials will be completed on schedule, if at all, as the commencement and successful completion of clinical trials can be delayed or prevented for a number of reasons, including but not limited to:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;
- delays in the completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- the FDA or other equivalent competent authorities in foreign jurisdictions may deny permission to proceed with our ongoing or planned trials or any other clinical trials we may initiate, or may place a clinical trial on hold or be suspended;

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- delays in filing or receiving authorization to proceed under an additional investigational new drug application, or IND, or similar foreign application if required;
- delays in reaching a consensus with the FDA and other regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulties in obtaining Institutional Review Board, or IRB, and/or ethics committee approval or opinion to conduct a clinical trial at a prospective site or sites;
- since many already diagnosed patients are at academic sites, delays in conducting clinical trials at academic sites due to the particular challenges and delays typically associated with those sites, as well as the lack of alternatives to these sites which have already diagnosed patients;

- inadequate quantity or quality of setmelanotide, RM-718, LB54640 or other materials necessary to conduct clinical trials, including delays in the manufacturing of sufficient supply of finished drug product;
- challenges in identifying, recruiting and training suitable clinical investigators;
- challenges in recruiting and enrolling suitable patients to participate in clinical trials;
- severe or unexpected drug related side effects experienced by patients in a clinical trial, including side effects previously identified in our completed clinical trials;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements, or GCPs, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with setmelanotide, RM-718 or LB54640 that are viewed to outweigh their potential benefits, or occurrence of adverse events in trial of the same or similar class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;

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- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates; and
- development of antibodies to the drug or adjuvants may result in loss of efficacy or safety events.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other equivalent competent authorities in foreign jurisdictions, the IRB at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board, or DSMB, or Safety Monitoring Committee, or SMC, overseeing the clinical trial at issue or other equivalent competent authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other equivalent competent authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical trial supply materials; and
- lack of adequate funding to continue the clinical trial.

Delays in the completion of any preclinical studies or clinical trials of setmelanotide, RM-718 or LB54640 will increase our costs, slow down our product candidate development and the regulatory approval processes and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of a regulatory approval for setmelanotide, RM-718 or LB54640. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to

commercialize setmelanotide, RM-718 or LB54640, in each case if approved, and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state in which the clinical takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are

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ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the United Kingdom (UK) will seek to align its regulations with the EU. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations are aligned with the CTR. A decision by the UK not to closely align its regulations with the new approach adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Setmelanotide, RM-718 or LB54640 may cause undesirable side effects that could delay or prevent additional regulatory approvals, limit the commercial profile of approved labeling, or result in significant negative consequences following marketing approval.

First generation MC4R agonists were predominantly small molecules that failed in clinical trials due to significant safety issues, particularly increases in blood pressure, and had limited efficacy. Undesirable side effects caused by setmelanotide, RM-718 or LB54640 could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive labeling or the delay or denial of additional regulatory approvals by the FDA or other equivalent competent authorities in foreign jurisdictions. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may adversely affect our business, financial condition and prospects significantly.

Setmelanotide, RM-718 and LB54640 are MC4R agonists. Potential side effects of MC4R agonism, which have been noted either with setmelanotide or with other MC4R agonists in clinical trials and preclinical studies, may include:

- adverse effects on cardiovascular parameters, such as increases in heart rate and blood pressure;

- erections in males and similar effects in women, such as sexual arousal, clitoral swelling and hypersensitivity;
- nausea and vomiting;
- reduced appetite;
- headache;
- effects on mood, depression, anxiety and other psychiatric manifestations; and
- other effects, for which most investigators reported as unrelated to setmelanotide and for which no increased incidence or pattern is currently evident.

In addition, injection site reactions have been seen in subcutaneous, or SC, injections with setmelanotide. Also, setmelanotide has likely off target effects on the closely related MC1 receptor, which mediates tanning in response to sun exposure. Other MC1 receptor mediated effects include darkening of skin blemishes, such as freckles and moles, and hair color change. The cosmetic effects are not tolerated by all patients, as a small number of patients have withdrawn from treatment due to skin darkening. These effects have generally been reversible in clinical trials after discontinuation of setmelanotide, but it is still unknown if they will be reversible with long term exposure. The MC1 receptor mediated effects

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may also carry risks. The long term impact of MC1 receptor activation has not been tested in clinical trials, and could potentially include increases in skin cancer, excess biopsy procedures and cosmetic blemishes. These skin changes may also result in unblinding, which could make interpretation of clinical trial results more complex and possibly subject to bias. We have also initiated trials of setmelanotide in potential new indications that include patients who might have more serious underlying conditions. It is possible that the underlying conditions in these patients, such as congestive heart failure and potentially other conditions, may confound the understanding of the safety profile of setmelanotide.

If these or other significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may also suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude setmelanotide, RM-718 or LB54640 from obtaining or maintaining marketing approval or obtaining additional approvals, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially adversely affect our business, financial condition and prospects.

Further, if we or others identify undesirable side effects caused by the products, or any other similar product, before or after regulatory approvals, a number of potentially significant negative consequences could result, including:

- regulatory authorities may request that we withdraw the product from the market or may limit or vary their approval of the product through labeling or other means;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- the FDA, the EU competent authorities and other equivalent competent authorities in foreign jurisdictions may require the addition of a Risk Evaluation and Mitigation Strategy, or REMS, or other specific obligations as a condition for marketing authorization due to the need to limit treatment to rare patient populations, or to address safety concerns;
- we may be required to change the way the product is distributed or administered or change the labeling of the product;
- we may be required to conduct additional studies and clinical trials or comply with other post-market requirements to assess possible serious risks;

- we may be required to conduct long term safety follow-up evaluations, including setting up disease and drug based registries;
- we may decide to remove the product from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of setmelanotide, RM-718 or LB54640, and could substantially increase the costs of commercializing setmelanotide, RM-718 or LB54640 and significantly impact our ability to successfully commercialize setmelanotide, RM-718 or LB54640 and generate revenues.

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We may not be able to obtain or maintain orphan drug designations for setmelanotide, RM-718 or LB54640 or to obtain or maintain exclusivity in any use. Even with exclusivity, competitors may obtain approval for different drugs that treat the same indications as setmelanotide, RM-718 and LB54640.

The FDA may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, or the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is defined under the Federal Food, Drug and Cosmetic Act, or FDCA, as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of seven years of marketing exclusivity, which precludes the FDA from approving another marketing application for a product that constitutes the same drug treating the same disease or condition for that marketing exclusivity period, except in limited circumstances.

The exclusivity period in the United States can be extended by six months if the NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. Orphan drug exclusivity may be revoked if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Other potential benefits of orphan drug designation and/or approval of a designated drug include eligibility for: exemption from certain prescription drug user fees, tax credits for certain qualified clinical testing expenses, and waivers from the pediatric assessment requirements of the Pediatric Research Equity Act.

In the EU, orphan designation is granted by the EC based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products. A medicinal product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than 5 in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for marketing authorization.

Grant of orphan designation by the EC also entitles the holder of this designation to financial incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. In addition to a range of other benefits during the development and regulatory review, orphan medicinal products are, upon grant of marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, entitled to ten years of exclusivity in all EU member states for the approved therapeutic indication, which means that the competent authorities cannot accept another MAA, grant a marketing authorization, or accept an application to extend a marketing authorization for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan

indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity, or where the prevalence of the condition has increased above the threshold. Additionally granting of an authorization for another similar orphan medicinal product where another product has market exclusivity can happen at any time: (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant cannot supply enough orphan medicinal product or (iii) where the applicant consents to a second orphan medicinal product application.

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In connection with IMCIVREE's approval, the FDA granted us seven years of orphan drug exclusivity for setmelanotide for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to POMC, PCSK1, or LEPR deficiency confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance. The FDA also granted us seven years of orphan drug exclusivity for setmelanotide for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to BBS. In the EU, we obtained ten years of market exclusivity for setmelanotide for the treatment of obesity and the control of hunger associated with genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic leptin receptor (LEPR) deficiency in adults and children 6 years of age and above.

We have also been granted orphan designation for setmelanotide for the treatment of Alström syndrome in both the United States and the EU. Setmelanotide has also been granted orphan designation for setmelanotide in treating Prader-Willi syndrome and acquired hypothalamic obesity in the EU. There can be no assurance that we will be able to maintain the benefits orphan drug exclusivity, or that the FDA or the EC will grant orphan designations for setmelanotide for other uses. In addition, orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Even though we have obtained orphan drug exclusivity for certain uses of setmelanotide, such exclusivities may not effectively protect setmelanotide from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. As discussed above, similar rules apply in the EU.

Although we have obtained PRIME designation in the EU for setmelanotide for the treatment of obesity and the control of hunger associated with deficiency disorders of the MC4R receptor pathway and Breakthrough Therapy designation for setmelanotide for the treatment of obesity associated with certain defects upstream of the MC4R in the leptin melanocortin pathway, which includes POMC deficiency obesity, LEPR deficiency obesity, Bardet-Biedl syndrome and Alström syndrome, as well as hypothalamic obesity in the United States, the FDA may rescind the Breakthrough Therapy designation and we may be unable to obtain Breakthrough Therapy designation for other uses. In addition, Breakthrough Therapy designation by the FDA or PRIME designation by the EMA may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that setmelanotide will receive additional marketing approvals in the United States or additional marketing authorizations in the EU.

The FDA is authorized under the FDCA to give certain product candidates "Breakthrough Therapy designation." A Breakthrough Therapy product candidate is defined as a product candidate that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life threatening disease or condition, where preliminary clinical evidence indicates that such product candidate may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of Breakthrough Therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross disciplinary review. In addition, the FDA may consider reviewing portions of an NDA before the sponsor submits the complete application, a process also known as rolling review. Product candidates designated as breakthrough therapies by the FDA may be eligible for other expedited programs, such as priority review, provided the relevant criteria are met.

Designation as Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe our product candidates meet the criteria for designation as Breakthrough Therapy, the FDA may disagree. In any event, the receipt of Breakthrough Therapy designation for a product candidate, or acceptance for one or more of the FDA's other expedited programs, may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not guarantee ultimate approval by the FDA. Regulatory standards to demonstrate safety and efficacy must still be met. Additionally, the FDA may later decide that the product candidate no longer meets the conditions for designation and may withdraw designation at any time or decide that the time period for FDA review or approval will not be shortened.

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The PRIME (PRIority MEdicines) scheme was launched by the EMA in 2016. In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process. In late June 2018, setmelanotide was granted eligibility to PRIME by the Committee for Medicinal Products for Human Use, or CHMP for the treatment of obesity and the control of hunger associated with deficiency disorders of the MC4R receptor pathway. Acknowledging that setmelanotide targets an unmet medical need, the EMA offers enhanced support in the development of the medicinal product through enhanced interaction and early dialogue to optimize our development plans and speed up regulatory evaluation in the EU. As part of this designation, the EMA has provided guidance to us concerning the development of setmelanotide. However, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened. Neither does the PRIME designation guarantee that the EC will grant additional marketing authorizations for setmelanotide.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

We may not be able to translate the once-daily, subcutaneous injection formulations of setmelanotide for into alternate formulations, including alternate methods of delivery that would be acceptable to the FDA or other equivalent competent authorities in foreign jurisdictions or commercially successful.

Setmelanotide is currently administered by once-daily SC subcutaneous (SC) injection using small insulin type needles and syringes. SC injection is generally less well received by patients than other methods of administration, such as oral administration. Considerable additional resources and efforts, including potential studies, may be necessary in order to translate the once-daily formulation of setmelanotide into a once-weekly formulation that may be well received by patients.

We have entered into a license agreement with Camurus AB, or Camurus, for the use of Camurus' drug delivery technology, FluidCrystal, to formulate once-weekly setmelanotide. This formulation, if successfully developed for setmelanotide, and approved by the FDA and other regulatory authorities, will be delivered subcutaneously, similar to our once-daily formulation, except that we anticipate it would be injected once weekly. In addition, we have initiated development of an auto-injector device designed to make administration of our once-weekly product candidate easier and more convenient for our patients.

While we have started consultations with regulatory authorities about the potential path for approval of the once-weekly formulation, and have initiated clinical studies of the once-weekly formulation, we cannot yet estimate the requirements for non-clinical and clinical data, manufacturing program, time, cost, and probability of success for approval. Regulatory authorities have limited experience evaluating Camurus' formulations, which further complicates our understanding regarding the information that may be required to obtain approval of a once-weekly formulation.

We received FDA approval of the once-daily formulation in the initial NDA submission for setmelanotide, and plan to seek approval of the once-weekly formulation at a later time. While we plan to develop the once-weekly formulation, or to develop other new and useful formulations and delivery technology for setmelanotide, we cannot estimate the probability of success, nor the resources and time needed to succeed. If we are unable to gain approval and utilize the once-weekly formulation, or to develop new formulations, setmelanotide may not achieve significant market acceptance and our business, financial condition and results of operations may be materially harmed.

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Our approach to treating patients with MC4R pathway deficiencies requires the identification of patients with unique genetic subtypes, for example, POMC genetic deficiency. The FDA or other equivalent competent authorities in foreign jurisdictions could require the clearance, approval or certification of an in vitro companion diagnostic device to ensure appropriate selection of patients as a condition of approving setmelanotide in additional indications. The requirement that we obtain clearance, approval or certification of an in vitro companion diagnostic device will require substantial financial resources, and could delay or prevent the receipt of additional regulatory approvals for setmelanotide, or adversely affect those we have already obtained.

We have focused our development of setmelanotide as a treatment for obesity caused by certain genetic deficiencies affecting the MC4R pathway. To date, we have employed *in vitro* genetic diagnostic testing to select patients for enrollment in our clinical trials, including our clinical trials for IMCIVREE and for other potential indications for setmelanotide. If the safe and effective use of any of our product candidates depends on an *in vitro* diagnostic that is not otherwise commercially available, then the FDA may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time as, or in connection with, the FDA approval of such product candidates.

In the EU, until May 25, 2022, in vitro diagnostic medical devices were regulated by Directive 98/79/EC, or the IVDD, which has been repealed and replaced by Regulation (EU) No 2017/746, or the IVDR. Unlike the IVDD, the IVDR is directly applicable in EU member states without the need for member states to implement into national law. The regulation of companion diagnostics is now subject to further requirements set forth in the IVDR. However, on October 14, 2021, the EC proposed a “progressive” roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. The European Parliament and Council adopted the proposed regulation on December 15, 2021. The IVDR became applicable on May 26, 2022 but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation. For instance, under these provisions, class C devices (including devices that are intended to be used as companion diagnostics) have had until May 26, 2026 to comply with the new requirements. In January June 2024, to address issues related to notified body capacity, the EC proposed adopted an extension of the grace period, which would lead, if adopted, to a resulting in an extended transition period until December 31, 2028 for certain class C devices, for instance, subject to compliance with the transitional provisions. The IVDR introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue an EU certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or MAA for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national competent authorities or the EMA. These modifications may make it more difficult and costly for us to obtain regulatory clearances or approvals or certification for our companion diagnostics or to manufacture, market or distribute our products after clearance, approval or certification is obtained. Compliance with the new requirements may impact our development plans for setmelanotide.

If the FDA or a comparable regulatory authority requires clearance, approval or certification of a companion diagnostic for setmelanotide, RM-718 or LB54640, any delay or failure by us or our current and future collaborators to develop or obtain regulatory clearance or approval of, or certification of, such tests, if necessary, could delay or prevent us from obtaining additional approvals for setmelanotide, or adversely affect the approvals we have already obtained. For example, in November 2020, the FDA approved IMCIVREE for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to POMC, PCSK1, or LEPR deficiencies confirmed by genetic testing demonstrating variants in *POMC, PCSK1,* or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance. Although the FDA did not require that we obtain approval of a companion diagnostic prior to approving the New Drug Application, or NDA, for IMCIVREE, in connection with the NDA approval we agreed as a post-marketing commitment to conduct adequate analytical and

clinical validation testing to develop and establish an *in vitro* companion diagnostic device to accurately and reliably detect patients with variants in the *POMC, PCSK1,* and *LEPR* genes that may benefit from setmelanotide therapy. In September 2020, our collaboration partner, Prevention Genetics, submitted a *de novo* request seeking FDA authorization to market such an *in vitro* companion diagnostic device for IMCIVREE as a Class II medical device. In January 2022, the FDA granted the *de novo* request for classification for the POMC/PCSK1/LEPR CDx Panel for market authorization as a Class II device. If the FDA or a comparable regulatory

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authority requires clearance, approval or certification of a companion diagnostic when we seek additional approvals for

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setmelanotide, RM-718 or LB54640, any delay or failure by us or our current and future collaborators to develop or obtain regulatory clearance or approval of, or certification of, such tests, if necessary, could delay or prevent us from obtaining such additional approvals for setmelanotide, or adversely affect the approvals we have already obtained.

We rely, and expect that we will continue to rely, on third parties to conduct clinical trials for setmelanotide, RM-718 and LB54640. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain additional regulatory approvals for or commercialize setmelanotide, RM-718 or LB54640, and our business could be substantially harmed.

We have agreements with third-party CROs to operationalize, provide monitors for and to manage data for our ongoing clinical trials. We rely heavily on these parties for the execution of clinical trials and control only certain aspects of their activities. As a result, we have less direct control over the start-up, conduct, timing and completion of these clinical trials, and the management of data developed through the clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. However, we remain responsible for the conduct of these trials and are subject to enforcement which may include civil and criminal liabilities for any violations of FDA rules and regulations and the comparable foreign regulatory provisions during the conduct of our clinical trials. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- devote inadequate resources to our clinical trials;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form more favorable relationships with other entities, some of which may be our competitors.

These factors, among others, may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines

enforced by the FDA, the competent authorities of the EU member states and equivalent competent authorities in foreign jurisdictions for any products in clinical development. The FDA and foreign regulatory authorities enforce GCPs through periodic inspections of clinical trial sponsors, principal investigators, and trial sites, and IRBs. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other equivalent competent authorities in foreign jurisdictions may require us to perform additional clinical trials before approving our marketing applications, if ever. We cannot assure you that, upon inspection, the FDA or foreign regulatory authorities will determine that any of our clinical trials have complied with GCPs. In addition, our clinical trials must be conducted with products produced under current Good Manufacturing Practices, or cGMPs and similar foreign requirements. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize,

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setmelanotide, RM-718 or LB54640. As a result, our financial results and the commercial prospects for setmelanotide, RM-718 or LB54640, would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Risks Related to the Commercialization of IMCIVREE and, if Approved, our Products Candidates

The successful commercialization of IMCIVREE and any other product candidates for which we obtain approval will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement levels. Failure to obtain or maintain coverage and adequate reimbursement for IMCIVREE or our other product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Our ability to successfully commercialize IMCIVREE or any other product candidates for which we obtain approval will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for recently approved products, such as IMCIVREE, and, as a result, they may not cover or provide adequate payment. Even if we show improved efficacy or improved convenience of administration, third-party payors may deny or revoke the reimbursement status of our product candidates, if approved, or establish prices for our product candidates at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize IMCIVREE or other product candidates, and may not be able to obtain a satisfactory financial return. Further, as we continue to grow as an organization, previously-established prices may no longer be sufficient and could create additional pricing pressure for us.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of IMCIVREE to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

In some foreign countries, particularly in Canada, Great Britain and in the EU member states, the pricing and reimbursement of prescription only medicinal products is subject to strict governmental control which varies widely between countries. In these countries, pricing

negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of IMCIVREE with other available therapies. If reimbursement for IMCIVREE is unavailable in any country in which we seek reimbursement, if it is limited in scope or amount, if it is conditioned upon our completion of additional clinical trials or if pricing is set at unsatisfactory levels, our operating results could be materially adversely affected.

In the EU, in particular, each EU member state can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed in its territory. As a result, following receipt of marketing authorization in an EU member state, through any application route, an applicant is required to engage in pricing discussions and negotiations with the competent pricing authority in the individual EU member states. Some EU member states operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. Other EU member states approve a specific price for the medicinal product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new

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products. In addition, we may face competition for IMCIVREE from lower priced products in foreign countries that have placed price controls on pharmaceutical products.

Health Technology Assessment, or HTA, of medicinal products, however, is becoming an increasingly common part of the pricing and reimbursement procedures in the United Kingdom and some EU member states, including France, Germany, Italy, Spain, the Netherlands, Belgium, Norway and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product varies between EU member states. In addition, pursuant to Directive 2011/24/EU on the application of patients' rights in cross border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU member states and in pricing and reimbursement decisions and may negatively affect price in at least some EU member states.

On December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. This Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

If we are unable to establish, maintain or expand our sales, marketing and marketing distribution capabilities or enter into agreements with third parties to market, sell, and sell distribute IMCIVREE, we may not be able to generate any revenue.

In order to market IMCIVREE, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. Although we have received FDA and Health Canada approval,

and EC and MHRA marketing authorization for certain indications, we are early in our commercialization efforts. Therefore, you should not compare us to commercial-stage biotechnology companies, and you should not expect that we will generate substantial revenues or become profitable in the near term. If we are unable to establish, adequate maintain or expand our sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects would be materially adversely affected.

We may never receive regulatory approval to market setmelanotide outside of the United States, Canada, the European Union and Great Britain.

We intend to seek marketing authorizations in various countries worldwide. In order to market any product outside of the United States, Canada, the EU or Great Britain, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Marketing authorization procedures vary among countries and can involve additional setmelanotide testing and additional administrative review periods. The time required to obtain marketing authorization in other countries might differ from that required to obtain FDA approval or marketing authorization from the EC or the MHRA. The marketing authorization processes in other countries may

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implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States and Europe, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Grant of marketing authorization in one country does not ensure grant of marketing authorization in another country, but a failure or delay in obtaining marketing authorization in one country may have a negative effect on the regulatory process or commercial activities in others. Failure to obtain marketing authorization in other countries or any delay or other setback in obtaining such authorizations would impair our ability to market setmelanotide in such foreign markets. Any such impairment would reduce the size of our potential market share and could have a material adverse impact on our business, results of operations and prospects.

We may not achieve or maintain market acceptance for IMCIVREE, which would limit the revenue that we generate from the sale of IMCIVREE.

The commercial success of IMCIVREE will also depend upon the awareness and acceptance of IMCIVREE within the medical community, including physicians, patients and third-party payors. If IMCIVREE does not achieve or maintain an adequate level of acceptance by patients, physicians and third-party payors, we may not generate sufficient revenue to become or remain profitable. Before granting reimbursement approval, third-party payors may require us to demonstrate that, in addition to treating obesity caused by certain genetic deficiencies affecting the MC4R pathway, IMCIVREE also provides incremental health benefits to patients. Our efforts to educate the medical community and third-party payors about the benefits of IMCIVREE may require significant resources and may never be successful. All of these challenges may impact our ability to ever successfully market and sell IMCIVREE.

Market acceptance of IMCIVREE will depend on a number of factors, including, among others:

- the ability of IMCIVREE to provide chronic weight management in patients with obesity caused by certain genetic deficiencies affecting the MC4R pathway and, if required by any competent authority in connection with the approval for these indications, to provide patients with incremental health benefits, as compared with other available treatments, therapies, devices or surgeries;
- the complexities of genetic testing, including obtaining genetic results that support patient treatment with IMCIVREE;
- the relative convenience and ease of SC injections as the necessary method of administration of IMCIVREE, including as compared with other treatments for patients with obesity;
- the prevalence and severity of any adverse side effects associated with IMCIVREE;

- limitations or warnings contained in the labeling approved for IMCIVREE by the FDA or the specific obligations imposed as a condition for marketing authorization imposed by other equivalent competent authorities in foreign jurisdictions, particularly by the EC;
- availability of alternative treatments, including a number of obesity therapies already approved or expected to be commercially launched in the near future;
- our ability to increase awareness of these diseases among our target populations through marketing and other cross-functional efforts;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the ability of IMCIVREE to treat the maximum range of pediatric patients, and any limitations on its indications for use;

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- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning IMCIVREE or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of IMCIVREE through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage; and
- the likelihood that competent authorities in foreign jurisdictions may require development of a REMS or other specific obligations as a condition of approval or post-approval, may not agree with our proposed REMS or other specific obligations, or may impose additional requirements that limit the promotion, advertising, distribution or sales of IMCIVREE.

Our industry is intensely competitive. If we are not able to compete effectively against current and future competitors, we may not be able to generate revenue from the sale of IMCIVREE, our business will not grow and our financial condition and operations will suffer.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop compounds that could make IMCIVREE obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful. In addition, payors may require that patients try other medications known as step therapy or a “step-edit,” including medications approved for treatment of general obesity, before receiving reimbursement for IMCIVREE. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to IMCIVREE and our other product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Currently, IMCIVREE is the only approved treatment for providing chronic weight management in patients with obesity due to BBS or POMC, PCSK1 or LEPR deficiencies, and there are no approved treatments for chronic weight management in patients with deficiencies with deficiencies due to a variant in one of the two alleles in the *POMC, PCSK1, or LEPR* genes (HET obesity), SRC1 deficiency obesity, SH2B1 deficiency obesity, MC4R deficiency obesity, and hypothalamic obesity. Bariatric surgery is not a good treatment option for these genetic diseases of obesity because the severe obesity and hyperphagia associated with these diseases are considered to be risk factors for bariatric surgery. Also, existing therapies indicated for general obesity, including glucagon-like peptide-1 (GLP-1) receptor agonists, such as Wegovy®,

and glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) agonists, such as tirzepatide which is being investigated as a treatment for obesity, do not specifically restore function impaired by genetic deficiencies in the MC4R pathway, which we believe is the root cause of hyperphagia and obesity in patients with MC4R genetic variants. Based on search results from ClinicalTrials.gov, we are unaware of any competitive products in therapeutic clinical studies for the obesity and hyperphagia caused by upstream MC4R pathway deficiencies. New competitors may emerge which could limit our business opportunity in the future.

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We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of setmelanotide, RM-718, and LB54640 in clinical trials and the sale of IMCIVREE exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with IMCIVREE. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design or a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection laws and any equivalent laws in foreign countries. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

- withdrawal of patients from our clinical trials;
- substantial monetary awards to patients or other claimants;
- decreased demand for IMCIVREE or any future product candidates following marketing approval, if obtained;
- damage to our reputation and exposure to adverse publicity;
- litigation costs;
- distraction of management's attention from our primary business;
- loss of revenue; and
- the inability to successfully commercialize IMCIVREE or any future product candidates, if approved.

We maintain product liability insurance coverage for our clinical trials and commercial product with a $10.0 million annual aggregate coverage limit. Our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely affected.

We rely completely on third-party suppliers to manufacture our clinical and commercial drug supplies of setmelanotide, RM-718, and LB54640, and we intend to rely on third parties to produce preclinical, clinical and commercial supplies of any future product candidate.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture our clinical and commercial drug supply internally for setmelanotide, or any future product candidates, for use in the conduct of our preclinical studies and clinical trials, and we lack the internal resources and the capability to manufacture any product candidate on a clinical or commercial scale. The facilities used by our contract manufacturing organizations, or CMOs, to manufacture the active pharmaceutical ingredient, or API, and final drug product must successfully complete inspection by the FDA and other equivalent competent authorities in foreign jurisdictions pursuant to inspections that

have been and will be conducted following submission of NDAs, NDA supplements or comparable foreign regulatory submissions to the other equivalent competent authorities in foreign jurisdictions. Our failure or the failure of our CMOs to successfully

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complete preappr oval inspection any potential preapproval inspections of the manufacturing facilities of setmelanotide, RM-718, and LB54640 could delay the regulatory approval process. In addition, our clinical trials must be conducted with products produced under in accordance with GMP and similar foreign regulations. Our failure or the failure of our CROs or CMOs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action, including civil and criminal penalties. When we import any drugs or drug substances, we would be subject to FDA, United States Department of Agriculture, and U.S. Bureau of Customs and Border Patrol import regulation requirements. Such enforcement for our failure or our CROs or CMOs' failure to comply with these regulations could result in import delays, detention of products, and, depending on criteria such as the history of violative activities, the FDA could place a foreign firm or certain drug substances or products on Import Alert and require that all such drug substances or products be subject to detention without physical examination which could significantly impact the global supply chain for setmelanotide, RM-718, and LB54640. With the exception of those on the FDA's drug shortage list or properly imported by individuals, the FDCA prohibits the importation of prescription drug products for commercial use if they were manufactured in a foreign country, unless they have been approved or are otherwise authorized to be marketed in the United States and are labeled accordingly.

We currently contract with third parties for the manufacture of setmelanotide, RM-718, and LB54640 and intend to continue to do so in the future. We have entered into process development and manufacturing service agreements with our CMOs, Corden Pharma Switzerland, LLC, or Corden, (formerly Peptisyntha SA prior to its acquisition by Corden), and Neuland Laboratories for certain process development and manufacturing services for regulatory starting materials and/or raw materials in connection with the manufacture of setmelanotide. We have entered into long-term commercial supply agreements with PolyPeptide Group and Recipharm Monts S.A.S. for manufacturing of drug substance and drug product for IMCIVREE. Under our agreements, we pay these third parties for services in accordance with the terms of mutually agreed upon work orders, which we may enter into from time to time. We may need to engage additional third-party suppliers to manufacture our clinical and/or commercial (subject to approval) drug supplies. We also have engaged other third parties to assist in, among other things, distribution, post-approval safety reporting and pharmacovigilance activities. We cannot be certain that we can engage third-party suppliers on terms as favorable as those that are currently in place.

We do not perform the manufacturing of any drug products and are completely dependent on our CMOs to comply with GMPs and similar foreign requirements for manufacture of both drug substance, or API and finished drug product. We recognize that we are ultimately responsible for ensuring that our drug substances and finished drug product are manufactured in accordance with GMPs and similar foreign requirements, and, therefore, the company's management practices and oversight, including routine auditing, are critical. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other equivalent competent authorities in foreign jurisdictions, they may be subject to administrative and judicial enforcement for non-compliance and the drug products would be deemed misbranded or adulterated and prohibited from distribution into interstate commerce. Furthermore, all of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those other company materials and products may affect the regulatory clearance of our CMOs' facilities generally. In addition, satisfying the regulatory requirements for production of setmelanotide, RM-718, and LB54640 with multiple suppliers, while assuring more robust drug availability in the future, adds additional complexity and risk to regulatory approval. If the FDA or another equivalent competent foreign regulatory agency does not approve these facilities for the manufacture of setmelanotide, RM-718, and LB54640 or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop, obtain regulatory approval for or market setmelanotide, RM-718, or LB54640.

We Our CMOs are manufacturing finished drug product for use in our upcoming or ongoing clinical trials and for commercial supply. We believe we currently have a sufficient amount of finished setmelanotide, RM-718, LB54640, and placebo to complete our ongoing and planned clinical trials, and for commercial IMCIVREE supply. However, these projections could change based on delays encountered with manufacturing activities, equipment scheduling and material lead times. Any such delays in the manufacturing of finished drug product could

delay our planned clinical trials of setmelanotide, RM-718, and LB54640, and our commercial IMCIVREE supply, which could delay, prevent or limit our ability to generate revenue and continue our business.

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We do not have long term supply agreements in place with all of our contractors involved with the manufacturing of our weekly formulation of setmelanotide and RM-718, and LB54640. We currently place individual batch or campaign orders with the CMOs/suppliers that are individually contracted under existing master services and quality agreements for the weekly formulation of setmelanotide, RM-718, and LB54640. If we engage new contractors, such contractors must be approved by the FDA and other equivalent competent authorities in foreign jurisdictions. We will need to submit information to the FDA and other equivalent competent authorities in foreign jurisdictions describing the manufacturing changes. If manufacturing changes occur post-approval, the FDA and foreign regulatory authorities may have to approve these changes. We plan to continue to rely upon CMOs and, potentially, collaboration partners to manufacture commercial quantities of setmelanotide, RM-718, and LB54640, if approved. Our current scale of manufacturing appears adequate to support all of our current needs for clinical trial and initial commercial supplies for setmelanotide, RM-718, and LB54640, if approved. Going forward, we may need to identify additional CMOs or partners to produce setmelanotide, RM-718, and LB54640 on a larger scale.

In light of our election to terminate the exclusive license agreement with RareStone Group Ltd., or RareStone, the development of setmelanotide in certain indications and commercialization of IMCIVREE in certain markets could be delayed or terminated and our business could be adversely affected.

In December 2021, we entered into an Exclusive License Agreement with RareStone, or the RareStone License. Pursuant to the RareStone License, we granted to RareStone an exclusive, sublicensable, royalty-bearing license under certain patent rights and know-how to develop, manufacture, commercialize and otherwise exploit any pharmaceutical product that contains setmelanotide in the diagnosis, treatment or prevention of conditions and diseases in humans in China, including mainland China, Hong Kong and Macao. RareStone has a right of first negotiation in the event that the Company chooses to grant a license to develop or commercialize the licensed product in Taiwan.

Under the RareStone License, we are dependent upon RareStone to successfully commercialize any applicable collaboration products in China, including mainland China, Hong Kong and Macao. We cannot directly control RareStone's commercialization activities or the resources it allocates to setmelanotide. Our interests and RareStone's interests may differ or conflict from time to time, or we may disagree with RareStone's level of effort or resource allocation. RareStone may internally prioritize setmelanotide differently than we do or it may not allocate sufficient resources to effectively or optimally commercialize setmelanotide.

On October 28, 2022, we delivered a written notice to RareStone that we have terminated the RareStone License for cause. In accordance with the notice, we maintain that RareStone has materially breached its obligations under the RareStone License to fund, perform or seek certain key clinical studies and waivers, including with respect to the Company's global EMANATE trial, among other obligations. On December 21, 2022, RareStone provided written notice to the Company that it objects to the claims in our October 28, 2022 notice, including the Company's termination of the RareStone License for cause. On March 16, 2023, we provided written notice to RareStone reaffirming our position that RareStone has materially breached its obligations under the RareStone License and that we have terminated the RareStone License for cause, and also requested documentation supporting RareStone's purported dispute notice objecting to the claims in the Notice. On May 10, 2023, RareStone provided written notice to the Company reaffirming its objections to the claims in our October 28, 2022 notice and March 16, 2023 notice, including to the Company's termination of the RareStone License for cause. On November 29, 2023, RareStone wrote to us seeking to negotiate and execute a commercial supply agreement as contemplated under the Exclusive License Agreement, and on January 19, 2024, we responded in writing again reaffirming our position that RareStone has materially breached its obligations under the RareStone License and that we have terminated the RareStone License for cause.

There can be no assurance that we will be able to negotiate an appropriate cure to the alleged material breaches, which we believe are incurable, and, if required, we expect to seek appropriate relief under the terms of the RareStone License. Termination of, or any possible litigation focused on, the RareStone License could cause significant delays in our product development and commercialization efforts for setmelanotide and could prevent us from commercializing IMCIVREE in the markets covered by the RareStone License without first expanding our internal capabilities or entering into another agreement with a third party. Any alternative collaboration or license could also be on less

favorable terms to us. In addition, under the agreement, RareStone agreed to provide funding for certain clinical development activities. To date, no such funding has been provided. If the agreement were terminated, however, we may need to refund any such

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potential payments and seek additional funding to support the research and development of setmelanotide or discontinue any research and development activities for setmelanotide in China, including mainland China, Hong Kong and Macao, which could have a material adverse effect on our business.

Risks Related to Our Intellectual Property Rights

If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect setmelanotide, RM-718, and LB54640, others could compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect setmelanotide, RM-718, and LB54640. Other parties have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap with our patent applications, either by claiming the same methods or formulations or by claiming subject matter that could dominate our patent position. The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty.

Although an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and such patent may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. U.S. patents and patent applications or the patents and patent application obtained or submitted pursuant to comparable foreign laws, may also be subject to interference proceedings, *ex parte* reexamination, *inter partes* review proceedings, post-grant review proceedings, supplemental examination and challenges in court. Patents may be subjected to opposition or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize setmelanotide.

Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering setmelanotide are invalidated or found unenforceable, our financial position and results of operations would be materially and adversely impacted. In addition, if a court found that valid, enforceable patents held by third parties covered setmelanotide, our financial position and results of operations would also be materially and adversely impacted.

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The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect setmelanotide;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize IMCIVREE or our other product candidates before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or product candidates that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants, collaborators and vendors. We also have agreements with employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person who is not a party to such an agreement. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, collaborators, vendors, former employees and current employees. Furthermore, if the parties to our confidentiality agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the attention of our management and key personnel from our business operations. Even if we prevail in any lawsuits that we initiate, the damages or other remedies awarded may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of

litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing IMCIVREE or our other product candidates.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties. For example, numerous third-party U.S. and non U.S. patents and pending applications exist that cover melanocortin receptor analogs and methods of using these analogs.

The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that setmelanotide or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced or choose to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing IMCIVREE or our other product candidates.

If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion.

In addition, in order to avoid infringing the intellectual property rights of third parties and any resulting intellectual property litigation or claims, we could be forced to do one or more of the following, which may not be possible and, even if possible, could be costly and time consuming:

- cease development of setmelanotide and commercialization of IMCIVREE or our other product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, rename setmelanotide and/or its trade name IMCIVREE.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, such intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Issued patents covering setmelanotide or our other product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners threatened or initiated legal proceedings against a third party to enforce a patent covering setmelanotide, the defendant could claim that the patent covering setmelanotide or our other product candidates are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any one of several statutory requirements, including novelty, non-obviousness and enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld material information from the U.S. PTO, or made a misleading statement, during patent prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions, for example, opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover setmelanotide or competitive products. The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on setmelanotide. Such a loss of patent protection would have a material adverse impact on our business.

We do not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on setmelanotide in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2017 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around

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the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing setmelanotide or LB54640.

We have licensed our rights to setmelanotide from Ipsen Pharma SAS, or Ipsen, and our rights to LB54640 from LG Chem, Ltd, or LG Chem. LGC. Our licenses with Ipsen and LG Chem LGC impose various obligations on us, and provides provide Ipsen and LG Chem LGC the right to terminate the license in the event of our material breach of the license agreement, our failure to initiate or complete certain development of a licensed product, or our commencement of an action seeking to have an Ipsen or LG Chem LGC licensed patent right declared invalid. Termination of our license from Ipsen or LG Chem LGC would result in our loss of the right to use the licensed intellectual property, which would materially adversely affect our ability to develop and commercialize setmelanotide and LB54640, respectively, as well as harm our competitive business position and our business prospects. Furthermore, if our license agreement with LG Chem LGC were terminated, we may be subject to certain refunds or be subject to certain payments to LG Chem. LGC.

We also have licensed from Camurus its drug delivery technology, FluidCrystal, to formulate once-weekly setmelanotide. Our license with Camurus imposes various obligations on us, and provides Camurus the right to terminate the license in the event of our material breach of the license agreement. Termination of our license from Camurus would result in our inability to use the licensed intellectual property.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Future licensors may also allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, future licensors may have the right to terminate our license at will. Any termination could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize setmelanotide, as well as harm our competitive business position and our business prospects.

Any termination could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize setmelanotide or LB54640, as well as harm our competitive business position and our business prospects.

While we have registered trademarks for the commercial trade name IMCIVREE (setmelanotide) in the United States, the EU, and other countries, we have not yet obtained trademark protection for IMCIVREE in certain foreign jurisdictions and failure to secure such registrations could adversely affect our business.

While we have received registered trademarks for the commercial trade name IMCIVREE (setmelanotide) and its logo in the United States, the EU, and other countries, we have not yet obtained trademark protection for IMCIVREE in certain foreign jurisdictions and are pursuing trademark registrations in other jurisdictions. Our trademark applications may be rejected during trademark registration proceedings. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome them. In addition, in the U.S. PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive those proceedings.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation by extending the patent terms and obtaining product exclusivity for setmelanotide and our other product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval for setmelanotide and our other product candidates, one or more of the U.S. patents we license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch Waxman Amendments. The Hatch Waxman Amendments permit a patent term restoration of up to five years as compensation for patent term lost during product development and the FDA regulatory review process, and we have applied to the U.S. PTO for patent term

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extension. However, we may not be granted an extension because of, for example, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or otherwise failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

Because setmelanotide contains active ingredients that the FDA has determined to be a new chemical entity, it has been afforded five years of non-patent data exclusivity by the FDA. Following the expiration of this exclusivity period, the FDA may approve generic products referencing the information included in our NDA for setmelanotide. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for setmelanotide. Recent legislation enacted by Congress created, among other things, new causes of action against innovator companies that refuse to offer samples of drugs for purposes of testing and developing generic or biosimilar products or to allow companies to participate in a shared Risk Evaluation and Mitigation Strategy (REMS). Competition that setmelanotide may face from generic versions could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in setmelanotide.

If we fail to obtain an extension of patent protection under similar foreign legislation, where applicable, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected in the foreign countries concerned.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and is currently implementing the America Invents Act of 2011, wide ranging patent reform legislation. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain future patents, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents or future patents.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize setmelanotide, which would materially adversely affect our commercial development efforts.

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Risks Related to Regulatory Approval and Marketing of Setmelanotide and Other Legal and Compliance Matters

Even if we complete the necessary clinical trials, the regulatory and marketing approval process is expensive, time consuming and uncertain and may prevent us from obtaining additional approvals for the commercialization of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize such candidates and our ability to generate revenue will be materially impaired.

Our business depends largely on its successful clinical development, regulatory approval and commercialization of our product candidates. In the United States, IMCIVREE is approved for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to POMC, PCSK1 or LEPR deficiency as determined by a FDA-approved test demonstrating variants in *POMC*, *PCSK1* or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance, or BBS. Health Canada has approved IMCIVREE for weight management in adult and pediatric patients 6 years of age and older with obesity due to BBS or genetically-confirmed POMC, PCSK1, or LEPR deficiency due to variants interpreted as pathogenic, likely pathogenic, or of VUS. The EC has authorized setmelanotide for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. The UK's MHRA authorized setmelanotide for the treatment of obesity and the control of hunger associated with genetically confirmed BBS or genetically confirmed loss-of-function biallelic POMC, including PCSK1, deficiency or biallelic LEPR deficiency in adults and children 6 years of age and above. Setmelanotide will require substantial additional clinical development, testing and regulatory approval before we are permitted to commence commercialization in indications beyond those currently approved for IMCIVREE in the United States, the EU and Great Britain, and our other product candidates will require similar efforts before we are permitted to commercialize them for any indication. The clinical trials, manufacturing and marketing of our product candidates are subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market such product candidates.

Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through nonclinical testing and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years and approval, if any, may be conditional on postmarketing studies and surveillance, and will require the expenditure of substantial resources beyond our existing cash resources. Of the large number of drugs in development in the United States and in other countries, only a small percentage will successfully complete the FDA regulatory approval process or the equivalent process in foreign jurisdictions and will be commercialized. In addition, we have not discussed all of our proposed development programs with the FDA or the competent authorities of foreign jurisdictions. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical trials, we cannot assure you that setmelanotide will be successfully developed or commercialized.

In addition, obtaining FDA or EC approval is a complex, lengthy, expensive and uncertain process, and the FDA, EMA or equivalent competent authorities in foreign jurisdictions may delay, limit or deny approval of our product candidates for many reasons, including, among others:

- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions may disagree with our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- we may not be able to demonstrate to the satisfaction of the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions that our product candidates are safe and effective for their intended uses;
- the results of our clinical trials may not be interpretable or meet the level of statistical or clinical significance required by the FDA, the EMA, or other equivalent competent authorities in foreign

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jurisdictions for marketing approval. For example, the potential unblinding of setmelanotide studies due to easily identifiable AEs may raise the concern that potential bias has affected the clinical trial results;

- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions may disagree with the number, size, conduct or implementation of our clinical trials;
- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions may require that we conduct additional clinical trials or pre-clinical studies;
- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions or the applicable foreign regulatory agency may identify deficiencies in our chemistry, manufacturing or controls of our product candidates, or in the commercial production of such product candidates that may be required to support product approval;

- the CROs that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions may find the data from preclinical studies and clinical trials insufficient to demonstrate that clinical and other benefits of a product candidate outweigh its safety risks;
- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or other equivalent competent authorities in foreign jurisdictions may not approve the formulation, labeling or specifications of our product candidates;
- the FDA, the EMA, or other equivalent competent authorities in foreign jurisdictions may not accept data generated at our clinical trial sites;
- the FDA, the EMA, or the equivalent competent authorities in foreign jurisdictions may require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- we may not be able to meet any post-market requirements or commitments agreed to in connection with regulatory approvals
- the FDA may require development of a REMS as a condition of additional approvals or may impose additional requirements that limit the promotion, advertising, distribution, or sales of our product candidate;
- the EC may grant only conditional approval marketing authorization or based on the EMA's opinion impose specific obligations as a condition for marketing authorization, or may require us to conduct post authorization safety studies as a condition of grant of marketing authorization;
- the FDA or other equivalent competent foreign regulatory agencies may deem our manufacturing processes or our facilities or the facilities of our CMOs inadequate to preserve the identity, strength, quality, purity, or potency of our product; or

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- the FDA or the equivalent competent authorities in foreign jurisdictions may change its approval policies or adopt new regulations and guidance.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain additional regulatory approvals, or to successfully market IMCIVREE. Moreover, because our business is largely dependent upon setmelanotide, any such setback in our pursuit of regulatory approvals would have a material adverse effect on our business and prospects.

Future regulatory legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

The EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC's proposal for a revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions, may however have a significant impact on the pharmaceutical industry and our business in the long term.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's and foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in

recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA, following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our failure to obtain marketing approval in foreign jurisdictions would prevent setmelanotide or our other product candidates from being marketed abroad, and any current or future approvals we have been or may be granted for setmelanotide or other products in the United States would not assure approval of setmelanotide or other products in foreign jurisdictions.

In order to market and sell setmelanotide and any other product candidate that we may develop in the EU and many other jurisdictions, we or our third-party collaborators must obtain separate marketing authorizations and comply with numerous and varying regulatory requirements. The marketing authorization procedure varies among countries and can involve additional testing. The time required to obtain marketing authorization may differ substantially from that required to obtain FDA approval. The marketing authorization process outside the United States generally includes all of

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the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or these third parties may not obtain marketing authorization from competent authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure grant of marketing authorization by competent authorities in other countries or jurisdictions, and grant of marketing authorization by one competent authority outside the United States does not ensure grant of marketing authorization by competent authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing authorizations and may not receive necessary marketing authorization to commercialize setmelanotide in any market. Additionally, the UK's withdrawal from the EU, commonly referred to as Brexit, has resulted in the relocation of the EMA from the UK to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the MHRA, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of setmelanotide, or any other product candidates in the EU and/or the UK. Although we have obtained FDA approval and marketing authorization from the EC and the MHRA for setmelanotide, any delay in obtaining, or an inability to obtain, any marketing authorization, for any of our other product candidates, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek marketing authorization in the UK and/or EU for any of our other product candidates, which could significantly and materially harm our business.

The terms of our current and future potential marketing approvals for setmelanotide and other product candidates and ongoing regulation may limit how we manufacture and market setmelanotide and other products, and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Regulatory authorities may impose significant restrictions on setmelanotide's indicated uses or marketing or impose ongoing requirements for potentially costly post approval studies, and the same may be true for our other product candidates, if approved. We and

setmelanotide will also be subject to ongoing requirements by the FDA and foreign regulatory authorities, governing labeling, packaging, storage, advertising, promotion, marketing, distribution, importation, exportation, post-approval changes, manufacturing, recordkeeping, and submission of safety and other post market information. Advertising and promotional materials must comply with the FDCA and implementing regulations and foreign regulations, and are subject to FDA and foreign regulatory authorities oversight and post-marketing reporting obligations, in addition to other potentially applicable federal and state laws. The FDA and the other competent foreign authorities have significant post market authority, including, for example, the authority to require labeling changes based on new safety information and to require post market studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA and foreign regulatory authorities also has the authority to require, as part of an NDA or similar foreign application or post approval, the submission of a REMS or other specific obligations, which may include Elements to Assure Safe Use. Any REMS or other specific obligations required by the FDA or foreign regulatory authorities may lead to increased costs to assure compliance with new post approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue. The holder of an approved NDA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process, or adding new manufacturers. Similar requirements apply in foreign jurisdictions.

Manufacturers of drug products and their facilities may be subject to payment of application and program fees and are subject to continual review and periodic inspections by the FDA and other equivalent competent authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with setmelanotide, such as AEs of unanticipated severity or frequency, or problems with the facility where setmelanotide is manufactured or disagrees with the promotion, marketing or labeling of the product, a regulatory agency may impose restrictions on setmelanotide, the manufacturer or us, including requiring withdrawal of setmelanotide from the market or suspension of manufacturing. If we or the manufacturing facilities for setmelanotide fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;

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- seek an injunction or impose civil or criminal penalties or monetary fines;
- vary, suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain setmelanotide, refuse to permit the import or export of setmelanotide, or request that we initiate a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

Accordingly, we and our CMOs will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for setmelanotide withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

In addition, a sponsor's responsibilities and obligations under the FDCA and FDA regulations, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the

adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU member states, both before and after grant of the manufacturing and marketing authorizations. This oversight includes control of compliance with GMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers would be required to ensure that all of our processes, methods, and equipment are compliant with GMP. Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with EU laws and the related national laws of individual EU member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, both before and after grant of marketing authorization, and marketing of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, revocation or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

In addition, EU legislation related to pharmacovigilance, or the assessment and monitoring of the safety of medicinal products, provides that the EMA and the competent authorities of the EU member states have the authority to require companies to conduct additional post-approval clinical efficacy and safety studies. The legislation also governs the obligations of marketing authorization holders with respect to additional monitoring, AE management and reporting. Under the pharmacovigilance legislation and its related regulations and guidelines, we may be required to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and may be required to engage in ongoing

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assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability. Noncompliance with such obligations can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to commercialize setmelanotide and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post-approval activities with respect to IMCIVREE and affect our ability, or the ability of any future collaborators, to profitably sell our products. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States and elsewhere, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for IMCIVREE or any product candidates approved for sale.

The Patient Protection and Affordable Care Act (ACA) was signed into law in 2010. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affects the U.S. pharmaceutical industry. Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any product candidates that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, revising the "average manufacturer price" definition, and extending rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well;

- expansion of the list of entity types eligible for participation in the Public Health Service 340B drug pricing program, or the 340B program, to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, but exempting "orphan drugs," such as IMCIVREE, from the 340B ceiling price requirements for these covered entities;

- establishment of the Medicare Part D coverage gap discount program (to be replaced by a new discount program in 2025, as discussed below), which requires manufacturers to provide a 70% point of sale discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- a Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and

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- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, including prescription drug spending.

Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through 2032, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. Previously, the Medicaid rebate was capped at 100% of a drug's average manufacturer price, or AMP.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which was fully implemented in 2019. At this time, it is unclear how the introduction of this Medicare quality payment program will impact overall physician reimbursement. The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States. There have been several Congressional inquiries, as well as legislative and regulatory initiatives and executive orders designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure, drug price increase reporting, and other transparency measures. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for IMCIVREE or the frequency with which IMCIVREE is prescribed or used.

Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things,

the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026); imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

Under the IRA discounting program that will replace the coverage gap discount program in 2025, manufacturers must give a 10 percent discount on Part D drugs in the initial coverage phase, and a 20 percent discount on Part D drugs in the so-called "catastrophic phase" (the phase after the patient incurs costs above the initial phase out-of-pocket threshold, which will be $2,000 beginning in 2025). The IRA allows the 10 and 20 percent discounts to be phased in over time for certain drugs for "specified manufacturers." In April 2024, CMS informed us that we are deemed a specified manufacturer. We are still evaluating the potential impact of this status on our future revenues.

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IMCIVREE is reimbursed under Medicare Part D, and the reimbursement amount will be impacted by the 10 and 20 percent discounts under the IRA's new discounting program. We anticipate that these increased discounts will impact IMCIVREE revenues, while also having an industry-wide impact on the cost of Part D drugs. The impact on IMCIVREE revenues could be offset because the IRA's redesign of certain Part D components, some of which went into effect in 2024, resulted in an increase in the number of patients able to afford this therapy. The amount of the offset, if any, is inherently uncertain and difficult to predict.

The IRA discounting program that will replace the coverage gap discount program will also increase financial obligations of Part D prescription drug plans with respect to beneficiaries in the catastrophic coverage phase. This may incentivize Part D prescription drug plans to seek greater price concessions from us in order to include IMCIVREE on their formularies.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage and payment criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of setmelanotide to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. For more details concerning the risks related to pricing and reimbursement in the EU, please refer to the discussion in the risk factor *"The successful commercialization of IMCIVREE and any other product candidates for which we obtain approval will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement levels. Failure to obtain or maintain coverage and adequate reimbursement for IMCIVREE or our other product candidates, if any and if approved, could limit our ability to market those products and decrease our ability to generate revenue"* in this Quarterly Report.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and

fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We participate in and have certain price reporting obligations under the Medicaid Drug Rebate Program, or the MDRP, as a condition of having covered outpatient drugs payable under Medicaid and, if applicable, under Medicare Part B. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services, or CMS, the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price (AMP) for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result

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of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results.

The ACA made significant changes to the MDRP, as described under the risk factor "*Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize setmelanotide and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations*," above. In addition, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' MDRP rebate liability, effective January 1, 2024. Previously, under law enacted as part of the ACA, drug manufacturers' MDRP rebate liability was capped at 100% of the AMP for a covered outpatient drug. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the MDRP. Additional legislation or the issuance of regulations relating to the MDRP could have a material adverse effect on our results of operations.

The recently-enacted IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation (first due in 2023), as described under the risk factor "*Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize setmelanotide and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations*," above. The Medicare Part D rebate will be calculated on the basis of the AMP figures we report pursuant to the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and, if applicable, Medicare Part B. We participate in the 340B program, which is administered by the Health Resources and Services Administration, or HRSA, and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs," such as IMCIVREE, from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized a revised regulation implementing an administrative

dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA or other legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results.

In order for IMCIVREE or any product candidates, if approved, to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (VA, U.S. Department of Defense, or DOD, Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we must calculate and report to

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the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and

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regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health & Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the

government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA/FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

In the United States, the FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for IMCIVREE is limited to chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due POMC, PCSK1, or LEPR, deficiency confirmed by FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance, and due to BBS. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our drugs and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. For example, we are actively evaluating IMCIVREE in subjects with

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other forms of obesity caused by defects in the MCR4 pathway. We are not currently permitted to, and do not, market or promote setmelanotide for these uses.

Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from

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the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

In the EU, the advertising and promotion of our products are subject to EU laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU member states may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off label promotion. The off label promotion of medicinal products is prohibited in the EU. The applicable laws at EU level and in the individual EU member states also prohibit the direct to consumer advertising of prescription only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

We may be subject to federal, state and foreign healthcare laws and regulations, including fraud and abuse laws, health information privacy and security laws, and antitrust laws. If we are unable to comply or have not fully complied with such laws and regulations, we could face criminal sanctions, damages, substantial civil penalties, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of setmelanotide, and other product candidates, if approved. Our arrangements and interactions with healthcare professionals, third-party payors, patients and others will expose us to broadly applicable fraud and abuse, antikickback, false claims and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute setmelanotide, if we obtain marketing approval. The U.S. federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The United States federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, or receiving remuneration, (anything of value), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease order or arranging for or recommending the purchase, lease or order of any good or service for which payment may be made, in whole or in part, by federal healthcare programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers, formulary managers, and patients on the other. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals or patients as consultants, advisors, or speakers, may be subject to scrutiny if they do not fit

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squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product and patient support programs.

- The federal civil False Claims Act prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to made or used a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding,

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decreasing or concealing an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Such private individuals may share in amounts paid by the entity to the government in recovery or settlement. Many pharmaceutical manufacturers have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper activities including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses, inflating prices reported to private price publication services which are used to set drug payment rates under government healthcare programs, and other interactions with prescribers and other customers including those that may have affected their billing or coding practices and submission to the federal government. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Settlements may require companies to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.

- The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, including private third-party payors, and also imposes obligations, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Penalties for failure to comply with a requirement of HIPAA vary significantly and include civil monetary penalties as well as criminal penalties for knowingly obtaining or disclosing individually identifiable health information in violation of HIPAA. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

- The federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies to report payments and other transfers of value to physicians for which payment is available under Medicare, Medicaid or the

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Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must submit reports on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year.

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- Analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, regardless of the payer, including private insurers. Some state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Other states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

- Analogous foreign laws and regulations, including restrictions imposed on the promotion and marketing of medicinal products in the EU member states and other countries, restrictions on interactions with healthcare professionals and requirements for public disclosure of payments made to physicians. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our international distribution partners could have implications for us.

Ensuring that our business arrangements and interactions with healthcare professionals, third-party payors, patients and others comply with applicable healthcare laws and regulations will require substantial resources. Various state, federal and foreign regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools.

It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable antitrust, fraud and abuse, privacy, or other healthcare laws and regulations. If our operations, including our engagements with healthcare professionals, researchers and patients, or our disease awareness and/or patient identification initiatives including genetic testing programs, or anticipated activities to be conducted by our field teams, were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to costly investigations, significant civil, criminal and administrative monetary penalties, imprisonment, damages, fines, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations or financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and generate negative publicity, which could harm our financial condition and divert our management's attention from the operation of our business.

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Our employees may engage in misconduct or other improper activities, whether knowingly or unknowingly, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional or unintentional failures to comply with the regulations of the FDA and applicable non U.S. regulators, provide accurate information to the FDA and applicable non U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and any precautions

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we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Some of these laws and related risks are described under the risk factor *"We may be subject to federal and state healthcare laws and regulations. If we are unable to comply or have not fully complied with such laws and regulations, we could face criminal sanctions, damages, substantial civil penalties, reputational harm and diminished profits and future earnings"* of this Quarterly Report.

Actual or perceived failure to comply with data protection, privacy and security laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our financial performance, business and operating results.

In the United States, numerous federal and state laws and regulations, including HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and regulations implemented thereunder, collectively HIPAA, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, which govern the collection, use, disclosure and protection of health-related and other personal information, may apply to our operations and the operations of current and future collaborators. We may obtain health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. In addition, state laws govern the privacy and security of health, research and genetic information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, the California Consumer Privacy Act of 2018, or CCPA, went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that

has increased the likelihood, and risks associated with data breach litigation. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023, and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at

the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In addition, some of our research activities involve minors, which may be subject to additional laws and can require specialized consent processes, privacy protections, and compliance procedures. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

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Furthermore, the Federal Trade Commission, or FTC, and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the collection and use of personal data, including health and genetic data, is governed by the provisions of the GDPR. The GDPR became effective on May 25, 2018, and imposes strict requirements for the processing of the personal data of individuals within the European Economic Area, or EEA, or in the context of our activities in the EEA, including health data from clinical trials and AE reporting. In particular, these requirements include certain obligations concerning the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA, security breach notifications, and security and confidentiality of the personal data, and violations of these requirements could result in substantial fines, up to the greater of 20 million Euros or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/change our processing of our data, enforcement notices, and/or assessment notices for a compulsory audit. We may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm. Data protection authorities from the different EU and EEA member states may also interpret the GDPR and national laws differently and impose additional requirements, which adds to the complexity of processing personal data in the EU and the EEA.

Additionally, from January 1, 2021, we have had to comply with the GDPR and also the United Kingdom GDPR, or UK GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law following Brexit. The UK GDPR mirrors the fines under the GDPR, e.g., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover.

Among other requirements, the GDPR and UK GDPR also regulate transfers of personal data subject to the GDPR or UK GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States. Case law from the Court of Justice of the European Union, or the CJEU, states that reliance on the standard contractual clauses - a standard form of contract approved by the EC as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On October 7, 2022, President Biden signed an Executive Order on 'Enhancing Safeguards for United States Intelligence Activities' which introduced new redress mechanisms and binding safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework ("DPF"), as released on December 13, 2022. The DPF also introduced a new redress mechanism for EU and UK citizens which addresses a key concern in the previous CJEU judgments and may mean transfers under standard contractual clauses are less likely to be challenged in the future. The EC adopted its Adequacy Decision in relation

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to the DPF on July 10, 2023, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF. We currently rely on the EU standard contractual clauses and the UK Addendum to the EU standard contractual clauses as relevant to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third-party transfers. Following a period of legal complexity and uncertainty regarding international personal data transfers, particularly to the United States, we expect the regulatory guidance and enforcement landscape to continue to develop, in relation to transfers to the United States and elsewhere. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and implement revised standard contractual clauses and other relevant documentation for existing data transfers arrangements within required time frames.

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Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Our failure to comply with our obligations under the GDPR or UK GDPR, including any failure to adopt measures to ensure that we can continue to conduct the data processing activities that we initiated in the EU before the GDPR entered into application, the UK GDPR, and other countries' privacy or data security-related laws could adversely impact our ability to use the data generated in our studies. And any actual or perceived failure to comply with these data protection laws or adequately address privacy and security concerns could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

Our future growth depends, in part, on our ability to continue to penetrate foreign markets, where we will be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to continue to commercialize setmelanotide and our other product candidates in foreign markets for which we intend to rely on collaborations with third parties. As we continue to commercialize setmelanotide in foreign markets, we will be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for setmelanotide in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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Foreign sales of setmelanotide could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling setmelanotide or our other product candidates outside of the United States and require us to develop and implement costly compliance programs.

If we continue to expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act of 1977, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The

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FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates and products outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

The results of the United Kingdom's departure from the EU may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the UK, the UK formally withdrew from the EU on January 31, 2020.

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU law and has operated under a separate regulatory regime to the EU. It is currently unclear to what extent the UK Government will

seek to align its regulations with the EU. EU law which has been transposed into UK law through secondary legislation still remains applicable in Great Britain, however, new EU legislation such as the CTR is not applicable in Great Britain post-Brexit. While the UK has indicated a general intention that new laws regarding the development, manufacture and commercialization of medicinal products in the UK will align closely with EU law, there remain limited detailed proposals for the future regulation of medicinal products.

Under the terms of the Ireland/Northern Ireland Protocol, EU law still generally applies to Northern Ireland. However, on February 27, 2023 the UK Government and the EC reached a political agreement in the “Windsor Framework” to address discrepancies in the Protocol’s operation. This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great

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Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Whilst the EU-UK Trade and Cooperation Agreement (TCA) includes the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, it does not contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards. There may be divergent local requirements in Great Britain from the EU in the future, which may impact clinical and development activities that occur in the UK. Similarly, clinical trial submissions in the UK will not be able to be bundled with those of EU Member States within the

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EMA Clinical Trial Information System, or CTIS. Any divergences may increase the cost and complexity of running our business, including with respect to the conduct of clinical trials.

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, the withdrawal could continue to impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK. Great Britain is no longer covered by the EU’s procedures for the grant of MA (Northern Ireland is covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures). A separate MA is required to market drugs in Great Britain. Such changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain regulatory approvals, as a result of Brexit or otherwise, may prevent us from commercializing our product candidates in Great Britain and restrict our ability to generate revenue and achieve or sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in Great Britain for our product candidates, which could significantly and materially harm our business.

Any further changes in relation to international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may reduce global trade and, in particular, trade between the impacted nations and the UK.

It is unclear what financial, regulatory and legal implications the withdrawal of the UK from the EU will have in the long-term and how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

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Risks Related to the Acquisition of Xinvento B.V.

We may fail to realize the anticipated benefits of our acquisition of Xinvento B.V., those benefits may take longer to realize than expected, and we may encounter significant integration difficulties.

In February 2023, in order to expand our pipeline and build on our focus on rare endocrinology diseases, we acquired Xinvento B.V., a Netherlands-based biotech company focused on developing therapies for congenital hyperinsulinism (CHI). We expect that the integration process will be complex, costly and time-consuming. As a result, we are devoting, and will continue to be required to devote, significant management attention and resources to integrating Xinvento B.V. into our business. The integration process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The Xinvento B.V. intellectual property may not have the scientific value and commercial potential which we envision. We may not be able to integrate the two businesses successfully, and we could assume unknown or contingent liabilities. It is possible that the integration process could result in the diversion of our management's attention, the disruption or interruption of, or the loss of momentum in, our ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with third parties or the ability to achieve the anticipated benefits of the acquisition of Xinvento B.V., or could otherwise adversely affect our business and financial results.

We do not anticipate generating revenue from any Xinvento B.V. therapeutic candidate or technology sales for many years.

We do not expect to derive revenue from the sale of any Xinvento B.V. therapeutic candidate or technology for many years, if at all, and there can be no assurance that regulatory approvals will be received or if received that they will be received when anticipated.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on our executive leadership team. We have employment agreements with these individuals but any individual may terminate his or her employment with us at any time. The loss of their services might

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impede the achievement of our research, development and commercialization objectives. We also do not have any key-person life insurance on any of these key employees. We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us and may not be subject to non-compete agreements. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from

universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to develop and expand our Company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We expect to increase our number of employees and the scope of our operations. In particular, we will need to continue our transition from a research and development focused company to a commercial commercial-stage company. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business and commercial opportunities, loss of

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employees and reduced productivity among remaining employees. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy.

The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of setmelanotide and our other product candidates. Many of our suppliers and collaborative and clinical trial relationships are located outside the United States, and we have and may continue to hire employees located outside of the United States. Accordingly, our business has and may continue to be subject to economic, political, regulatory and other risks associated with international operations, such as compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, workforce uncertainty in countries where labor unrest is more common than in the United States, as well as difficulties associated with staffing and managing international operations, including differing labor relations. Any of these factors could materially affect our business, financial condition and results of operations. Our future financial performance and our ability to commercialize our approved products and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our Company.

Our information technology systems, or those of our third-party CROs, CMOs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of setmelanotide and other product candidate development programs, regulatory investigations, enforcement actions and lawsuits.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of employees. Similarly, our third-party CROs, CMOs and other contractors and consultants possess certain of our sensitive data. The secure maintenance of this information is material to our operations and business strategy. Despite the implementation of security measures, our information technology systems and those of our third-party CROs, CMOs and other contractors and consultants are vulnerable to attack, damage, or interruption by hacking, cyberattacks, computer viruses and malware (e.g. ransomware), malicious code, phishing attacks and other social engineering schemes, unauthorized access, natural disasters, terrorism, telecommunication and electrical failures, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Any such attack, incident or breach could compromise our information technology systems and the information stored there could be accessed, publicly disclosed, lost, corrupted or stolen. Further, attacks upon information technology systems are increasing in their frequency,

levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the continued hybrid work environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification, some also require implementation of reasonable security measures and provide a private right of action in the event of a breach. Costs of breach response, mitigation, investigation, remediation, notice and ongoing assessments can be considerable. Thus, any access, disclosure, damage or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under state, federal and international privacy laws, disruption of our operations, and damage to our reputation, which could adversely affect our business.

We and certain of our service providers have been and from time to time will continue to be subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material

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disruption of our programs. For example, the loss of clinical trial data for setmelanotide or other product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of setmelanotide and our product candidates could be delayed. It could also expose us to risks, including an inability to provide our services and fulfill contractual demands, and could cause management distraction and the obligation to devote significant financial and other resources to mitigate such problems, which would increase our future information security costs, including through organizational changes, deploying additional personnel, reinforcing administrative, physical and technical safeguards, further training of employees, changing third-party vendor control practices and engaging third-party subject matter experts and consultants and reduce the demand for our product and services. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

Risks Related to Our Common Stock

Our directors and executive officers and their affiliated entities own a significant percentage of our stock and, if they choose to act together, will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers and directors and their respective affiliates, in the aggregate, hold shares representing approximately 5.9% of our outstanding voting stock as of April 22, 2024. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders could significantly influence elections of directors, any amendments of our organizational documents, or approval of any merger,

sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, even one that may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We are a Delaware corporation. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively will provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Any provision in our amended and restated certificate of incorporation and amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Market volatility may affect our stock price and the value of your investment.

The market price for our common stock has been volatile and may continue to fluctuate significantly in response to a number of factors, most of which we cannot control, including, among others:

- plans for, progress of, or results from preclinical studies and clinical trials of setmelanotide and our other product candidates;

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- the failure of the FDA or EMA to approve IMCIVREE for additional indications;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- the success or failure of other weight loss therapies and companies targeting rare diseases and orphan drug treatment;
- regulatory or legal developments in the United States and other countries;
- failure of setmelanotide or our other product candidates, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;

- global macroeconomic conditions, including with respect to inflation rates or interest rates, labor shortages, supply chain shortages, disruptions and instability in the banking industry and other parts of the financial services sector, or other economic, political or legal uncertainties or adverse developments;
- terrorism and/or political instability, unrest and wars, such as the conflicts involving Ukraine and Russia or Israel and Hamas, which could delay or disrupt our business, and if such political unrest escalates or spills over to or otherwise impacts additional regions it could heighten many of the other risk factors included in this sections;

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- natural disasters (including as a result of climate change), which could cause significant damage to the infrastructure upon which our business operations rely, and the timing, nature or severity of which we may be unable to prepare for;
- economic instability, outbreak of disease or epidemics, boycotts, curtailment of trade and other business restrictions;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- our ability to raise additional capital and the terms on which we can raise it;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of key personnel;
- discussion of us or our stock price by the press and by online investor communities; and
- other risks and uncertainties described in these risk factors.

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Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting setmelanotide and our other product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the achievement and timing of milestone payments under our existing collaboration and license agreements; and

- the level of underlying demand for setmelanotide and customers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

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Our ability to use certain net operating loss carryovers and other tax attributes may be limited.

Under the Code, a corporation is generally allowed a deduction for net operating losses, or NOLs, carried over from a prior taxable year, and can use such NOLs to offset future taxable income, if any, until such losses are used or, for NOLs arising in taxable years ending on or before December 31, 2017, until such NOLs expire. Other unused tax attributes, such as research tax credits may also be carried forward to offset future taxable income, if any, until such attributes are used or expire. As of December 31, 2023, we had approximately $555.6 million and $598.0 million of unused federal and state NOL carryforwards, respectively, and approximately $13.1 million and $3.8 million of unused federal and state carryforwards of research tax credits, respectively. Of the federal NOL carryforwards at December 31, 2023, $482.4 million can be carried forward indefinitely, while $73.2 million will begin to expire in 2033. Additionally, as of December 31, 2023, we had federal orphan drug credits related to qualifying research of $25.5 million.

If a corporation undergoes an "ownership change," very generally defined as a greater than 50% change by value in its equity ownership by certain shareholders or groups of shareholders over a rolling three-year period, Sections 382 and 383 of the Code limit the corporation's ability to use carryovers of its pre-change NOLs, credits and certain other tax attributes to reduce its tax liability for periods after the ownership change. Our issuance of common stock pursuant to prior public offerings may have resulted in a limitation under Code Sections 382 and 383, either separately or in combination with certain prior or subsequent shifts in the ownership of our common stock. Future changes in our stock ownership, some of which are outside of our control, could also result in an ownership change under Sections 382 and 383 of the Code. In addition, for taxable years beginning after December 31, 2020, utilization of federal NOLs generated in tax years beginning after December 31, 2017 are limited to a maximum of 80% of the taxable income for such year, after taking into account utilization of NOLs generated in years beginning before January 1, 2018 and determined without regard to such NOL deduction. Further regulatory changes could also limit our ability to utilize our NOLs. As a result, our ability to use carryovers of NOLs and credits to reduce our future U.S. federal income tax liability may be subject to limitations. This could result in increased U.S. federal income tax liability for us if we generate taxable income in a future period. Limitations on the use of NOLs and other tax attributes could also increase our state tax liability. Any such limitation could have a material adverse effect on our results of operations in future years. We have not completed a study to assess

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whether an ownership change for purposes of Section 382 or 383 has occurred, or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such study.

The use of our tax attributes will also be limited to the extent that we do not generate positive taxable income in future tax periods. We do not expect to generate positive taxable income in the near future and we may never achieve tax profitability.

Substantial future sales or perceived potential sales of our common stock in the public market could cause the price of our common stock to decline significantly.

Sales of our common stock in the public market, or the perception that these sales could occur, could cause the market price of our common stock to decline significantly. As of March 31, 2024 June 30, 2024, we had 60,964,468 61,095,949 shares of common stock outstanding. In addition, on July 10, 2023, we filed with the SEC a prospectus supplement to the prospectus included in the Company's registration statement on Form S-3ASR filed with the SEC on March 2, 2023, covering the resale from time to time by the holders of the Convertible Preferred Stock of up to an aggregate of 3,124,995 shares of common stock, to satisfy registration rights that the Company granted to such holders in connection with the issuance of the Convertible Preferred Stock. To the extent the holders of the Convertible Preferred Stock convert their shares to common stock and sell such shares, the price of our common stock could be significantly impacted.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our common stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. Additionally, Convertible Preferred Stock will rank senior to the shares of the Company's common stock, with respect to the payment of dividends and the distribution of assets upon a liquidation, dissolution or winding up of the Company. Holders of the Convertible Preferred Stock will be entitled to a regular dividend at a rate as specified in the Amended and Restated Certificate of Designations filed by the Company with the Secretary of State of the State of Delaware.

Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them.

Our common stock is subordinated to our Convertible Preferred Stock.

In connection with the closing of our Investment Agreement, the Company issued 150,000 shares of a new series of the Company's Convertible Preferred Stock for an aggregate purchase price of $150.0 million, or $1,000 per share. The Convertible Preferred Stock will rank senior to the shares of the Company's common stock, with respect to the payment of dividends and the distribution of assets upon a liquidation, dissolution or winding up of the Company. The Convertible Preferred Stock will initially have a liquidation preference of $1,000 per share; provided that the liquidation preference in dissolution or upon a change of control shall be increased to be 175% of the then applicable liquidation preference, as described in the Amended and Restated Certificate of Designations. The Convertible Preferred Stock will be is convertible into shares of our common stock at the option of the holders thereof at any time following subject to the expiration or termination of any applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act.

Additionally, holders terms of the Convertible Preferred Stock will not initially be entitled to voting rights in the election Amended and Restated Certificate of directors of the Company. Following the expiration or termination of any applicable waiting period under the HSR Act, Designations.

Additionally, holders of the Convertible Preferred Stock generally will be entitled to vote with the holders of the shares of our common stock, subject to certain restrictions pursuant to the terms of the Amended and Restated Certificate of Designations, on all matters submitted for a vote of holders of shares of our common stock (voting together with the holders of shares of our common stock as one class) on an as-converted basis, subject to certain ownership limitations. On May 7,

2024, May 7, 2024, the Company filed an Amended and Restated Certificate of Designations in respect of the Convertible Preferred Stock containing certain technical amendments to the terms of the Convertible Preferred Stock. The amendments contained in the Amended and Restated Certificate of Designations (x) limited the voting rights of the Convertible Preferred Stock to 24.9438 shares of the Company's common stock per $1,000 liquidation preference of Convertible Preferred Stock and (y) eliminated a 1% step up in the interest rate that otherwise would have applied in the unlikely event that the Company was required to obtain and failed to obtain stockholder approval for certain conversion shares underlying the Convertible Preferred Stock. Additionally, certain matters will require the approval of the holders of two-thirds of the outstanding Convertible Preferred Stock, voting as a separate class, including (1) the authorization, creation, increase in the authorized amount of, or issuance of any class or series of senior or pari passu equity securities or any security convertible into, or exchangeable or exercisable for, shares of senior or pari passu equity securities, (2) amendments, modifications or repeal of any provision of the Company's charter or of the Amended and Restated Certificate of Designations that would adversely affect the rights, preferences or voting powers of the Convertible Preferred Stock, and (3) certain business combinations and binding or statutory share exchanges or reclassification involving the Convertible Preferred Stock unless such events do not adversely affect the rights, preferences or voting powers of the Convertible Preferred Stock.

In the future, we may make additional offerings of debt or preferred equity securities, including convertible or non-convertible senior or subordinated notes, convertible or non-convertible preferred stock, medium-term notes and trust preferred securities, to raise cash or bolster our liquidity, to refinance indebtedness, for working capital, to finance strategic initiatives and future acquisitions or for other purposes. Upon liquidation, holders of our debt securities and shares of preferred stock and lenders with respect to other borrowings may receive distributions of our available assets prior to the holders of our common stock. In addition, any preferred stock we may issue could have a preference on liquidating distributions or a preference on distribution payments that could limit our ability to make a distribution to the holders of our common stock. Since our decision to issue securities in any future offering will depend on market conditions and other

factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings. Thus, our stockholders bear the risk of our future offerings reducing the market price of our common stock.

Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the market price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our Company or changes in our management that the stockholders of our Company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;

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- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders and our bylaws designate the federal district courts of the United States as the exclusive forum for actions arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable an alternate preferred judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of

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fiduciary duty; (iii) any action asserting a claim against us arising under the DGCL, our certificate of incorporation or our bylaws; and (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our bylaws provide that the federal district courts of the United States are the exclusive forum for any complaint raising a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to the provisions of our certificate of incorporation and bylaws described above. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find these provisions of our certificate of incorporation or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

General Risk Factors

We may acquire businesses or products, form strategic alliances or create joint ventures in the future, and we may not realize their benefits.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance, joint venture or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

An active market for our common stock may not be maintained.

Our stock began trading on the Nasdaq Global Market in October 2017 and we can provide no assurance that we will be able to continue to maintain an active trading market on the Nasdaq Global Market or any other exchange in the future. If an active market for our common stock is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

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If securities or industry analysts do not continue to publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not control these analysts. If we lose securities or industry analysts coverage of our Company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts issues unfavorable commentary or ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. From time to time we may raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, such as our sale of Convertible Preferred Stock under the Investment Agreement, which did cause in the case of the Investment Agreement and may cause in the future a stockholder's ownership interest in our Company to be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect the rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring

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dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to setmelanotide, our intellectual property or future revenue streams, or grant licenses on terms that are not favorable to us. See "*Our common stock is subordinated to our Convertible Preferred Stock*."

Unfavorable global political or economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. A severe or prolonged economic downturn or recession and a continued increase in inflation rates or interest rates could result in a variety of risks to our business, including weakened demand for setmelanotide and our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Increased inflation rates and related increases in interest rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, geopolitical conflicts and war could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have and may in the future be initiated by nations including the U.S., the EU or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with which we conduct business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Business interruptions could adversely affect our operations.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, public health crises and pandemic diseases, and other natural and man-made disasters or events beyond our control. Our facilities are located in regions that experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, public health crisis, pandemic diseases or other disasters and do not

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have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We have incurred and will continue to incur substantial costs as a result of operating as a public company, our management will continue to devote substantial time to new compliance initiatives and corporation governance policies, and we will need to hire additional qualified accounting and financial personnel with appropriate public company experience.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will continue to devote a substantial amount of time to these compliance initiatives and we will need to continue to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and make some activities more time consuming and costly.

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These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in future uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. As described further below, we have identified a material weakness in our internal control over financial reporting. Any testing by us conducted in connection with Section 404, or any testing by our independent registered public accounting firm, may reveal additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. To continue to achieve and maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, from time to time we may not be able to conclude that our internal control over financial reporting is effective as required by Section 404, as is the case of our Annual Report on Form 10-K for the year ended December 31, 2023, due to the material weakness identified and described below. Additionally, the material weakness in our internal control over financial reporting has resulted in our management being unable to conclude, and any additional material weakness in our internal control over financial reporting may in the future result in our management being unable to conclude, that our disclosure controls and procedures were effective for the applicable period.

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In addition, as we no longer qualify as a non-accelerated filer, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, our independent registered public accounting firm may issue a report that is adverse, as it did in our Annual Report on Form 10-K for the year ended December 31, 2023. A material weakness could result in a restatement of our financial statements, failure to meet our reporting obligations in a timely manner, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Ineffective internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. Any of these could, in turn, result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We have identified a material weakness in our internal controls over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. We identified a material weakness in internal control related to ineffective information technology general controls ("ITGCs") in the areas of user access and program change management over our key accounting and reporting information technology ("IT") system. As a result, the related

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business process controls (specifically, the IT application controls and IT-dependent manual controls) that are dependent on the ineffective ITGCs, or that use data produced from the system impacted by the ineffective ITGCs, were also ineffective. Although the material weakness identified above did not result in any material misstatements in our consolidated financial statements for the periods presented and there were no changes to previously released financial results, our management concluded that these control deficiencies constitute a material weakness and that our internal control over financial reporting was not effective as of December 31, 2023.

Our management, under the oversight of the Audit Committee of our Board of Directors and in consultation with outside advisors, has begun evaluating and implementing measures designed to remediate the material weakness. In particular, we are taking steps to remediate this material weakness by (i) developing and implementing additional training and awareness programs addressing ITGCs and policies, including educating control owners concerning the principles and requirements of each control, with a focus on user access; (ii) increasing the extent of oversight and verification checks included in the operation of user access and program change management controls and processes; (iii) deploying additional tools to support administration of user access and program change management; and (iv) enhancing quarterly management reporting on the remediation measures to the Audit Committee of the Board of Directors. The above controls need to operate for a sufficient period of time so that management can conclude that our controls are operating effectively. As such, the material weakness will not be considered remediated until management has concluded through the implementation of these remediation measures and additional testing that these controls are effective. Additionally, a material weakness in our internal control over financial reporting has resulted in our management being unable to conclude, and any additional material weakness in our internal control over financial reporting may in the future result in our management being unable to conclude, that our disclosure controls and procedures were effective for the applicable period.

We are designing and implementing new controls and measures to remediate this material weakness as noted above. However, we cannot assure you that the measures we are taking will be sufficient to remediate the material weakness or avoid the identification of additional material weaknesses in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our consolidated financial statements that could result in a restatement of our financial statements and could cause us to fail to meet our periodic reporting obligations, any of which could diminish investor confidence in us and cause a decline in the price of our common stock.

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The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, customers, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In the future, we may engage in sustainability-related initiatives and voluntary disclosures or commitments, which may be costly and may not have the desired effect. We may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have a materially adverse impact on our business and financial condition. In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted. Moreover, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement or activism.

Additionally, many of our business partners and suppliers may be subject to similar reporting and stakeholder expectations, which may augment or create additional risks, including risks that may not be known to us.

Short sellers of our stock may be manipulative and may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed or intends to borrow from a third party with the intention of buying identical securities at a later date to return to the lender. A short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. It is therefore in the short seller's interest for the price of the stock to decline, and some short sellers publish, or arrange for the

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publication of, opinions or characterizations regarding the relevant issuer, often involving misrepresentations of the issuer's business prospects and similar matters calculated to create negative market momentum, which may permit them to obtain profits for themselves as a result of selling the stock short.

As a public entity, we may be the subject of concerted efforts by short sellers to spread negative information in order to gain a market advantage. In addition, the publication of misinformation may also result in further lawsuits, the uncertainty and expense of which could adversely impact our business, financial condition, and reputation. There are no assurances that we will not face further short sellers' efforts or similar tactics in the future, and the market price of our common stock may decline as a result of their actions.

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

Unregistered Sales of Equity Securities

Except as previously disclosed in our Current Report on Form 8-K filed on April 1, 2024, we did not make any unregistered sales of equity securities during the period covered by the report.

Use of Proceeds

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

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Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

Item 3.03. Material Modification to Rights of Security Holders; Item 5.03. Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

As previously disclosed, on April 1, 2024, the Company entered into an Investment Agreement with certain affiliates of Perceptive Advisors LLC and certain other investors relating to the issuance and sale of 150,000 shares of a new series of the Company's Series A Convertible Preferred Stock, par value $0.001 per share, titled the "Series A

Convertible Preferred Stock" (the "Convertible Preferred Stock"), for an aggregate purchase price of $150,000,000, or $1,000 per share, and on April 15, 2024, the Company filed the Certificate of Designations with the Secretary of State of the State of Delaware, effective the same day.

On May 7, 2024, the Company filed an Amended and Restated Certificate of Designations in respect of the Convertible Preferred Stock containing certain technical amendments to the terms of the Convertible Preferred Stock. The amendments contained in the Amended and Restated Certificate of Designations (x) limited the voting rights of the Convertible Preferred Stock to 24.9438 shares of the Company's common stock per $1,000 liquidation preference of Convertible Preferred Stock and (y) eliminated a 1% step up in the interest rate that otherwise would have applied in the unlikely event that the Company was required to obtain and failed to obtain stockholder approval for certain conversion shares underlying the Convertible Preferred Stock.

The foregoing description Amended and Restated Certificate of Designations is not complete and is qualified in its entirety by reference to the full text of such document, a copy of which is filed as Exhibit 3.4 to this Quarterly Report on Form 10-Q and is incorporated by reference herein. None.

(b) Material changes to the procedures by which security holders may recommend nominees to the board of directors.

None.

(c) Insider Trading Arrangements and Policies.

During the three months ended March 31, 2024 June 30, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

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Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1	Amended and Restated Certificate of Incorporation.	10-Q	05/04/2020	3.1
3.2	Amended and Restated Bylaws.	8-K	12/18/2023	3.1
3.3	Certificate of Designations	8-K	04/16/2024	3.1
3.4*	Amended and Restated Certificate of Designations			
10.1*	Summary of Non-Employee Director Compensation Policy.			
10.2‡‡	Exclusive License Agreement, dated January 4, 2024, by and between Rhythm Pharmaceuticals, Inc. and LG Chem, Ltd.	10-K	02/29/2024	10.25
10.3	Investment Agreement dated April 1, 2024, by and between Rhythm Pharmaceuticals, Inc., certain affiliates of Perceptive Advisors LLC, and certain other investors	8-K	04/01/2024	10.1
10.4*	Rhythm Pharmaceuticals, Inc. 2017 Equity Incentive Plan Performance Unit Agreement			
10.5*	Third Amendment to Lease, dated May 2, 2024, by and between the Registrant and 500 Boylston & 222 Berkeley Owner (DE) LLC.			
31.1*	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
31.2*	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.1**	Certification of the Principal Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.2**	Certification of the Principal Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
101.INS*	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.			
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.			

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1	Amended and Restated Certificate of Incorporation.	10-Q	05/04/2020	3.1
3.2	Amended and Restated Bylaws.	8-K	12/18/2023	3.1

3.3	Certificate of Designations	8-K	04/16/2024	3.1
3.4	Amended and Restated Certificate of Designations	10-Q	05/07/2024	3.4
10.1*	Non-Employee Director Compensation Program.			
10.2	Investment Agreement dated April 1, 2024, by and between Rhythm Pharmaceuticals, Inc., certain affiliates of Perceptive Advisors LLC, and certain other investors	8-K	04/01/2024	10.1
10.3	Rhythm Pharmaceuticals, Inc. 2017 Equity Incentive Plan Performance Unit Agreement	10-Q	05/07/2024	10.4
10.4	Third Amendment to Lease, dated May 2, 2024, by and between the Registrant and 500 Boylston & 222 Berkeley Owner (DE) LLC.	10-Q	05/07/2024	10.5
31.1*	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
31.2*	Certification of the Principal Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.1**	Certification of the Principal Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.2**	Certification of the Principal Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
101.INS*	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.			
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.			

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101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

‡‡ Indicates that portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and the registrant customarily and actually treats such information as private or confidential.

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SIGNATURES

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

RHYTHM PHARMACEUTICALS, INC.

Dated: May 7, 2024 August 6, 2024

By: /s/ David P. Meeker, M.D.
Name: David P. Meeker, M.D.
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: May 7, 2024 August 6, 2024

By: /s/ Hunter C. Smith
Name: Hunter C. Smith
Title: Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 3.4 10.1

RHYTHM PHARMACEUTICALS, INC.

AMENDED AND RESTATED

Certificate of Designations Non-Employee Director Compensation Program

Series A Convertible Preferred Stock

May 7, 2024

TableNon-employee members of Contents

Amended and Restated
Certificate of Designations

Series A Convertible Preferred Stock

Rhythm Pharmaceuticals, Inc. (the "***Company"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), in accordance with the provisions of Section 151 of the DGCL, does hereby certify that:***

WHEREAS, the Board of Directors of the Company (the "Board") previously adopted a resolution authorizing the creation shall receive cash and issuance of a series of preferred stock designated equity compensation as the "Series A Convertible Preferred Stock" (the "Series A Convertible Preferred Stock") and the Certificate of Designations for the Series

A Convertible Preferred Stock was filed with the Secretary of State of the State of Delaware on April 15, 2024 (the "Original Certificate of Designations");

WHEREAS, on May 6, 2024, the Board approved and adopted the following resolution for purposes of amending certain provisions of the Series A Convertible Preferred Stock and the Original Certificate of Designations; and

WHEREAS, on May 6, 2024, the holders of at least two thirds of the shares of Series A Convertible Preferred Stock then outstanding (the "Requisite Holders"), voting separately as a class, approved the amendments to the Original Certificate of Designations set forth in the resolution below. this Non-Employee Director Compensation Program (this "

NOW THEREFORE, BE IT RESOLVED, that, subject to approval Program"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Requisite Holders, the Original Certificate of Designations shall be amended and the designation and amount thereof and the voting powers, preferences and relative, participating, optional and other special rights Board, to each member of the shares of such series and the qualifications, limitations or restrictions thereof are as follows and the Original Certificate of Designations is hereby amended and restated in its entirety to read as follows:

Section 1. ***DEFINITIONS*****.**

"Abeyance Shares" has the meaning set forth in Section 10(h).

"Abeyance Dividend" has the meaning set forth in Section 10(h).

"Affiliate" has the meaning set forth in Rule 144.

"Antitrust Clearance Date" means the date on which the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("HSR"), has expired or been terminated, and any other required clearances, approvals or authorizations of filings and registrations with, and notifications to government authorities under other applicable antitrust and competition laws have been received, in each case, with respect to the ownership by the Holders of voting securities in the Company. The Antitrust Clearance Date shall be deemed to have

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occurred with respect to any shares of Convertible Preferred Stock held by a Holder Board who is not required to undergo the HSR waiting period.

"Antitrust Redemption" has the meaning set forth in Section 7(h).

"Antitrust Redemption Date" means a Business Day of the Company's choosing that is no more than thirty five (35), nor less than twenty (20), Business Days after the Antitrust Trigger Event occurs.

"Antitrust Trigger Event" means, with respect to any share of Convertible Preferred Stock the event that the Antitrust Clearance Date has not occurred as of the one-year anniversary of the Initial Issue Date with respect to such share.

"Attribution Parties" has the meaning set forth in Section 10(h)(i).

"Board of Directors" means the Company's board of directors or a committee of such board duly authorized to act on behalf of such board.

"Business Day" means any day other than a Saturday, a Sunday or any day on which the Federal Reserve Bank of New York is authorized or required by law or executive order to close or be closed.

"Buy-In" has the meaning set forth in Section 10(e)(v).

"Capital Stock" of any Person means any and all shares of, interests in, rights to purchase, warrants or options for, participations in, or other equivalents of, in each case however designated, the equity of such Person, but excluding any debt securities convertible into such equity.

"Certificate" means any Physical Certificate or Electronic Certificate.

"Certificate of Designations" means this Amended and Restated Certificate of Designations, as amended, supplemented and/or restated from time to time.

"Certificate of Incorporation" means the Company's Amended and Restated Certificate of Incorporation, as the same may be further amended, supplemented or restated from time to time.

"Change of Control" means any of the following events:

(a) ***a "person" or "group" (within the meaning of Section 13(d)(3) of the Exchange Act), other than the Company, its Wholly Owned Subsidiaries or a Holder (together with its Affiliates), has become the direct or indirect "beneficial owner" (as defined below) of shares of the Company's common equity representing at least fifty percent (50%) of the voting power of all of the Company's then-outstanding common equity; or***

(b) ***the consummation of (i) any sale, lease, transfer, exclusive license or other disposition, in one transaction or a series of transactions, of all or substantially all of the assets of the Company and its Subsidiaries, taken as a whole, to any Person; or (ii) any transaction or series***

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of related transactions in connection with which (whether by means of merger, consolidation, share exchange, combination, reclassification, recapitalization, acquisition, liquidation or otherwise) all of the Common Stock is exchanged for, converted into, acquired for, or constitutes solely the right to receive, other securities, cash or other property; provided, however, that any merger, consolidation, share exchange or combination of the Company pursuant to which the Persons that directly or indirectly "beneficially owned" (as defined below) all classes of the Company's common equity immediately before such transaction directly or indirectly "beneficially own," immediately after such transaction, at least fifty percent (50%) of all classes of common equity of the surviving, continuing or acquiring company or other transferee, as applicable, or the parent thereof, will be deemed not to be a Change of Control pursuant to this clause (b).

For the purposes of this definition, (x) any transaction or event described in both clause (a) and in clause (b)(i) or (ii) above (without regard to the proviso in clause (b)) will be deemed to occur solely pursuant to clause (b) above (subject to such proviso); and (y) whether a Person is a "beneficial owner" and whether shares are "beneficially owned" will be determined in accordance with Rule 13d-3 under the Exchange Act.

"Change of Control Notice" has the meaning set forth in Section 8(e).

"Change of Control Repurchase Date" means the date fixed, pursuant to Section 8(c), for the repurchase of any Convertible Preferred Stock by the Company pursuant to a Repurchase Upon Change of Control.

"Change of Control Repurchase Notice" means a notice (including a notice substantially in the form of the "Change of Control Repurchase Notice" set forth in Exhibit A) containing the information, or otherwise complying with the requirements, set forth in Section 8(f)(i) and Section 8(f)(ii).

"Change of Control Repurchase Price" means the cash price payable by the Company to repurchase any share of Convertible Preferred Stock upon its Repurchase Upon Change of Control, calculated pursuant to Section 8(d).

"Change of Control Repurchase Right" has the meaning set forth in Section 8(a).

"Close of Business" means 5:00 p.m., New York City time.

"Code" means the Internal Revenue Code of 1986, as amended.

"Common Stock" means the common stock, par value $0.001 per share, of the Company, subject to Section 10(i).

"Common Stock Abeyance Dividend" has the meaning set forth in Section 10(h).

"Common Stock Change Event" has the meaning set forth in Section 10(i)(i).

"Common Stock Liquidity Conditions" will be satisfied with respect to a Mandatory

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Conversion or Redemption if:

(a) *either (i) each share of Common Stock to be issued upon such Mandatory Conversion of any share of Convertible Preferred Stock or that may be issued upon conversion of any share of Convertible Preferred Stock that is subject to such Redemption would be eligible to be offered, sold or otherwise transferred by the Holder of such share of Convertible Preferred Stock pursuant to Rule 144 under the Securities Act (or any successor rule thereto), without any requirements as to volume, manner of sale, availability of current public information (whether or not then satisfied) or notice; or (ii) the offer and sale of such share of Common Stock by such Holder are registered pursuant to an effective registration statement under the Securities Act and such registration statement is reasonably expected by the Company to remain effective and usable, by the Holder to sell such share of Common Stock, continuously during the period from, and including, the date the related Mandatory Conversion Notice or Redemption Notice Date, as applicable, is sent to, and including, the thirtieth (30th) calendar day after the date such share of Common Stock is issued; provided, however, that each Holder will supply all information reasonably requested by the Company for inclusion, and required to be included, in any registration statement or prospectus supplement related to the resale of the Common Stock issuable upon conversion of the Convertible Preferred Stock; provided, further, that if a Holder fails to provide such information to the Company within fifteen (15) calendar days following any such request, then this clause (a)(ii) will automatically be deemed to be satisfied with respect to such Holder;*

(b) *each share of Common Stock referred to in clause (a) above (i) will, when issued (or, in the case of clause (a)(ii), when sold or otherwise transferred pursuant to the registration statement referred to in such clause) (1) be admitted for book-entry settlement through the Depositary with an "unrestricted" CUSIP number; and (2) not be represented by any certificate that bears a legend referring to transfer restrictions under the Securities Act or other securities laws; and (ii) will, when issued, be listed and admitted for trading, without suspension or material limitation on trading, on any of The New York Stock Exchange, The Nasdaq Global Market or The Nasdaq Global Select Market (or any of their respective successors);*

(c) *(i) the Company has not received any written threat or notice of delisting or suspension by the applicable exchange referred to in clause (b)(ii) above with a reasonable prospect of delisting, after giving effect to all applicable notice and appeal periods; and (ii) no such delisting or suspension is reasonably likely to occur or is pending based on the Company falling below the minimum listing maintenance requirements of such exchange;*

(d) *the number of shares of Common Stock issuable upon conversion of the Convertible Preferred Stock, together with the shares of Common Stock previously issued upon conversion of the Convertible Preferred Stock, does not exceed the Share Cap, unless the Requisite Stockholder Approval has been obtained or the Share Cap Fall Away has occurred; and*

(e) *with respect to any Holder, the Company shall not have provided such Holder information that, at the time such Common Stock Liquidity Condition is determined, constitutes material non-public information under the U.S. federal securities laws regarding the Company.*

"Common Stock Participating Dividend" has the meaning set forth in Section 5(b)(i).

"Company" means Rhythm Pharmaceuticals, Inc., a Delaware corporation.

"Conversion Share" means any share of Common Stock issued or issuable upon conversion of any Convertible Preferred Stock.

"Conversion Consideration" means, with respect to the conversion of any Convertible Preferred Stock, the type and amount of consideration payable to settle such conversion, determined in accordance with Section 10.

"Conversion Date" means an Optional Conversion Date or a Mandatory Conversion Date.

"Conversion Notice" means a notice substantially in the form of the "Conversion Notice" set forth in Exhibit A.

"Conversion Price" means, as of any time, an amount equal to (a) the Initial Liquidation Preference per share of Convertible Preferred Stock divided by (b) the Conversion Rate in effect at such time.

"Conversion Rate" initially means 20.8333 shares of Common Stock per one thousand dollars ($1,000.00) of Liquidation Preference of the Convertible Preferred Stock; provided, however, that the Conversion Rate is subject to adjustment pursuant to Sections 10(f) and 10(g). Each reference in this Certificate of Designations or the Convertible Preferred Stock to the Conversion Rate as of a particular date without setting forth a particular time on such date will be deemed to be a reference to the Conversion Rate immediately before the Close of Business on such date.

"Convertible Preferred Stock" has the meaning set forth in Section 3(a).

"Degressive Issuance" has the meaning set forth in Section 10(f)(i)(2).

"Degressive Issuance Sunset Date" means the date on which the Company releases unblinded results for FRI065 Trial Design Of A Double-blind, Randomized, Placebo-controlled, Phase 3 Study Of Setmelanotide In Patients With Hypothalamic Obesity (ClinicalTrials.gov Identifier: NCT05774756) including the results of the Primary Endpoints.

"Depositary" means The Depository Trust Company or its successor.

"Depositary Participant" means any member of, or participant in, the Depositary.

"Dividend" means any Regular Dividend or Participating Dividend.

"Dividend Junior Stock" means any class or series of the Company's stock whose terms do not expressly provide that such class or series will rank senior to, or equally with, the Convertible Preferred Stock with respect to the payment of dividends (without regard to whether or not dividends accumulate cumulatively). As of the Initial Issue Date, the Common Stock is the

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only Dividend Junior Stock.

"Dividend Parity Stock" means any class or series of the Company's stock (other than the Convertible Preferred Stock) whose terms expressly provide that such class or series will rank equally with the Convertible Preferred Stock with respect to the payment of dividends (without regard to whether or not dividends accumulate cumulatively). As of the Initial Issue Date, no shares of Dividend Parity Stock are issued or outstanding.

"Dividend Payment Date" means each Regular Dividend Payment Date with respect to a Regular Dividend and each date on which any declared Participating Dividend is scheduled to be paid on the Convertible Preferred Stock.

"Dividend Senior Stock" means any class or series of the Company's stock whose terms expressly provide that such class or series will rank senior to the Convertible Preferred Stock with respect to the payment of dividends (without regard to whether or not dividends accumulate cumulatively). As of the Initial Issue Date, no shares of Dividend Senior Stock are issued or outstanding.

"Effective Price" has the following meaning with respect to the issuance or sale of any shares of Common Stock or any Equity-Linked Securities:

(a) ***in the case of the issuance or sale of shares of Common Stock, the value of the consideration received or receivable by (or at the direction of) the Company or any of its Affiliates for such shares, expressed as an amount per share of Common Stock; and***

(b) ***in the case of the issuance or sale of any Equity-Linked Securities, an amount equal to a fraction whose:***

(i) ***numerator is equal to sum, without duplication, of (x) the value of the aggregate consideration received by the Company for the issuance or sale of such Equity-Linked Securities; and (y) the value of the minimum aggregate additional consideration, if any, payable to purchase or otherwise acquire shares of Common Stock pursuant to such Equity-Linked Securities; and***

(ii) ***denominator is equal to the maximum number of shares of Common Stock underlying such Equity-Linked Securities;***

provided, however, that:

(w) ***for purposes of clauses (a) and (b)(i) above, all underwriting commissions, placement agency commissions or similar commissions paid to any broker-dealer by the Company or any of its Affiliates in connection with such issuance or sale (excluding any other fees or expenses incurred by the Company or any of its Affiliates) will be added to the aggregate consideration referred to in such clause;***

(x) ***for purposes of clause (b) above, if such minimum aggregate consideration, or such maximum number of shares of Common Stock, is not determinable at the time such***

Equity-Linked Securities are issued or sold, then (1) the initial consideration payable under such Equity-Linked Securities, or the initial number of shares of Common Stock underlying such Equity-Linked Securities, as applicable, will be used; and (2) at each time thereafter when such amount of consideration or number of shares becomes determinable or is otherwise adjusted (including pursuant to "anti-dilution" or similar provisions), there will be deemed to occur, for purposes of Section 10(f)(i)(2) and without affecting any prior adjustments theretofore made to the Conversion Rate, an issuance of additional Equity-Linked Securities;

(y) ***for purposes of clause (b) above, the surrender, extinguishment, maturity or other expiration of any such Equity-Linked Securities will be deemed not to constitute consideration payable to purchase or otherwise acquire shares of Common Stock pursuant to such Equity-Linked Securities; and***

(z) *the "value" of any such consideration will be the fair value thereof, as of the date such shares or Equity-Linked Securities, as applicable, are issued or sold, determined in good faith by the Board of Directors (or, in the case of cash denominated in U.S. dollars, the face amount thereof).*

"Electronic Certificate" means any electronic book-entry maintained by the Transfer Agent that represents any share(s) of Convertible Preferred Stock.

"Equity-Linked Securities" means any rights, options or warrants to purchase or otherwise acquire (whether immediately, during specified times, upon the satisfaction of any conditions or otherwise) any shares of Common Stock.

"Ex-Dividend Date" means, with respect to an issuance, dividend or distribution on the Common Stock, the first date on which shares of Common Stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such issuance, dividend or distribution (including pursuant to due bills or similar arrangements required by the relevant stock exchange). For the avoidance of doubt, any alternative trading convention on the applicable exchange or market in respect of the Common Stock under a separate ticker symbol or CUSIP number will not be considered "regular way" for this purpose.

"Excess Shares" has the meaning set forth in Section 10(h)(i).

"Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended.

"Exempt Issuance" means (a) the Company's issuance of any securities as full or partial consideration in connection with a merger, acquisition, consolidation or purchase of all or substantially all of the securities or assets of a corporation or other entity; (b) the Company's issuance or grant of shares of Common Stock, options to purchase shares Common Stock, or any other form of equity-based or equity-related awards (including restricted stock units), to employees, prospective employees who have accepted an offer of employment, directors or consultants employee of the Company or any of its Subsidiaries pursuant to plans that have been approved by a majority subsidiary of the members Company (each, a "Non-Employee Director") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors, or that exist except for equity compensation previously granted to a Non-Employee Director. This Program is effective as of the Initial Issue Date; (c) June 18, 2024 (the "Effective Date").

I. ***CASH COMPENSATION***

A. ***Annual Retainers**. Each Non-Employee Director shall receive an annual retainer of $50,000 for service on the Board.*

B. ***Additional Annual Retainers**. In addition, each Non-Employee Director shall receive the following annual retainers:*

1. Chair of the Board. A Non-Employee Director serving as Chair of the Board shall receive an additional annual retainer of $30,000 for such service.

2.Lead Director. A Non-Employee Director serving as Lead Director shall receive an additional annual retainer of $35,000 for such service.

3. Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of $10,000 for such service.

4.Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of $10,000 for such service.

5. Governance and Nominating Committee. A Non-Employee Director serving as Chairperson of the Governance and Nominating Committee shall receive an additional annual retainer of $10,000 for such service. A Non-

Employee Director serving as a member other

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than the Chairperson of the Governance and Nominating Committee shall receive an additional annual retainer of $5,000 for such service.

C.Payment of Retainers. The retainers described in Sections I(A) and (B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

II. ***EQUITY COMPENSATION***

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's issuance of securities upon 2017 Equity Incentive Plan or any other applicable Company equity incentive plan then-maintained by the exercise, exchange or conversion of any securities that are exercisable or exchangeable for, or convertible into, shares of Common Stock Company (the "Equity Plan") and are outstanding as shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Initial Issue Date, provided that such exercise, exchange or conversion is effected pursuant Equity Plan apply to this Program as if fully set forth herein, and all grants of equity awards under this Program are subject in all respects to the terms of such securities as in effect on the Initial Issue Date; (d) the Company's issuance of the Convertible Preferred Stock and any shares of Common Stock upon conversion of the Convertible Preferred Stock; and (e) the Company's issuance or sale of shares of Common Stock or Equity-Linked Securities in connection with sponsored research, collaboration, technology license, development, marketing or other similar agreements or strategic partnerships approved by a majority of the members of the Board of Directors; provided, however, that the aggregate number of shares of Common Stock or Equity-Linked Securities issued pursuant to clause (a) and (e) shall not exceed 10% of the total number of shares of Common Stock issued and outstanding. For purposes of this definition, "consultant" means a consultant that may participate in an "employee benefit plan" in accordance with the definition of such term in Rule 405 under the Securities Act.

"Holder" means a person in whose name any Convertible Preferred Stock is registered in the Register.

"Initial Issue Date" means April 15, 2024.

"Initial Liquidation Preference" means one thousand dollars ($1,000.00) per share of Convertible Preferred Stock.

"Last Reported Sale Price" of the Common Stock for any Trading Day means the closing sale price per share (or, if no closing sale price is reported, the average of the last bid price Equity Plan and the last ask price per share or, if more than one in either case, the average of the average last bid prices and the average last ask prices per share) of the Common Stock on such Trading Day as reported in composite transactions for the principal U.S. national or regional securities exchange on which the Common Stock is then listed. If the Common Stock is not listed on a U.S. national or regional securities exchange on such Trading Day, then the Last Reported Sale Price will be the last quoted bid price per share of Common Stock on such Trading Day in the over-the-counter market as reported by OTC Markets Group Inc. or a similar organization. If the Common Stock is not so quoted on such Trading Day, then the Last Reported Sale Price will be the average of the mid-point of the last bid price and the last ask price per share of Common Stock on such Trading Day from each of at least three nationally recognized independent investment banking firms the Company selects.

"Liquidation Junior Stock" means any class or series of the Company's stock whose terms do not expressly provide that such class or series will rank senior to, or equally with, the Convertible Preferred Stock

with respect to the distribution of assets upon the Company's liquidation, dissolution or winding up. As of the Initial Issue Date, the Common Stock is the only Liquidation Junior Stock.

"Liquidation Parity Stock" means any class or series of the Company's stock (other than the Convertible Preferred Stock) whose terms expressly provide that such class or series will rank equally with the Convertible Preferred Stock with respect to the distribution of assets upon the

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Company's liquidation, dissolution or winding up. As of the Initial Issue Date, no shares of Liquidation Parity Stock are issued or outstanding.

"Liquidation Preference" means, with respect to the Convertible Preferred Stock, an amount initially equal to the Initial Liquidation Preference per share of Convertible Preferred Stock; provided, however, that the Liquidation Preference is subject to adjustment pursuant to Sections 5(a)(ii)(1).

"Liquidation Senior Stock" means any class or series of the Company's stock whose terms expressly provide that such class or series will rank senior to the Convertible Preferred Stock with respect to the distribution of assets upon the Company's liquidation, dissolution or winding up. As of the Initial Issue Date, no shares of Liquidation Senior Stock are issued or outstanding.

"Mandatory Conversion" has the meaning set forth in Section 10(c)(i).

"Mandatory Conversion Date" means a Conversion Date designated with respect to any Convertible Preferred Stock pursuant to Section 10(c)(i) and 10(c)(iii).

"Mandatory Conversion Notice" has the meaning set forth in Section 10(c)(iv).

"Mandatory Conversion Notice Date" means, with respect to a Mandatory Conversion, the date on which the Company sends the Mandatory Conversion Notice for such Mandatory Conversion pursuant to Section 10(c)(iv).

"Mandatory Conversion Right" has the meaning set forth in Section 10(c)(i).

"Mandatory Conversion Threshold Price Percentage" means two-hundred and fifty percent (250%).

"Market Disruption Event" means, with respect to any date, the occurrence or existence, during the one-half hour period ending at the scheduled close of trading on such date on the principal U.S. national or regional securities exchange or other market on which the Common Stock is listed for trading or trades, of any material suspension or limitation imposed on trading (by reason of movements in price exceeding limits permitted by the relevant exchange or otherwise) in the Common Stock or in any options contracts or futures contracts relating to the Common Stock.

"Maximum Percentage" has the meaning set forth in Section 10(h)(i).

"Minimum Price Conversion Rate" means 23.0786 shares of Common Stock per one thousand dollars ($1,000.00) of Liquidation Preference of the Convertible Preferred Stock, subject to adjustment in the manner set forth in Section 10(f)(i)(1).

"Minimum Price Voting Rate" means 24.9438 shares of Common Stock per one thousand dollars ($1,000.00) of Liquidation Preference of the Convertible Preferred Stock, subject to adjustment in the manner set forth in Section 10(f)(i)(1).

"Officer" means the Chairman of the Board of Directors, the Chief Executive Officer, the President, the Chief Operating Officer, the Chief Financial Officer, the Treasurer, any Assistant Treasurer, the Controller, the Secretary, any Assistant Secretary or any Vice-President of the Company.

"Open of Business" means 9:00 a.m., New York City time.

"Optional Conversion" means the conversion of any Convertible Preferred Stock other than a Mandatory Conversion.

"Optional Conversion Date" means, with respect to the Optional Conversion of any Convertible Preferred Stock, the first Business Day on which the requirements set forth in Section 10(d)(ii) for such conversion are satisfied.

"Ownership Limitation" has the meaning set forth in Section 10(h)(i).

"Participating Dividend" has the meaning set forth in Section 5(b)(i).

"Person" or "person" means any individual, corporation, partnership, limited liability company, joint venture, association, joint-stock company, trust, unincorporated organization or government or other agency or political subdivision thereof. Any division or series of a limited liability company, limited partnership or trust will constitute a separate "person" under this Certificate of Designations.

"Physical Certificate" means any certificate (other than an Electronic Certificate) representing any share(s) of Convertible Preferred Stock, which certificate is substantially in the form set forth in Exhibit A, registered in the name of the Holder of such share(s) and duly executed by the Company and countersigned by the Transfer Agent.

"Record Date" means, with respect to any dividend or distribution on, or issuance to holders of, Convertible Preferred Stock or Common Stock, the date fixed (whether by law, contract or the Board of Directors or otherwise) to determine the Holders or the holders of Common Stock, as applicable that are entitled to such dividend, distribution or issuance.

"Redemption" means the repurchase of any Convertible Preferred Stock by the Company pursuant to Section 7.

"Redemption Date" means the date fixed, pursuant to Section 7(d), for the settlement of the repurchase of the Convertible Preferred Stock by the Company pursuant to a Redemption.

"Redemption Notice" has the meaning set forth in Section 7(f).

"Redemption Notice Date" means, with respect to a Redemption of the Convertible Preferred Stock, the date on which the Company sends the related Redemption Notice pursuant to Section 7(f).

"Redemption Price" means the consideration payable by the Company to repurchase any Convertible Preferred Stock upon its Redemption, calculated pursuant to Section 7(e).

"Redemption Trigger Date" means the fifth anniversary of the Initial Issue Date.

"Reference Property" has the meaning set forth in Section 10(i)(i).

"Reference Property Unit" has the meaning set forth in Section 10(i)(i).

"Register" has the meaning set forth in Section 3(e).

"Regular Dividend Payment Date" means, with respect to any share of Convertible Preferred Stock, each January 1, April 1, July 1 and October 1 of each year, beginning on July 1, 2026 (or beginning on such other date specified in the Certificate representing such share).

"Regular Dividend Period" means each period from, and including, a Regular Dividend Payment Date (or, in the case of the first Regular Dividend Period, from, and including, the Initial Issue Date) to, but excluding, the next Regular Dividend Payment Date.

"Regular Dividend Rate" means (a) for the period beginning on, and including, the Initial Issue Date and ending on, but excluding, the second anniversary of the Initial Issue Date, zero percent (0%) per annum and (b) for the period beginning on, and including, the second anniversary of the Initial Issue Date, six percent (6%) per annum.

"Regular Dividends" has the meaning set forth in Section 5(a)(i)(1).

"Reported Share Outstanding Number" has the meaning set forth in Section 10(h)(i).

"Repurchase Upon Change of Control" means the repurchase of any Convertible Preferred Stock by the Company pursuant to Section 8.

"Requisite Stockholder Approval" means the stockholder approval contemplated by the Nasdaq listing rules with respect to the issuance of shares of Common Stock upon conversion of the Convertible Preferred Stock in excess of the limitations imposed by such rule; provided, however, that the Requisite Stockholder Approval will be deemed to be obtained if, due to any amendment or binding change in the interpretation of the applicable listing standards of The Nasdaq Stock Market, such stockholder approval is no longer required for the Company to settle all conversions of the Convertible Preferred Stock in shares of Common Stock without regard to Section 10(h).

"Restricted Stock Legend" means a legend substantially in the form set forth in Exhibit B.

"Revenue Interest Financing Agreement" means that certain Revenue Interest

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Financing Agreement, dated as of June 16, 2022, among Rhythm Pharmaceuticals, Inc., entities managed by Healthcare Royalty Management, LLC identified therein, as investors, and HCR Collateral Management, LLC, as Investor Representative.

"Rule 144" means Rule 144 under the Securities Act (or any successor rule thereto), as the same may be amended from time to time.

"Scheduled Trading Day" means any day that is scheduled to be a Trading Day on the principal U.S. national or regional securities exchange on which the Common Stock is then listed or, if the Common Stock is not then listed on a U.S. national or regional securities exchange, on the principal other market on which the Common Stock is then traded. If the Common Stock is not so listed or traded, then "Scheduled Trading Day" means a Business Day.

"SEC" means the U.S. Securities and Exchange Commission.

"Securities Act" means the U.S. Securities Act of 1933, as amended.

"Security" means any Convertible Preferred Stock or Conversion Share.

"Share Cap" means 12,186,607 shares of Common Stock, subject to adjustment in the manner set forth in Section 10(f)(i)(1).

"Share Cap Fall Away" means the event that, as of the Degressive Issuance Sunset Date, the Conversion Rate has not been adjusted as set forth in Section 10(f)(i)(2) to be greater than the Minimum Price Conversion Rate.

"Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, for the Company's primary trading market or quotation system with respect to the Common Stock that is in effect on the Conversion Date, which as of the Initial Issue Date was "T+2."

"Share Delivery Date" has the meaning set forth in Section 10(e)(iv).

"Stockholder Voting Power" means the aggregate number of votes entitled to be cast generally at a meeting of the Company's stockholders held for the election of directors, with the calculation of such aggregate number of votes being conclusively made for all purposes under this Certificate of Designations and the Certificate of Incorporation, absent manifest error, by the Company based on the Company's review of the Register, the Company's other books and records, each Holder's public filings pursuant to Section 13 or Section 16 of the Exchange Act and any other written evidence satisfactory to the Company regarding any Holder's beneficial ownership of any securities of the Company.

"Subsidiary" means, with respect to any Person, (a) any corporation, association or other business entity (other than a partnership or limited liability company) of which more than 50% of the total voting power of the Capital Stock entitled (without regard to the occurrence of any contingency, but after giving effect to any voting agreement or stockholders' agreement that

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effectively transfers voting power) to vote in the election of directors, managers or trustees, as applicable, of such corporation, association or other business entity is owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of such Person; and (b) any partnership or limited liability company where (x) more than fifty percent (50%) of the capital accounts, distribution rights, equity and voting interests, or of the general and limited partnership interests, as applicable, of such partnership or limited liability company are owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of such Person, whether in the form of membership, general, special or limited partnership or limited liability company interests or otherwise; and (y) such Person or any one or more of the other Subsidiaries of such Person is a controlling general partner of, or otherwise controls, such partnership or limited liability company.

"Successor Person" has the meaning set forth in Section 10(i)(iii).

"Survivor of a Change of Control" means the issuer of the securities received by the holders of Common Stock upon the consummation of a Change of Control, to the extent the holders of Common Stock receive other securities in exchange, conversion or substitution of their Common Stock in the transaction that resulted in such Change of Control.

"Trading Day" means any day on which (a) trading in the Common Stock generally occurs on the principal U.S. national or regional securities exchange on which the Common Stock is then listed or, if the Common Stock is not then listed on a U.S. national or regional securities exchange, on the principal other market on which the Common Stock is then traded; and (b) there is no Market Disruption Event. If the Common Stock is not so listed or traded, then "Trading Day" means a Business Day.

"Transfer Agent" means Computershare Trust Company N.A. or its successor.

"Transfer-Restricted Security" means any Security that constitutes a "restricted security" (as defined in Rule 144); provided, however, that such Security will cease to be a Transfer-Restricted Security upon the earliest to occur of the following events:

(a) ***such Security is sold or otherwise transferred to a Person (other than the Company or an Affiliate of the Company) pursuant to a registration statement that was effective under the Securities Act at the time of such sale or transfer;***

(b) ***such Security is sold or otherwise transferred to a Person (other than the Company or an Affiliate of the Company) pursuant to an available exemption (including Rule 144) from the registration and prospectus-delivery requirements of, or in a transaction not subject to, the Securities Act and, immediately after such sale or transfer, such Security ceases to constitute a "restricted security" (as defined in Rule 144); and***

(c) ***(i) such Security is eligible for resale, by a Person that is not an Affiliate of the Company and that has not been an Affiliate of the Company during the immediately preceding three (3) months, pursuant to Rule 144 without any limitations thereunder as to volume, manner of sale, availability of current public information or notice; and (ii) the Company has received such certificates or other documentation or evidence as the Company may reasonably require to***

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determine that the security is eligible for resale pursuant to clause (i) and the Holder, holder or beneficial owner of such Security is not, and that has not been during the immediately preceding three (3) months, an Affiliate of the Company.

"Wholly Owned Subsidiary" of a Person means any Subsidiary of such Person all of the outstanding Capital Stock or other ownership interests of which (other than directors' qualifying shares) are owned by such Person or one or more Wholly Owned Subsidiaries of such Person.

Section 2. ***RULES OF CONSTRUCTION. For purposes of this Certificate of Designations:***

(a) ***"or" is not exclusive;***

(b) ***"including" means "including without limitation";***

(c) ***"will" expresses a command;***

(d) ***the "average" of a set of numerical values refers to the arithmetic average of such numerical values;***

(e) ***a merger involving, or a transfer of assets by, a limited liability company, limited partnership or trust will be deemed to include any division of or by, or an allocation of assets to a series of, such limited liability company, limited partnership or trust, or any unwinding of any such division or allocation;***

(f) ***words in the singular include the plural and in the plural include the singular, unless the context requires otherwise;***

(g) ***"herein," "hereof" and other words of similar import refer to this Certificate of Designations as a whole and not to any particular Section or other subdivision of this Certificate of Designations, unless the context requires otherwise;***

(h) ***references to currency mean the lawful currency of the United States of America, unless the context requires otherwise; and***

(i) ***the exhibits, schedules and other attachments to this Certificate of Designations are deemed to form part of this Certificate of Designations.***

Section 3. ***THE CONVERTIBLE PREFERRED STOCK.***

(a) ***Designation; Par Value. A series of stock of the Company titled the "Series A Convertible Preferred Stock" (the "Convertible Preferred Stock") is hereby designated and created out of the authorized and unissued shares of preferred stock of the Company. The par value of the Convertible Preferred Stock is $0.001 per share.***

(b) ***Number of Authorized Shares. The total authorized number of shares of Convertible Preferred Stock is one hundred and fifty thousand (150,000); provided, however that, by resolution***

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of the Board of Directors, the total number of authorized shares of Convertible Preferred Stock may hereafter be reduced to a number that is not less than the number of shares of Convertible Preferred Stock then outstanding.

(c) ***Form, Dating and Denominations.***

(i) ***Form and Date of Certificates Representing Convertible Preferred Stock. Each Certificate representing any Convertible Preferred Stock will bear the legends required by Section 3(f) and may bear notations, legends or endorsements required by law, stock exchange rule or usage or the Depositary.***

(ii) ***Certificates.***

(1)Generally. The Convertible Preferred Stock will be originally issued initially in the form of one or more Electronic Certificates. Electronic Certificates may be exchanged for Physical Certificates, and Physical Certificates may be exchanged for Electronic Certificates, upon request by the Holder thereof pursuant to customary procedures.

(2)Electronic Certificates; Interpretation. For purposes of this Certificate of Designations, (A) each Electronic Certificate will be deemed to include the text of the stock certificate set forth in Exhibit A; (B) any legend or other notation that is required to be included on a Certificate will be deemed to be included in any Electronic Certificate notwithstanding that such Electronic Certificate may be in a form that does not permit affixing legends thereto; (C) any reference in this Certificate of Designations to the "delivery" of any Electronic Certificate will be deemed to be satisfied upon the registration of the electronic book-entry representing such Electronic Certificate in the name of the applicable Holder; (D) upon satisfaction of any applicable requirements of the Delaware General Corporation Law, the Certificate of Incorporation and the Bylaws of the Company, and any related requirements of the Transfer Agent, in each case for the issuance of Convertible Preferred Stock in the form of one or more Electronic Certificates, such Electronic Certificates will be deemed to be executed by the Company and countersigned by the Transfer Agent.

(iii) ***No Bearer Certificates; Denominations. The Convertible Preferred Stock will be issued only in registered form and only in whole numbers of shares.***

(iv) ***Registration Numbers. Each Certificate representing any Convertible Preferred Stock will bear a unique registration number that is not affixed to any other Certificate representing any other outstanding share of Convertible Preferred Stock.***

(d) ***Method of Payment; Delay When Payment Date is Not a Business Day.***

(i) ***Method of Payment. The Company will pay all cash amounts due on any Convertible Preferred Stock by check issued in the name of the Holder thereof; provided, however, that if such Holder has delivered to the Company, no later than the time set forth***

in the next sentence, a written request to receive payment by wire transfer to an account of such Holder within the United States, then the Company will pay all such cash amounts by wire transfer of immediately available funds to such account. To be timely, such written request must be delivered no later than the Close of Business on the following date: (x) with respect to the payment of any declared cash Participating Dividend due on a Dividend Payment Date for the Convertible Preferred Stock, the related Record Date; and (y) with respect to any other payment, the date that is fifteen (15) calendar days immediately before the date such payment is due.

(ii) *Delay of Payment when Payment Date is Not a Business Day. If the due date for a payment on any Convertible Preferred Stock as provided in this Certificate of Designations is not a Business Day, then, notwithstanding anything to the contrary in this Certificate of Designations, such payment may be made on the immediately following Business Day and no interest, dividend or other amount will accrue or accumulate on such payment as a result of the related delay. Solely for purposes of the immediately preceding sentence, a day on which the applicable place of payment is authorized or required by law or executive order to close or be closed will be deemed not to be a "Business Day."*

(e) *Register. The Company will, or will retain another Person (who may be to the Transfer Agent) to act as registrar who will, keep a record (the "Register") of the names and addresses of the Holders, the number of shares of Convertible Preferred Stock held by each Holder and the transfer, exchange, repurchase, Redemption and conversion of the Convertible Preferred Stock. Absent manifest error, the entries in the Register will be conclusive, and the Company and the Transfer Agent may treat each Person whose name is recorded as a Holder in the Register as a Holder for all purposes. The Register will be in written form or in any form capable of being converted into written form reasonably promptly. The Company will promptly provide a copy of the Register to any Holder upon its request.*

(f) *Legends.*

(i) *Restricted Stock Legend.*

(1)Each Certificate representing any share of Convertible Preferred Stock that is a Transfer-Restricted Security will bear the Restricted Stock Legend.

(2)If any share of Convertible Preferred Stock is issued in exchange for, in substitution of, or to effect a partial conversion of, any other share(s) of Convertible Preferred Stock (such other share(s) being referred to as the "old share(s)" for purposes of this Section 3(f)(i)(2)), including pursuant to Section 3(h) or 3(j), then the Certificate representing such share will bear the Restricted Stock Legend if the certificate representing such old share(s) bore the Restricted Stock Legend at the time of such exchange or substitution, or on the related Conversion Date with respect to such conversion, as applicable; provided, however, that the Certificate representing such share need not bear the Restricted Stock Legend if such share does not constitute a Transfer-Restricted Security immediately after such exchange or substitution, or as of such Conversion Date, as applicable.

(ii) *Other Legends. The Certificate representing any Convertible Preferred Stock may bear any other legend or text, not inconsistent with this Certificate of Designations, as may be required by applicable law or by any securities exchange or automated quotation system on which such Convertible Preferred Stock is traded or quoted or as may be otherwise reasonably determined by the Company to be appropriate.*

(iii) *Legends on Conversion Shares.*

(1)Each Conversion Share will bear a legend substantially to the same effect as the Restricted Stock Legend if the Convertible Preferred Stock upon the conversion of which such Conversion Share was issued was (or would have been had it not been converted) a Transfer-Restricted Security at the time such

Conversion Share was issued; provided, however, that such Conversion Share need not bear such a legend if the Company determines, in its reasonable discretion, that such Conversion Share need not bear such a legend.

(2)Notwithstanding anything to the contrary in Section 3(f)(iii)(1), a Conversion Share need not bear a legend pursuant to Section 3(f)(iii)(1) if such Conversion Share is issued in an uncertificated form that does not permit affixing legends thereto.

(g) *Transfers and Exchanges; Transfer Taxes; Certain Transfer Restrictions.*

(i) *Provisions Applicable to All Transfers and Exchanges.*

(1)Generally. Subject to this Section 3(g), Convertible Preferred Stock represented by any Certificate may be transferred or exchanged from time to time, and the Company will cause each such transfer or exchange to be recorded in the Register.

(2)No Services Charge; Transfer Taxes. The Company will not impose any service charge on any Holder for any transfer, exchange or conversion of any Convertible Preferred Stock, but the Company may require payment of a sum sufficient to cover any transfer tax or similar governmental charge that may be imposed in connection with any transfer, exchange or conversion, pursuant to Section 11(d), of Convertible Preferred Stock, other than exchanges pursuant to Section 3(h) or Section 3(o) not involving any transfer.

(3)No Transfers or Exchanges of Fractional Shares. Notwithstanding anything to the contrary in this Certificate of Designations, all transfers or exchanges of Convertible Preferred Stock must be in an amount representing a whole number of shares of Convertible Preferred Stock, and no fractional share of Convertible Preferred Stock may be transferred or exchanged.

(4)Legends. Each Certificate representing any share of Convertible Preferred Stock that is issued upon transfer of, or in exchange for, another share of Convertible Preferred Stock will bear each legend, if any, required by Section 3(f).

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(5)Settlement of Transfers and Exchanges. Upon satisfaction of the requirements of this Certificate of Designations to effect a transfer or exchange of any Convertible Preferred Stock as well as the delivery of all documentation reasonably required by the Transfer Agent or the Company in order to effect any transfer or exchange, the Company will cause such transfer or exchange to be effected as soon as reasonably practicable but in no event later than the number of Trading Days comprising the Standard Settlement Period after the date of such satisfaction.

(ii) *Transfers of Shares Subject to Redemption, Repurchase or Conversion. Notwithstanding anything to the contrary in this Certificate of Designations, the Company will not be required to register the transfer of or exchange any share of Convertible Preferred Stock:*

(1)that has been surrendered for conversion;

(2)that has been called for Redemption pursuant to a Redemption Notice, except to the extent that the Company fails to pay the related Redemption Price when due; or

(3)as to which a Change of Control Repurchase Notice has been duly delivered, and not withdrawn, pursuant to Section 8(f), except to the extent that the Company fails to pay the related Change of Control Repurchase Price when due.

(h) *Exchange and Cancellation of Convertible Preferred Stock to Be Converted or to Be Repurchased Pursuant to a Repurchase Upon Change of Control or a Redemption.*

(i) ***Partial Conversions of Certificates and Partial Repurchases of Certificates Pursuant to a Repurchase Upon Change of Control. If only a portion of a Holder's Convertible Preferred Stock represented by a Certificate (such Certificate being referred to as the "old Certificate" for purposes of this Section 3(h)(i)) is to be converted pursuant to Section 10 or repurchased pursuant to a Repurchase Upon Change of Control, then, as soon as reasonably practicable after such Certificate is surrendered for such conversion or repurchase, as applicable, the Company will cause such Certificate to be exchanged for (1) one or more Certificates that each represent a whole number of shares of Convertible Preferred Stock and, in the aggregate, represent a total number of shares of Convertible Preferred Stock equal to the number of shares of Convertible Preferred Stock represented by such old Certificate that are not to be so converted or repurchased, as applicable, and deliver such Certificate(s) to such Holder; and (2) a Certificate representing a whole number of shares of Convertible Preferred Stock equal to the number of shares of Convertible Preferred Stock represented by such old Certificate that are to be so converted or repurchased, as applicable, which Certificate will be converted or repurchased, as applicable, pursuant to the terms of this Certificate of Designations; provided, however, that the Certificate referred to in this clause (2) need not be issued at any time after which such shares subject to such conversion or repurchase, as applicable, are deemed to cease to be outstanding pursuant to Section 3(n).***

(ii) ***Cancellation of Convertible Preferred Stock that Is Converted and Convertible Preferred Stock that Is Repurchased Pursuant to a Repurchase Upon Change of Control or a Redemption. If a Holder's Convertible Preferred Stock represented by a Certificate (or any portion thereof that has not theretofore been exchanged pursuant to Section 3(h)(i)) (such Certificate being referred to as the "old Certificate" for purposes of this Section 3(h)(ii)) is to be converted pursuant to Section 10 or repurchased pursuant to a Repurchase Upon Change of Control or a Redemption, then, promptly after the later of the time such Convertible Preferred Stock is deemed to cease to be outstanding pursuant to Section 3(n) and the time such Certificate is surrendered for such conversion or repurchase, as applicable, (A) such Certificate will be cancelled pursuant to Section 3(l); and (B) in the case of a partial conversion or repurchase, the Company will issue, execute and deliver to such Holder, and cause the Transfer Agent to countersign, one or more Certificates that (x) each represent a whole number of shares of Convertible Preferred Stock and, in the aggregate, represent a total number of shares of Convertible Preferred Stock equal to the number of shares of Convertible Preferred Stock represented by such old Certificate that are not to be so converted or repurchased, as applicable; (y) are registered in the name of such Holder; and (z) bear each legend, if any, required by Section 3(f).***

(i) ***Status of Retired Shares. Upon any share of Convertible Preferred Stock ceasing to be outstanding, such share will be deemed to be retired and to resume the status of an authorized and unissued share of preferred stock of the Company, and such share cannot thereafter be reissued as Convertible Preferred Stock.***

(j) ***Replacement Certificates. If a Holder of any Convertible Preferred Stock claims that the Certificate(s) representing such Convertible Preferred Stock have been mutilated, lost, destroyed or wrongfully taken, then the Company will issue, execute and deliver, and cause the Transfer Agent to countersign, in each case in accordance with Section 3(c), a replacement Certificate representing such Convertible Preferred Stock upon surrender to the Company or the Transfer Agent of such mutilated Certificate, or upon delivery to the Company or the Transfer Agent of evidence of such loss, destruction or wrongful taking reasonably satisfactory to the Transfer Agent and the Company. In the case of a lost, destroyed or wrongfully taken Certificate representing any Convertible Preferred Stock, the Company and the Transfer Agent may require the Holder thereof to provide such security or indemnity that is reasonably satisfactory to the Company and the Transfer Agent to protect the Company and the Transfer Agent from any loss that any of them may suffer if such Certificate is replaced.***

Every replacement Convertible Preferred Stock issued pursuant to this Section 3(j) will, upon such replacement, be deemed to be outstanding Convertible Preferred Stock, entitled to all of the benefits of this Certificate of Designations equally and ratably with all other Convertible Preferred Stock then outstanding.

(k) *Registered Holders. Only the Holder of any Convertible Preferred Stock will have rights under this Certificate of Designations as the owner of such Convertible Preferred Stock.*

(l) *Cancellation. The Company may at any time deliver Convertible Preferred Stock to the Transfer Agent for cancellation. The Company will cause the Transfer Agent to promptly*

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cancel all shares of Convertible Preferred Stock so surrendered to it in accordance with its customary procedures.

(m) *Shares Held by the Company or its Affiliates. Without limiting the generality of Section 3(n), in determining whether the Holders of the required number of outstanding shares of Convertible Preferred Stock have concurred in any direction, waiver or consent, shares of Convertible Preferred Stock owned by the Company or any of its Subsidiaries will be deemed not to be outstanding.*

(n) *Outstanding Shares.*

(i) *Generally. The shares of Convertible Preferred Stock that are outstanding at any time will be deemed to be those shares of Convertible Preferred Stock that, at such time, have been duly executed by the Company and countersigned by the Transfer Agent, excluding those shares of Convertible Preferred Stock that have theretofore been (1) cancelled by the Transfer Agent or delivered to the Transfer Agent for cancellation in accordance with Section 3(l); (2) paid in full upon their conversion or upon their repurchase pursuant to a Repurchase Upon Change of Control or a Redemption in accordance with this Certificate of Designations; or (3) deemed to cease to be outstanding to the extent provided in, and subject to, clause (ii), (iii), (iv) or (v) of this Section 3(n).*

(ii) *Replaced Shares. If any Certificate representing any share of Convertible Preferred Stock is replaced pursuant to Section 3(j), then such share will cease to be outstanding at the time of such replacement, unless the Transfer Agent and the Company receive proof reasonably satisfactory to them that such share is held by a "bona fide purchaser" under applicable law.*

(iii) *Shares to Be Repurchased Pursuant to a Redemption. If, on a Redemption Date, the Company has segregated, solely for the benefit of the applicable Holders, consideration in kind and amount that is sufficient to pay the aggregate Redemption Price due on such date, then (unless there occurs a default in the payment of the Redemption Price) (1) the Convertible Preferred Stock to be redeemed on such date will be deemed, as of such date, to cease to be outstanding; (2) Regular Dividends will cease to accumulate on such Convertible Preferred Stock from and after such Redemption Date; and (3) the rights of the Holders of such Convertible Preferred Stock, as such, will terminate with respect to such Convertible Preferred Stock, other than the right to receive the Redemption Price as provided in Section 7.*

(iv) *Shares to Be Repurchased Pursuant to a Repurchase Upon Change of Control. If, on a Change of Control Repurchase Date, the Company has segregated, solely for the benefit of the applicable Holders, consideration in kind and amount that is sufficient to pay the aggregate Change of Control Repurchase Price due on such date, then (unless there occurs a default in the payment of the Change of Control Repurchase Price) (1) the Convertible Preferred Stock to be repurchased on such date will be deemed, as of such date, to cease to be outstanding; (2) Regular Dividends will cease to accumulate on such Convertible Preferred Stock from and after such Change of Control Repurchase Date; and (3) the rights of the Holders of such Convertible Preferred Stock, as such, will terminate*

with respect to such Convertible Preferred Stock, other than the right to receive the Change of Control Repurchase Price as provided in Section 8 and, if applicable, Section 16.

(v) ***Shares to Be Converted.*** *If any Convertible Preferred Stock is to be converted, then, at the Close of Business on the Conversion Date for such conversion (unless there occurs a default in the delivery of the Conversion Consideration due pursuant to Section 10 upon such conversion): (1) such Convertible Preferred Stock will be deemed to cease to be outstanding; (2) Regular Dividends will cease to accumulate on such Convertible Preferred Stock from and after such Conversion Date; and (3) the rights of the Holders of such Convertible Preferred Stock, as such, will terminate with respect to such Convertible Preferred Stock, other than the right to receive such Conversion Consideration as provided in Section 10 and, if applicable, Section 16.*

(o) ***Notations and Exchanges.*** *Without limiting any rights of Holders pursuant to Section 9, if any amendment, supplement or waiver to the Certificate of Incorporation or this Certificate of Designations changes the terms of any Convertible Preferred Stock, then the Company may, in its discretion, require the Holder of the Certificate representing such Convertible Preferred Stock to deliver such Certificate to the Transfer Agent so that the Transfer Agent may place an appropriate notation prepared by the Company on such Certificate and return such Certificate to such Holder. Alternatively, at its discretion, the Company may, in exchange for such Convertible Preferred Stock, issue, execute and deliver, and cause the Transfer Agent to countersign, in each case in accordance with Section 3(c), a new Certificate representing such Convertible Preferred Stock that reflects the changed terms. The failure to make any appropriate notation or issue a new Certificate representing any Convertible Preferred Stock pursuant to this Section 3(o) will not impair or affect the validity of such amendment, supplement or waiver.*

Section 4. ***RANKING.*** *The Convertible Preferred Stock will rank (a) senior to (i) Dividend Junior Stock with respect to the payment of dividends; and (ii) Liquidation Junior Stock with respect to the distribution of assets upon the Company's liquidation, dissolution or winding up; (b) equally with (i) Dividend Parity Stock with respect to the payment of dividends; and (ii) Liquidation Parity Stock with respect to the distribution of assets upon the Company's liquidation, dissolution or winding up; and (c) junior to (i) Dividend Senior Stock with respect to the payment of dividends; and (ii) Liquidation Senior Stock with respect to the distribution of assets upon the Company's liquidation, dissolution or winding up.*

Section 5. ***DIVIDENDS.***

(a) ***Generally.***

(i) ***Regular Dividends.***

(1)Accumulation and Payment of Regular Dividends. *The Convertible Preferred Stock will accumulate cumulative dividends at a rate per annum equal to the Regular Dividend Rate on the Liquidation Preference thereof (calculated in accordance with Section 5(a)(i)(2)), regardless of whether or not declared or funds are legally available for their payment (such dividends that accumulate on the Convertible Preferred Stock pursuant to this sentence, "Regular*

Dividends"). Subject to the other provisions of this Section 5 (including, for the avoidance of doubt, Section 5(a)(ii)(1)), such Regular Dividends will be payable quarterly in arrears on each Regular Dividend Payment Date. Regular Dividends on the Convertible Preferred Stock will accumulate on a daily basis from, and including, the last date on

which Regular Dividends have been paid (or, if no Regular Dividends have been paid, from, and including, the Initial Issue Date) to, but excluding, the next Regular Dividend Payment Date.

(2)Computation of Accumulated Regular Dividends. Accumulated Regular Dividends will be computed on the basis of a 360-day year comprised of twelve 30-day months. Regular Dividends on each share of Convertible Preferred Stock will accrue on the Liquidation Preference of such share as of immediately before the Close of Business on the preceding Regular Dividend Payment Date (or, if there is no preceding Regular Dividend Payment Date, on the Initial Liquidation Preference of such share).

(ii) *Methods of Payment of Regular Dividends; Payments in Kind.*

(1)Generally. Subject to the next sentence, each Regular Dividend on the Convertible Preferred Stock will be paid in cash. Notwithstanding anything to the contrary in this Certificate of Designations, if as of the Close of Business on any Regular Dividend Payment Date (or, if such Regular Dividend Payment Date is not a Business Day, the next Business Day), the Company has not paid all or any portion of the full amount of the Regular Dividends (regardless of whether or not declared) that have accumulated on the Convertible Preferred Stock in respect of the Regular Dividend Period ending on, but excluding, such Regular Dividend Payment Date then the dollar amount (expressed as an amount per share of Convertible Preferred Stock) of such Regular Dividend (or, if applicable, portion thereof) not paid in cash will (without duplication) be added, effective immediately before the Close of Business on the related Regular Dividend Payment Date, to the Liquidation Preference of each share of Convertible Preferred Stock outstanding as of such time. Such payment and addition will occur automatically, without the need of any action on the part of the Company or any other Person.

(2)Limitation on PIK Dividends. Notwithstanding anything to the contrary in Section 5(a)(i), the Company shall, solely to the extent permitted by its Revenue Interest Financing Agreement, be required to pay any Regular Dividend in cash if, prior to or immediately following the payment of any such Regular Dividend in kind, the number of shares of Common Stock issuable upon conversion of the then outstanding shares of Convertible Preferred Stock, together with any shares of Common Stock previously issued upon conversion of any shares of Convertible Preferred Stock, would exceed the Share Cap, unless the Requisite Stockholder Approval has been obtained or the Share Cap Fall Away has occurred. In such event the Company shall use reasonable best efforts to cause the payment of any Regular Dividend in cash to be permitted under its Revenue Interest Financing Agreement to pay any Regular Dividend in cash. For the avoidance of doubt, Regular Dividends shall continue to accumulate on each outstanding share

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of Convertible Preferred Stock, as set forth in Section 5(a)(i)(1), notwithstanding any limitations on the Company's ability to pay such Regular Dividend in cash.

(3)Construction. Any Regular Dividends the amount of which is added to the Liquidation Preference thereof pursuant to Section 5(a)(ii)(1) will be deemed to be "declared" and "paid" on the Convertible Preferred Stock for all purposes of this Certificate of Designations.

(b) *Participating Dividends.*

(i) *Generally. Subject to Section 5(b)(ii), no dividend or other distribution on the Common Stock (whether in cash, securities or other property, or any combination of the foregoing) will be declared or paid on the Common Stock unless, at the time of such declaration and payment, an equivalent dividend or distribution is declared and paid, respectively, on the Convertible Preferred Stock (such a dividend or distribution on the Convertible Preferred Stock, a "Participating Dividend," and such corresponding dividend or distribution on the Common Stock, the "Common Stock Participating Dividend"), such that (1) the Record Date and the payment date for such Participating*

Dividend occur on the same dates as the Record Date and payment date, respectively, for such Common Stock Participating Dividend and (2) the kind and amount of consideration payable per share of Convertible Preferred Stock in such Participating Dividend is the same kind and amount of consideration that would be payable in the Common Stock Participating Dividend in respect of a number of shares of Common Stock equal to the number of shares of Common Stock that would be issuable (determined in accordance with Section 10 but without regard to Section 10(e)(ii) and Section 10(h)) in respect of one (1) share of Convertible Preferred Stock that is converted pursuant to an Optional Conversion with a Conversion Date occurring on such Record Date (subject to the same arrangements, if any, in such Common Stock Participating Dividend not to issue or deliver a fractional portion of any security or other property, but with such arrangement applying separately to each Holder and computed based on the total number of shares of Convertible Preferred Stock held by such Holder on such Record Date).

(ii) *Common Stock Change Events and Stock Splits, Dividends and Combinations. Section 5(b)(i) will not apply to, and no Participating Dividend will be required to be declared or paid in respect of, a Common Stock Change Event, or an event for which an adjustment to the Conversion Rate is required pursuant to Section 10(f)(i)(1), as to which Section 10(i) or Section 10(f)(i)(1), respectively, will apply.*

(iii) *Treatment of Participating Dividends Upon Redemption, Repurchase Upon Change of Control or Conversion. If the Redemption Date, Change of Control Repurchase Date or Conversion Date of any share of Convertible Preferred Stock is after a Record Date for a declared Participating Dividend on the Convertible Preferred Stock and on or before the next Dividend Payment Date, then the Holder of such share at the Close of Business on such Record Date will be entitled, notwithstanding the related Redemption, Repurchase Upon Change of Control or conversion, as applicable, to receive, on or, at the Company's election, before such Dividend Payment Date, such declared Participating Dividend on such share.*

Section 6. ***RIGHTS UPON LIQUIDATION, DISSOLUTION OR WINDING UP.***

(a) ***Generally. If the Company liquidates, dissolves or winds up, whether voluntarily or involuntarily, then, subject to the rights of any of the Company's creditors or holders of any outstanding Liquidation Senior Stock, each share of Convertible Preferred Stock will entitle the Holder thereof to receive payment for the greater of the amounts set forth in clause (i) and (ii) below out of the Company's assets or funds legally available for distribution to the Company's stockholders, before any such assets or funds are distributed to, or set aside for the benefit of, any Liquidation Junior Stock:***

(i) ***1.75 multiplied by the sum of:***

(1)the Liquidation Preference per share of Convertible Preferred Stock; and

(2)all unpaid Regular Dividends that will have accumulated on such share to, but excluding, the date of such payment; and

(ii) ***the amount such Holder would have received in respect of the number of shares of Common Stock that would be issuable upon conversion of such share of Convertible Preferred Stock assuming the Conversion Date of such conversion occurs on the date of such payment and assuming all outstanding shares of Convertible Preferred Stock were converted into Common Stock (without regard as to whether sufficient shares of Common Stock are available out of the Company's authorized but unissued stock for the purpose of effecting the conversion of the Convertible Preferred Stock and without regard to any limitation on conversion in accordance with Section 10(h) or Section 10(j)).***

Upon payment of such amount in full on the outstanding Convertible Preferred Stock, Holders of the Convertible Preferred Stock will have no rights to the Company's remaining assets or funds, if any. If such assets or funds are insufficient to fully pay such amount on all outstanding shares of Convertible Preferred Stock and the corresponding amounts payable in respect of all outstanding shares of Liquidation Parity Stock, if any, then, subject to the rights of any of

the Company's creditors or holders of any outstanding Liquidation Senior Stock, such assets or funds will be distributed ratably on the outstanding shares of Convertible Preferred Stock and Liquidation Parity Stock in proportion to the full respective distributions to which such shares would otherwise be entitled.

(b) *Certain Business Combination Transactions Deemed Not to Be a Liquidation. For purposes of Section 6(a), the Company's consolidation or combination with, or merger with or into, or the sale, lease or other transfer of all or substantially all of the Company's assets (other than a sale, lease or other transfer in connection with the Company's liquidation, dissolution or winding up) to, another Person will not, in itself, constitute the Company's liquidation, dissolution or winding up, even if, in connection therewith, the Convertible Preferred Stock is converted into, or is exchanged for, or represents solely the right to receive, other securities, cash or other property, or any combination of the foregoing.*

Section 7. *RIGHT OF THE COMPANY TO REDEEM THE CONVERTIBLE PREFERRED STOCK.*

(a) *No Right to Redeem Before the Redemption Trigger Date. The Company may not redeem the Convertible Preferred Stock at its option at any time before the Redemption Trigger Date, except as set forth in Section 7(h).*

(b) *Right to Redeem the Convertible Preferred Stock on or After Redemption Trigger Date. Subject to the terms of this Section 7, the Company has the right, at its election, to redeem all, but not less than all, of the Convertible Preferred Stock, at any time, on a Redemption Date on or after the Redemption Trigger Date, for a cash purchase price equal to the Redemption Price.*

(c) *Redemption Prohibited in Certain Circumstances. The Company will not call for Redemption, or otherwise send a Redemption Notice in respect of the Redemption of, any Convertible Preferred Stock pursuant to this Section 7 unless (i) the Company has sufficient funds legally available, and is permitted under the terms of its indebtedness for borrowed money, to fully pay the Redemption Price in respect of all shares of Convertible Preferred Stock called for Redemption; and (ii) the Common Stock Liquidity Conditions are satisfied with respect to such Redemption.*

(d) *Redemption Date. The Redemption Date for any Redemption will be a Business Day of the Company's choosing that is no more than sixty (60), nor less than thirty (30), calendar days after the Redemption Notice Date for such Redemption.*

(e) *Redemption Price. The Redemption Price for any share of Convertible Preferred Stock to be repurchased pursuant to a Redemption is an amount in cash equal to the Liquidation Preference of such share at the Close of Business on the Redemption Date for such Redemption plus accumulated and unpaid Regular Dividends on such share to, but excluding, such Redemption Date (to the extent such accumulated and unpaid Regular Dividends are not included in such Liquidation Preference).*

(f) *Redemption Notice. To call any share of Convertible Preferred Stock for Redemption, the Company must send to the Holder of such share a notice of such Redemption (a "Redemption Notice"). Such Redemption Notice must state:*

(i) *that such share has been called for Redemption;*

(ii) *the Redemption Date for such Redemption;*

(iii) *the Redemption Price per share of Convertible Preferred Stock;*

(iv) *that Convertible Preferred Stock called for Redemption may be converted at any time before the Close of Business on the Business Day immediately before the Redemption Date (or, if the Company fails to pay the*

Redemption Price due on such Redemption Date in full, at any time until such time as the Company pays such Redemption Price in full); and

(v) ***the Conversion Rate in effect on the Redemption Notice Date for such Redemption.***

(g) ***Payment of the Redemption Price. The Company will cause the Redemption Price for each share of Convertible Preferred Stock subject to Redemption to be paid to the Holder thereof on or before the applicable Redemption Date.***

(h) ***Redemption Upon an Antitrust Trigger Event. Subject to the terms of this Section 7, upon the request of any Holder following the occurrence of the Antitrust Trigger Event with respect to the shares of Convertible Preferred Stock held by such Holder, the Company may, at its election, redeem all or any portion of the shares of Convertible Preferred Stock with respect to which the Antitrust Trigger Event has occurred, on the Antitrust Redemption Date, for a cash purchase price per share of Convertible Preferred Stock equal to the Initial Liquidation Preference (an "Antitrust Redemption"). The procedures set forth in Sections 7(d), (f) and (g) will apply to any Antitrust Redemption, except that the Redemption Price shall be the Initial Liquidation Preference and the Redemption Date shall be the Antitrust Redemption Date.***

Section 8. ***RIGHT OF HOLDERS TO REQUIRE THE COMPANY TO REPURCHASE CONVERTIBLE PREFERRED STOCK UPON A CHANGE OF CONTROL.***

(a) ***Right of Holders to Require the Company to Repurchase Convertible Preferred Stock upon a Change of Control. Subject to the other terms of this Section 8, if a Change of Control occurs, then each Holder will have the right (the "Change of Control Repurchase Right") to require the Company or the Survivor of a Change of Control (such Survivor of a Change of Control, the "Acquirer") to repurchase all, or any whole number of shares that is less than all, of such Holder's Convertible Preferred Stock on the Change of Control Repurchase Date for such Change of Control for a cash purchase price equal to the Change of Control Repurchase Price. For clarity, any shares of Convertible Preferred Stock in respect of which a Holder does not exercise the right to require the Company to repurchase as set forth in this Section 8 shall remain outstanding.***

(b) ***Funds Legally Available for Payment of Change of Control Repurchase Price; Covenant Not to Take Certain Actions. Notwithstanding anything to the contrary in this Section 8, but subject to Section 16, (i) the rights of the Holders to receive payment of the Change of Control Repurchase Price pursuant to this Section 8 upon the occurrence of a Change of Control are subject to the prior repayment in full of the loans and all other obligations that are accrued and payable under the terms of the Company's Revenue Interest Financing Agreement and the termination of the commitments and the termination of all outstanding letters of credit to the extent required under such Revenue Interest Financing Agreement; (ii) the Company or the Acquirer will not be obligated to pay the Change of Control Repurchase Price of any shares of Convertible Preferred Stock to the extent, and only to the extent, the Company or the Acquirer does not have sufficient funds legally available to pay the same; and (iii) if the Company or the Acquirer does not have sufficient funds legally available to pay the Change of Control Repurchase Price of all shares of Convertible Preferred Stock that are otherwise to be repurchased pursuant to a Repurchase Upon Change of Control, then (1) the Company or the Acquirer, as applicable, will pay the maximum amount of such Change of Control Repurchase Price that can be paid out of funds legally available for payment, which payment will be made pro rata to each Holder based on the total number of shares of Convertible Preferred Stock of such Holder that were otherwise to be repurchased pursuant to such Repurchase Upon Change of Control; and (2) at any time thereafter when additional funds of the Company or the Acquirer, as applicable, become legally***

available for the repurchase of the Convertible Preferred Stock, such funds will be used to redeem the balance of the shares of Convertible Preferred Stock which the Company was theretofore obligated to repurchase. Any shares of Convertible Preferred Stock which are not repurchased as a result of the circumstances described herein shall remain outstanding until such shares shall have been redeemed and the Change of Control Repurchase Price therefor, as applicable, shall have been paid or set aside for payment in full. The Company will not voluntarily take any action, or voluntarily engage in any transaction, that would result in a Change of Control unless the Company has (and will have through the date of payment) sufficient funds legally available to fully pay the maximum aggregate Change of Control Repurchase Price that would be payable in respect of such Change of Control on all shares of Convertible Preferred Stock then outstanding.

(c) *Change of Control Repurchase Date. The Change of Control Repurchase Date for any Change of Control will be a Business Day of the Company's choosing that is no more than thirty five (35), nor less than twenty (20), Business Days after the date the Company sends the related Change of Control Notice pursuant to Section 8(e).*

(d) *Change of Control Repurchase Price. The Change of Control Repurchase Price for any share of Convertible Preferred Stock to be repurchased upon a Repurchase Upon Change of Control following a Change of Control is an amount in cash equal to one hundred and seventy five percent (175%) of the sum of (i) Liquidation Preference of such share at the Close of Business on such Change of Control Repurchase Date plus (ii) accumulated and unpaid Regular Dividends on such share to, but excluding, such Change of Control Repurchase Date (to the extent such accumulated and unpaid Regular Dividends are not included in such Liquidation Preference).*

(e) *Change of Control Notice. On or before the tenth (10th) Business Day before the effective date (or anticipated effective date) of a Change of Control (or, if later, promptly after the Company discovers that a Change of Control may occur), the Company will send to each Holder a notice of such Change of Control (either concurrently with or after the public announcement of the same information) (a "Change of Control Notice"). Such Change of Control Notice must state:*

(i) *briefly, the events causing such Change of Control;*

(ii) *the expected effective date of such Change of Control;*

(iii) *the procedures that a Holder must follow to require the Company to repurchase its Convertible Preferred Stock pursuant to this Section 8, including the deadline for exercising the Change of Control Repurchase Right and the procedures for submitting and withdrawing a Change of Control Repurchase Notice;*

(iv) *the Change of Control Repurchase Date for such Change of Control;*

(v) *the Change of Control Repurchase Price per share of Convertible Preferred Stock;*

(vi) *the Conversion Rate in effect on the date of such Change of Control Notice and a description and quantification of any adjustments to the Conversion Rate that may*

result from such Change of Control;

(vii) *that shares of Convertible Preferred Stock for which a Change of Control Repurchase Notice has been duly tendered and not duly withdrawn must be delivered to the Company for the Holder thereof to be entitled to receive the Change of Control Repurchase Price; and*

(viii) *that shares of Convertible Preferred Stock that are subject to a Change of Control Repurchase Notice that has been duly tendered may be converted only if such Change of Control Repurchase Notice is withdrawn in accordance with this Certificate of Designations.*

(f) ***Procedures to Exercise the Change of Control Repurchase Right.***

(i) ***Delivery of Change of Control Repurchase Notice and Shares of Convertible Preferred Stock to Be Repurchased. To exercise its Change of Control Repurchase Right for any share(s) of Convertible Preferred Stock following a Change of Control, the Holder thereof must deliver to the Company:***

(1)before the Close of Business on the Business Day immediately before the related Change of Control Repurchase Date (or such later time as may be required by law), a duly completed, written Change of Control Repurchase Notice with respect to such share(s); and

(2)such share(s), duly endorsed for transfer, to the extent such share(s) are represented by one or more Physical Certificates.

(ii) ***Contents of Change of Control Repurchase Notices. Each Change of Control Repurchase Notice with respect to any share(s) of Convertible Preferred Stock must state:***

(1)if such share(s) are represented by one or more Physical Certificates, the certificate number(s) of such Physical Certificate(s);

(2)the number of shares of Convertible Preferred Stock to be repurchased, which must be a whole number; and

(3)that such Holder is exercising its Change of Control Repurchase Right with respect to such share(s).

(iii) ***Withdrawal of Change of Control Repurchase Notice. A Holder that has delivered a Change of Control Repurchase Notice with respect to any share(s) of Convertible Preferred Stock may withdraw such Change of Control Repurchase Notice by delivering a written notice of withdrawal to the Company at any time before the Close of Business on the Business Day immediately before the related Change of Control Repurchase Date. Such withdrawal notice must state:***

(1)if such share(s) are represented by one or more Physical

Certificates, the certificate number(s) of such Physical Certificate(s);

(2)the number of shares of Convertible Preferred Stock to be withdrawn, which must be a whole number; and

(3)the number of shares of Convertible Preferred Stock, if any, that remain subject to such Change of Control Repurchase Notice, which must be a whole number.

If any Holder delivers to the Company any such withdrawal notice withdrawing any share(s) of Convertible Preferred Stock from any Change of Control Repurchase Notice previously delivered to the Company, and such share(s) have been surrendered to the Transfer Agent or the Company, then such share(s) will be returned to the Holder thereof.

(g) ***Payment of the Change of Control Repurchase Price. Subject to Section 8(b), the Company or the Acquirer, as applicable, will cause the Change of Control Repurchase Price for each share of Convertible Preferred Stock to be repurchased pursuant to a Repurchase Upon Change of Control to be paid to the Holder thereof on or before the later of (i) the applicable Change of Control Repurchase Date; and (ii) the date such share is tendered to the Transfer Agent or the Company.***

(h) ***Compliance with Securities Laws. Notwithstanding anything in this Certificate of Designations to the contrary, in connection with any offer to repurchase by the Company or the Acquirer, as applicable in connection with a Change of Control or Antitrust Trigger Event, the Company or the Acquirer, as applicable, will, if required, (i) comply with the***

provisions of Rule 13e-4, Rule 14e-1 and any other tender offer rules under the Exchange Act; (ii) file a Schedule TO or any other required filing under the Exchange Act; and (iii) otherwise comply with all federal and state securities laws.

Section 9. *VOTING RIGHTS. The Convertible Preferred Stock will have no voting rights except as set forth in this Section 9 or as provided in the Certificate of Incorporation or required by the Delaware General Corporation Law.*

(a) *Voting and Consent Rights with Respect to Specified Matters.*

(i) *Generally. Subject to the other provisions of this Section 9(a), while any Convertible Preferred Stock is outstanding, each following event will require, and cannot be effected (either directly or indirectly) without, the affirmative vote or consent of Holders representing at least two thirds (2/3rds) of the then-outstanding shares of Convertible Preferred Stock:*

(1)any amendment or modification of the Certificate of Incorporation to authorize or create, or to increase the authorized number of shares of, any class or series of Dividend Parity Stock, Liquidation Parity Stock, Dividend Senior Stock or Liquidation Senior Stock;

(2)any amendment, modification, repeal or waiver of any

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provision of the Certificate of Incorporation or this Certificate of Designations that adversely affects the rights, preferences, privileges or powers of the Convertible Preferred Stock (other than an amendment, modification or repeal permitted by Section 9(a)(iii));

(3)increase or decrease the number of authorized shares of Convertible Preferred Stock (except as permitted herein) or issue additional shares of Convertible Preferred Stock;

(4)[Reserved]; or

(5)the Company's consolidation or combination with, or merger with or into, another Person, or any binding or statutory share exchange or reclassification involving the Convertible Preferred Stock, in each case unless:

(A)the Convertible Preferred Stock either (x) remains outstanding after such consolidation, combination, merger, share exchange or reclassification; or (y) is converted or reclassified into, or is exchanged for, or represents solely the right to receive, preference securities of the continuing, resulting or surviving Person of such consolidation, combination, merger, share exchange or reclassification, or the parent thereof;

(B)the Convertible Preferred Stock that remains outstanding or such preference securities, as applicable, have rights, preferences and voting powers that, taken as a whole, are not materially less favorable to the Holders or the holders thereof, as applicable, than the rights, preferences and voting powers, taken as a whole, of the Convertible Preferred Stock immediately before the consummation of such consolidation, combination, merger, share exchange or reclassification; and

(C)the issuer of the Convertible Preferred Stock that remains outstanding or such preference securities, as applicable, is a corporation duly organized and existing under the laws of the United States of America, any State thereof or the District of Columbia that, if not the Company, will succeed to the Company under this Certificate of Designations and the Convertible Preferred Stock;

provided, however, that (x) a consolidation, combination, merger, share exchange or reclassification that satisfies the requirements of clauses (A), (B) and (C) of Section 9(a)(i)(5) will not require any vote or consent pursuant to Section 9(a)(i)(1) or 9(a)(i)(2); and (y) each of the following will be deemed not to adversely affect the rights, preferences or voting powers of the Convertible Preferred Stock (or cause any of the rights, preferences or voting

powers of any such preference securities to be "materially less favorable" for purposes of Section 9(a)(i)(5)(B)) and will not require any vote or consent pursuant to Section 9(a)(i)(1), 9(a)(i)(2) or 9(a)(i)(5):

(I)any increase in the number of the authorized but unissued shares of

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the Company's undesignated preferred stock;

(II)the creation and issuance, in and of itself, or increase in the authorized or issued number, of any class or series of stock that constitutes both Dividend Junior Stock and Liquidation Junior Stock; and

(III)the application of Section 10(i), including the execution and delivery of any supplemental instruments pursuant to Section 10(i)(iii) solely to give effect to such provision.

(ii) *[Reserved]*

(iii) *Certain Amendments Permitted Without Consent. Notwithstanding anything to the contrary in Section 9(a), the Company may amend, modify or repeal any of the terms of the Convertible Preferred Stock without the vote or consent of any Holder to:*

(1)cure any ambiguity or correct any omission, defect or inconsistency in this Certificate of Designations or the Certificates representing the Convertible Preferred Stock, including the filing of a certificate of correction, or a corrected instrument, pursuant to Section 103(f) of the Delaware General Corporation Law (the "DGCL") in connection therewith; or

(2)make any other change to the Certificate of Incorporation, this Certificate of Designations or the Certificates representing the Convertible Preferred Stock that does not, individually or in the aggregate with all other such changes, adversely affect the rights of any Holder (other than any Holders that have consented to such change), as such, in any material respect.

(b) *Right to Vote with Holders of Common Stock on an As-Converted Basis. Subject to the other provisions of, and without limiting the other voting rights provided in, this Section 9, and except as provided in the Certificate of Incorporation or required by the DGCL, the Holders will have the right, from and after the Antitrust Clearance Date, to vote together as a single class with the holders of the Common Stock on each matter submitted for a vote or consent by the holders of the Common Stock, and, solely for these purposes, (i) the Convertible Preferred Stock of each Holder will entitle such Holder to cast a number of votes on such matter equal to the number of votes such Holder would have been entitled to cast if such Holder were the holder of record, as of the record or other relevant date for such matter, of a number of shares of Common Stock equal to the number of shares of Common Stock that would be issuable (determined in accordance with Section 10(e), including Section 10(e)(ii), but without regard to Section 10(e)(iii)) upon conversion of such Convertible Preferred Stock assuming such Convertible Preferred Stock were converted pursuant to an Optional Conversion with a Conversion Date occurring on such record or other relevant date (without regard as to whether sufficient shares of Common Stock are available out of the Company's authorized but unissued stock); provided that for purposes of determining the number of votes any Holder is entitled to cast under this clause (i), the Conversion Rate shall be deemed to be equal to the lesser of the actual Conversion Rate then in effect and the Minimum Price Voting Rate, and (ii) the Holders will be entitled to notice of all stockholder*

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meetings or proposed actions by written consent in accordance with the Certificate of Incorporation, the Bylaws of the Company, and the DGCL as if the Holders were holders of Common Stock. *award agreement. For the avoidance of doubt, the voting rights set forth* *share numbers in this Section 9(b) (i) will* *Sections II(A) and II(B) shall be limited or eliminated,* *subject to adjustment as applicable,* *provided in accordance with Section 10(h); and (ii) will not apply at any time before the Antitrust Clearance Date. For the avoidance of doubt, and without limiting the voting rights set forth in this Section 9(b), no Holder of Convertible Preferred Stock will be treated as the holder of the shares of Common Stock issuable upon conversion of such Convertible Preferred Stock before the time set forth in Section 10(d)(iv) in connection with the conversion of such Convertible Preferred Stock.* *Equity Plan.*

(c) *A. Procedures for Voting and Consents.*

(i) *Voting Power of the Convertible Preferred Stock* *Initial Awards. Each share of Convertible Preferred Stock will be entitled to one vote on each matter on which the Holders of the Convertible Preferred Stock are entitled to vote separately as a class and not together with the holders of any other class* *Non-Employee Director who is initially elected or series of stock.*

(ii) *Written Consent in Lieu of Stockholder Meeting. A consent or affirmative vote of the Holders pursuant to Section 9(a) may be given or obtained either in writing without a meeting or in person or by proxy at a regular annual meeting or a special meeting of stockholders.*

Section 10. *CONVERSION.*

(a) *Generally. Subject* *appointed to the provisions of this Section 10, the Convertible Preferred Stock may be converted only pursuant to a Mandatory Conversion or an Optional Conversion.*

(b) *Conversion at the Option of the Holders.*

(i) *Conversion Right; When Shares May Be Submitted for Optional Conversion. Subject to the provisions of this Section 10, from and* *Board after the Antitrust Clearance* *Effective Date Holders will have the right* *shall receive an option to submit all, or any whole number of* *purchase 28,000 shares that is less than all, of their shares of Convertible Preferred Stock pursuant to an Optional Conversion at any time after the Initial Issue Date; provided, however, that, notwithstanding anything to the contrary in this Certificate of Designations and in addition to any other requirements for Optional Conversion of such shares of Convertible Preferred Stock,*

(1) if a Change of Control Repurchase Notice is validly delivered pursuant to Section 8(f)(i) with respect to any share of Convertible Preferred Stock, then such share may not be submitted for Optional Conversion, except to the extent (A) such share is not subject to such notice; (B) such notice is withdrawn in accordance with Section 8(f)(iii); or (C) the Company fails to pay the Change of Control Repurchase Price for such share in accordance with this Certificate of Designations;

(2) shares of Convertible Preferred Stock that are called for

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Redemption may not be submitted for Optional Conversion after the Close of Business on the Business Day immediately before the related Redemption Date (or, if the Company fails to pay the Redemption Price due on such Redemption Date in full, at any time until such time as the Company pays such Redemption Price in full); and

(3)shares of Convertible Preferred Stock that are subject to Mandatory Conversion may not be submitted for Optional Conversion after the Close of Business on the Business Day immediately before the related Mandatory Conversion Date.

(ii) *Conversions of Fractional Shares Not Permitted. Notwithstanding anything to the contrary in this Certificate of Designations, in no event will any Holder be entitled to convert a number of shares of Convertible Preferred Stock that is not a whole number.*

(c) *Mandatory Conversion at the Company's Election.*

(i) *Mandatory Conversion Right. Subject to the provisions of this Section 10, the Company has the right (the "Mandatory Conversion Right"), exercisable at its election from and after the Antitrust Clearance Date, to designate any Business Day after the Initial Issue Date as a Conversion Date for the conversion (such a conversion, a "Mandatory Conversion") of all, but not less than all, of the outstanding shares of Convertible Preferred Stock, but only if the Last Reported Sale Price per share of Common Stock exceeds the product of the Mandatory Conversion Threshold Price Percentage and the Conversion Price on each of at least twenty (20) Trading Days (whether or not consecutive) during the thirty (30) consecutive Trading Days ending on, and including, the Trading Day immediately before the Mandatory Conversion Notice Date for such Mandatory Conversion.*

(ii) *Mandatory Conversion Prohibited in Certain Circumstances. The Company will not exercise its Mandatory Conversion Right, or otherwise send a Mandatory Conversion Notice, with respect to any Convertible Preferred Stock pursuant to this Section 10(c) unless the Common Stock Liquidity Conditions are satisfied with respect to the Mandatory Conversion. Notwithstanding anything to the contrary in this Section 10(c), the Company's exercise of its Mandatory Conversion Right, and any related Mandatory Conversion Notice, will not apply to any share of Convertible Preferred Stock as to which a Change of Control Repurchase Notice has been duly delivered, and not withdrawn, pursuant to Section 8(f).*

(iii) *Mandatory Conversion Date. The Mandatory Conversion Date for any Mandatory Conversion will be a Business Day of the Company's choosing that is no more than fifteen (15), nor less than ten (10), Business Days after the Mandatory Conversion Notice Date for such Mandatory Conversion.*

(iv) *Mandatory Conversion Notice. To exercise its Mandatory Conversion Right with respect to any shares of Convertible Preferred Stock, the Company must send to each Holder of such shares a written notice of such exercise (a "Mandatory Conversion*

Notice").

Such Mandatory Conversion Notice must state:

(1)that the Company has exercised its Mandatory Conversion Right to cause the Mandatory Conversion of the shares;

*(2)the Mandatory Conversion Date for such Mandatory Conversion **common stock** and the date scheduled for the settlement of such Mandatory Conversion;*

*(3)that shares of Convertible Preferred Stock subject to Mandatory Conversion may be converted earlier at the option of the Holders thereof pursuant to an Optional Conversion at any time before the Close of Business **8,000 restricted stock units** on the Business Day immediately before the Mandatory Conversion Date; and*

(4)the Conversion Price and the Conversion Rate in effect on the Mandatory Conversion Notice Date for such Mandatory Conversion.

(d) ***Conversion Procedures.***

(i) ***Mandatory Conversion. If the Company duly exercises, in accordance with this Section 10(c), its Mandatory Conversion Right with respect to any share of Convertible Preferred Stock, then (1) the Mandatory Conversion of such share will occur automatically and without the need for any action on the part of the Holder(s) thereof; and (2) the shares of Common Stock due upon such Mandatory Conversion will be registered in the name of, and, if applicable, the cash due upon such Mandatory Conversion will be delivered to, the Holder(s) of such share of Convertible Preferred Stock as of the Close of Business on the related Mandatory Conversion Date.***

(ii) ***Requirements for Holders to Exercise Optional Conversion Right.***

(1)Generally. To convert any share of Convertible Preferred Stock pursuant to an Optional Conversion, the Holder of such share must (w) complete, manually sign and deliver to the Company a Conversion Notice; (x) deliver any Physical Certificate representing such Convertible Preferred Stock to the Company (at which time such Optional Conversion will become irrevocable); (y) furnish any endorsements and transfer documents that the Company may reasonably require; and (z) if applicable, pay any documentary or other taxes as pursuant to Section 11(d).

(2)Optional Conversion Permitted only During Business Hours. Convertible Preferred Stock may be surrendered for Optional Conversion only after the Open of Business and before the Close of Business on a day that is a Business Day.

(iii) ***No Adjustments for Accumulated Regular Dividends. Without limiting any adjustments to the Liquidation Preference required by this Certificate of Designations, the***

Conversion Rate will not be adjusted to account for any accumulated and unpaid Regular Dividends on any Convertible Preferred Stock being converted.

(iv) ***When Holders Become Stockholders of Record of the Shares of Common Stock Issuable Upon Conversion. The Person in whose name any share of Common Stock is issuable upon conversion of any Convertible Preferred Stock will be deemed to become the holder of record of such share as of the Close of Business on the Conversion Date for such conversion.***

(e) ***Settlement upon Conversion.***

(i) ***Generally. Subject to Section 10(e)(ii), Section 10(h) and Section 14(b), the consideration due upon settlement of the conversion of each share of Convertible Preferred Stock will consist of a number of shares of Common Stock equal to the product of (A) the Conversion Rate in effect immediately before the Close of Business on the Conversion Date for such conversion; and (B) the quotient obtained by dividing (I) the sum of (x) the Liquidation Preference of such share of Convertible Preferred Stock immediately before the Close of Business on such Conversion Date and (y) an amount equal to accumulated and unpaid Regular Dividends on such share of Convertible Preferred Stock to, but excluding, such Conversion Date (but only to the extent such accumulated and unpaid Regular Dividends are not included in the Liquidation Preference referred to in the preceding clause (x)), by (II) the Initial Liquidation Preference per share of Convertible Preferred Stock.***

(ii) ***Payment of Cash in Lieu of any Fractional Share of Common Stock. Subject to Section 14(b), in lieu of delivering any fractional share of Common Stock otherwise due upon conversion of any Convertible Preferred Stock,***

the Company will, to the extent it is legally able to do so, pay cash based on the Last Reported Sale Price per share of Common Stock on the Conversion Date for such conversion (or, if such Conversion Date is not a Trading Day, the immediately preceding Trading Day).

(iii) ***[Reserved]***

(iv) ***Delivery of Conversion Consideration. The Company will pay or deliver, as applicable, the Conversion Consideration due upon conversion of any Convertible Preferred Stock on or before the number of Trading Days comprising the Standard Settlement Period after the Conversion Date for such conversion (the "Share Delivery Date"). The Company understands that a delay in the delivery of the shares of Common Stock after the Share Delivery Date could result in economic loss to the Holder. As compensation to the Holder for such loss, if (i) the Company fails to deliver the number of shares of Common Stock to which the Holder is entitled upon the Holder's conversion of the Convertible Preferred Stock within the time period specified above and (ii) the Holder has not exercised its Buy-In rights as provided below with respect to such shares, the Company agrees to pay (as liquidated damages and not as a penalty) to the Holder for late issuance of the shares of Common Stock upon exercise of the Convertible Preferred Stock the proportionate amount of $100 per Trading Day (increasing to $200 per Trading Day after the tenth (10th) Trading Day) after the Share Delivery Date for each $10,000 of shares***

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of Common Stock for which the Convertible Preferred Stock is converted which are not timely delivered. For purposes of clarification, if the Company is obligated to make payments of liquidated damages pursuant to this Section 10(e)(iv) for late issuance of shares of Common Stock, then it shall not also be obligated to make Buy-In payments as described below with respect to those same shares of Common Stock. The Company shall pay any payments incurred under this Section 10(e)(iv) in immediately available funds upon demand.

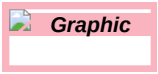
(v) ***Buy-In. In addition to any other rights available to the Holder, if the Company fails for any reason to effect delivery of the shares of Common Stock to the holder by the Share Delivery Date and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder or its brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Common Stock which the holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased, minus any amounts paid to the Holder by the Company as liquidated damages as described in Section 10(e)(iv) above, exceeds (y) the amount obtained by multiplying (1) the number of shares of Common Stock that the Company was required to deliver to the Holder in connection with the conversion at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Convertible Preferred Stock and equivalent number of shares of Common Stock for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted conversion of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000, assuming no liquidated damages. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of Convertible Preferred Stock as required pursuant to the terms hereof.***

(f) ***Conversion Rate Adjustments.***

(i) *Events Requiring an Adjustment to the Conversion Rate. The Conversion Rate will be adjusted from time to time as follows:*

(1)Stock Dividends, Splits and Combinations. If the Company issues solely shares of Common Stock as a dividend or distribution on all or substantially all shares of the Common Stock, or if the Company effects a

stock split or a stock combination of the Common Stock (in each case excluding an issuance solely pursuant to a Common Stock Change Event, as to which Section 10(i) will apply), then the Conversion Rate will be adjusted based on the following formula:



where:

CR_0 *=the Conversion Rate in effect immediately before the Close of Business on the Record Date for such dividend or distribution, or immediately before the Close of Business on the effective date of such stock split initial election or stock combination, as applicable;*

CR_1 *=the Conversion Rate in effect immediately after the Close of Business on such Record Date or effective date, as applicable;*

OS_0 *=the number of shares of Common Stock outstanding immediately before the Close of Business on such Record Date or effective date, as applicable, without giving effect to such dividend, distribution, stock split or stock combination; and*

OS_1 *=the number of shares of Common Stock outstanding immediately after giving effect to such dividend, distribution, stock split or stock combination.*

If any dividend, distribution, stock split or stock combination of the type appointment. The awards described in this Section 10(f)(i)(1) is declared or announced, but not so paid or made, then the Conversion Rate will II(A) shall be readjusted, effective referred to as of the date "Initial Awards." No Non-Employee Director shall be granted more than one Initial Award.

B.Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board of Directors, or any Officer acting pursuant to authority conferred by the Board of Directors, determines not to pay such dividend or distribution or to effect such stock split or stock combination, to the Conversion Rate that would then be in effect had such dividend, distribution, stock split or stock combination not been declared or announced.

(2)Degressive Issuances. If, for at any time during the period from, and including, the Initial Issue Date to, and including, the Degressive Issuance Sunset Date, the Company or any of its Subsidiaries issues or otherwise sells any shares of Common Stock, or any Equity-Linked Securities, in each case at an Effective Price per share of Common Stock that is less than the Conversion Price in effect (before giving effect to the adjustment required by this Section 10(f)(i)(2)) least six months as of the date of any annual meeting of the issuance Company's stockholders on or sale after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall receive an option to purchase 14,000 shares of the Company's common stock and 4,000 restricted stock units on the date of such shares or Equity-Linked Securities (such an issuance or sale, a annual meeting. The awards described in this Section II(B) shall be referred to as "Degressive IssuanceSubsequent Awards."), then, effective as of Notwithstanding the Close of

Business on such date, the Conversion Rate will be increased to an amount equal to (x) the Initial Liquidation Preference per share of Convertible

Preferred Stock, divided by (y) the product of (i) such Effective Price per share of Common Stock, multiplied by (ii) 1.2; provided, however, that (A) the Conversion Rate will not be adjusted pursuant to this Section 10(f)(i)(2) as a result of an Exempt Issuance; (B) the issuance of shares of Common Stock pursuant to any such Equity-Linked Securities will not constitute an additional issuance or sale of shares of Common Stock for purposes of this Section 10(f)(i)(2) (it being understood, for the avoidance of doubt, that the issuance or sale of such Equity-Linked Securities, or any re-pricing or amendment thereof, will be subject to this Section 10(f)(i)(2)); and (C) foregoing, in no event will the Conversion Rate aggregate Grant Date Fair Value (as defined below) of the Subsequent Awards granted to a given Non-Employee Director at an annual meeting exceed $600,000 (the "Award Limit"), and if the Grant Date Fair Value would exceed the Award Limit, the Subsequent Awards will be decreased pursuant reduced using a fixed ratio of 1.5 options for every 1 restricted stock unit to this Section 10(f)(i)(2).

For purposes of this Section 10(f)(i)(2), any re-pricing or amendment of any Equity-Linked Securities (including, the minimum extent necessary for the avoidance of doubt, any Equity-Linked Securities existing as of the Initial Issue Date) will be deemed Grant Date Fair Value to be the issuance of additional Equity-Linked Securities, without affecting any prior adjustments theretofore made to the Conversion Rate.

(ii) *No Other Required Adjustments. Without limiting the operation of Sections 5(a)(ii)(1) and 10(e)(i), the Company will not be required to adjust the Conversion Rate except pursuant to Section 10(f)(i).*

(iii) *Determination of the Number of Outstanding Shares of Common Stock. For purposes of Section 10(f)(i), the number of shares of Common Stock outstanding at any time will (1) include shares issuable in respect of scrip certificates issued in lieu of fractions of shares of Common Stock; and (2) exclude shares of Common Stock held in the Company's treasury (unless the Company pays any dividend or makes any distribution on shares of Common Stock held in its treasury).*

(iv) *Calculations. All calculations with respect to the Conversion Rate and adjustments thereto will be made to the nearest 1/10,000th of a share of Common Stock (with 5/100,000ths rounded upward).*

(v) *Notice of Conversion Rate Adjustments. Upon the effectiveness of any adjustment to the Conversion Rate pursuant to Section 10(f)(i), the Company will promptly send notice to the Holders containing (1) a brief description of the transaction or other event on account of which such adjustment was made; (2) the Conversion Rate in effect immediately after such adjustment; and (3) the effective time of such adjustment.*

(g) *Voluntary Conversion Rate Increases.*

(i) *Generally. To the extent permitted by law and applicable stock exchange rules, the Company, from time to time, may (but is not required to) increase the Conversion Rate by any amount if (1) the Board of Directors determines that such increase is in the Company's best interest or that such increase is advisable to avoid or diminish any income tax imposed on holders of Common Stock or rights to purchase Common Stock as a result of any dividend or distribution of shares (or rights to acquire shares) of Common Stock or any similar event; (2) such increase is in effect for a period of at least twenty (20) Business*

Days; and (3) such increase is irrevocable during such period.

(ii) *Notice of Voluntary Increase. If the Board of Directors determines to increase the Conversion Rate pursuant to Section 10(g)(i), then, no later than the first Business Day of the related twenty (20) Business Day period referred to in Section 10(g)(i), the Company will send notice to each Holder of such increase to the Conversion Rate, the amount thereof and the period during which such increase will be in effect.*

(h) *Restriction on Conversions.*

(i) *Limitation on Conversion Right. Notwithstanding anything to the contrary in this Certificate of Designations, unless and until the Requisite Stockholder Approval is obtained, no shares of Common Stock will be issued or delivered upon conversion of any Convertible Preferred Stock of any Holder, and no Convertible Preferred Stock of any Holder will be convertible, in each case to the extent, and only to the extent, that such issuance, delivery, conversion or convertibility would result in such Holder or a "person" or "group" (within the meaning of Section 13(d)(3) of the Exchange Act) beneficially owning in excess of nineteen and ninety-nine-one-hundredths percent (19.99%) of the then-outstanding Stockholder Voting Power (the restrictions set forth in this sentence, the "Ownership Limitation"). For these purposes, beneficial ownership and calculations of percentage ownership will be determined in accordance with Rule 13d-3 under the Exchange Act.*

Notwithstanding anything to the contrary herein, upon the written election of a holder of shares of Convertible Preferred Stock, no such holder of Convertible Preferred Stock shall be entitled to effect a conversion of any portion of its shares of Convertible Preferred Stock, to vote in its capacity as a holder of shares of Convertible Preferred Stock with respect to matters submitted to holders of the Common Stock or take delivery of shares of Common Stock upon conversion of such shares of Convertible Preferred Stock, in each case, to the extent that, after giving effect to such conversion, action or delivery, as applicable, such holder, together with all other Attribution Parties (as defined below), collectively would beneficially own in excess of 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise (such percentage, subject to such modifications in accordance with, and subject to the limitations set forth in, this paragraph, the "Maximum Percentage"). For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such holder and the other Attribution Parties shall include the number of shares of Common Stock held by the holder and all other Attribution Parties plus the number of shares of Common Stock issuable upon conversion of such shares of Convertible Preferred Stock with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (i) conversion of the remaining, unconverted portion of such shares of Convertible Preferred Stock beneficially owned by such holder or any other Attribution Party and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by such holder or any other Attribution Party subject to a limitation on conversion or exercise analogous to the limitation contained in this paragraph. For purposes of determining the number of shares of Common Stock the holder may acquire upon the conversion of shares of its Convertible

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Preferred Stock without exceeding the Maximum Percentage, such holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other public filing with the Securities and Exchange Commission, as the case may be, (2) a more recent public announcement by the Company or (3) any other written notice by the Company or the transfer agent setting forth the number of shares of Common Stock outstanding (the "Reported Outstanding Share Number"). If the Company receives a Conversion Notice from a holder of Convertible Preferred Stock at a time when the actual number of outstanding shares of Common Stock is less than the Reported Outstanding Share Number, the Company shall (i) notify such holder in writing of the number of shares of Common Stock then outstanding and, to the extent that such Conversion Notice would otherwise cause such holder's

beneficial ownership, as determined pursuant to this paragraph, to exceed the Maximum Percentage, such holder must notify the Company of a reduced number of shares of Convertible Preferred Stock to be converted pursuant to such Conversion Notice. For any reason at any time, upon the written or oral request of a holder of Convertible Preferred Stock, where such request indicates that it is being made pursuant to this Certificate of Designation, the Company shall within two (2) business days confirm orally and in writing or by electronic mail to such holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company by such holder and any other Attribution Party since the date as of which the Reported Outstanding Share Number was reported. In the event that the issuance of shares of Common Stock to the Holder upon the conversion of any of such holder's shares of Convertible Preferred Stock results in the Holder and the other Attribution Parties being deemed to beneficially own, in the aggregate, more than the Maximum Percentage of the number of outstanding shares of Common Stock, the number of shares so issued by which such holder's and the other Attribution Parties' aggregate beneficial ownership exceeds the Maximum Percentage (the "Excess Shares") shall be deemed null and void and shall be cancelled ab initio, and such holder shall not have the power to vote or to transfer the Excess Shares. As soon as reasonably practicable after the issuance of the Excess Shares has been deemed null and void and/or any other shares of Convertible Preferred Stock have been purported to be converted or mandatorily converted in excess of the limitations set forth in this paragraph, the Company shall return to the Holder the number of shares of Convertible Preferred Stock corresponding to such excess. Upon delivery of a written notice to the Company, a holder of Convertible Preferred Stock may from time to time increase (with such increase not effective until the sixty-first (61st) day after delivery of such notice) or decrease the Maximum Percentage to any other percentage that is not in excess of 19.99% (except that such increased percentage may exceed 19.99% in the event that (x) the Requisite Stockholder Approval is obtained or (y) the Company is not subject to rules of the relevant trading market limiting issuances of shares of Common Stock in excess of such amount) as specified in such notice; provided that (i) any such increase in the Maximum Percentage will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, and (ii) any such increase or decrease will apply only to such holder of shares of Convertible Preferred Stock and the other Attribution Parties and not to any other holder of Convertible Preferred Stock. For purposes of clarity, the shares of Common Stock

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underlying such holder's shares of Convertible Preferred Stock in excess of the Maximum Percentage shall not be deemed to be beneficially owned by such holder for any purpose including for purposes of Section 13(d) or Rule 16a-1(a)(1) of the Exchange Act. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this paragraph to the extent necessary to correct this paragraph or any portion of this paragraph which may be defective or inconsistent with the intended beneficial ownership limitation contained in this paragraph or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitation as contained in this paragraph may not be waived and shall apply to a successor holder of the Convertible Preferred Stock. The limitation contained in this paragraph shall apply to a holder from and after the delivery of such written election to the Company and shall cease to apply thereafter only upon sixty-one (61) days' written notice from such holder to the Company of an election to increase or decrease or remove such limitation; provided, that such election to be subject to such limitation shall be irrevocable if the holder so electing specifies in writing to the Company that such election is irrevocable. For the avoidance of doubt, the limitation contained in this paragraph shall not apply to any holder that has not elected in writing to be subject to such limitation. As used in this Certificate of Designation with respect to any holder of Convertible Preferred Stock, "Attribution Parties" means, collectively, the following persons and entities: such holder, any of its Affiliates or principals, any person acting or who could be deemed to be acting as a group together with such holder or any of the foregoing for purposes of Section 13(d) of the Exchange Act, and any other persons whose beneficial ownership of the Common Stock would or could be aggregated with such holder's and the other Attribution Parties' for purposes of Section 13(d) of the Exchange Act.

Any purported delivery of shares of Common Stock upon conversion of the Convertible Preferred Stock will be void and have no effect to the extent, but only to the extent, that such delivery would result in any Holder becoming the beneficial owner of shares of Common Stock outstanding at such time in excess of the Ownership Limitation or, if applicable, the Maximum Percentage. Award Limit. For the avoidance of doubt, a Holder may effect Non-Employee Director elected for the first time to the Board at an Optional Conversion, annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company may, upon exercise of its Mandatory Conversion Right, force conversion of, such Holder's Convertible Preferred Stock, up to the Ownership Limitation or if applicable, the Maximum Percentage, in each case subject to the immediately following paragraph and the other requirements of this Certificate of Designations applicable to such Optional Conversion any parent or Mandatory Conversion, as applicable.

If any Conversion Consideration otherwise due upon the conversion of any Convertible Preferred Stock (whether upon Redemption, Mandatory Conversion or otherwise) is not delivered as a result subsidiary of the Ownership Limitation or, if applicable, the Maximum Percentage, then the Company's obligation to deliver such Conversion Consideration (the "**Abeyance Shares**") will not be extinguished, and Company who subsequently terminate their employment with the Company will deliver the Abeyance Shares as soon as reasonably practicable after the Holder of such Convertible Preferred Stock provides written evidence satisfactory to the Company that such delivery will not contravene the Ownership Limitation and any parent or if applicable, the Maximum Percentage. A Holder will provide such evidence as soon as reasonably practicable after its beneficial ownership

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is such that the Abeyance Shares may be delivered without contravening the Ownership Limitation or, if applicable, the Maximum Percentage. Until the Abeyance Shares have been delivered:

(1)The number of Abeyance Shares shall be subject to adjustment as set forth in Section 10(f)(i)(1).

(2) No dividend or other distribution on the Common Stock (whether in cash, securities or other property, or any combination of the foregoing) will be declared or paid on the Common Stock unless, at the time of such declaration and payment, an equivalent dividend or distribution is declared and paid, respectively, on the Abeyance Shares (such a dividend or distribution on the Abeyance Shares, an "**Abeyance Dividend**," and such corresponding dividend or distribution on the Common Stock, the "**Common Stock Abeyance Dividend**"), such that (1) the Record Date and the payment date for such Abeyance Dividend occur on the same dates as the Record Date and payment date, respectively, for such Common Stock Abeyance Dividend and (2) the kind and amount of consideration payable per Abeyance Share in such Abeyance Dividend is the same kind and amount of consideration that would be payable in the Common Stock Abeyance Dividend.

(3)The provisions of Section 10(e)(iv) and (v) will apply to the delivery of the Abeyance Shares, mutatis mutandis.

(4)The Company will reserve, out of its authorized, unreserved and not outstanding shares of Common Stock, for delivery a number of shares of Common Stock that would be sufficient to settle the obligation to delivery of the Abeyance Shares.

(5)In the event of any Common Stock Change Event, the Company's obligation to deliver Abeyance Shares will be replaced by an obligation to deliver an equal number of Reference Property Units.

For the avoidance of doubt, such converted Convertible Preferred Stock will be extinguished, will no longer accrue Regular Dividends and will not benefit from any Liquidation Preference.

(i) *Effect of Common Stock Change Event*.

(i) *Generally*. If there occurs any:

(1)recapitalization, reclassification or change of the Common Stock, other than (x) changes solely resulting from a subdivision or combination of the Common Stock, (y) a change only in par value or from par value to no par value or no par value to par value or (z) stock splits and stock combinations that do not involve the issuance of any other series or class of securities;

(2)consolidation, merger, combination or binding or statutory share exchange involving the Company;

(3)sale, lease or other transfer of all or substantially all of the assets subsidiary of the Company and its Subsidiaries, taken as a whole, remain on the Board will not receive an Initial Award pursuant to any Person; or

(4)other similar event,

and, as a result of which, the Common Stock is converted into, or is exchanged for, or represents solely the right to receive, other securities, cash or other property, or any combination of the foregoing (such an event, a "**Common Stock Change Event**," and such other securities, cash or property, the "**Reference Property**," and the amount and kind of Reference Property that a holder of one (1) share of Common Stock would be entitled to receive on account of such Common Stock Change Event (without giving effect to any arrangement not to issue or deliver a fractional portion of any security or other property), a "**Reference Property Unit**"), then, notwithstanding anything Section II(A) above, but to the contrary in this Certificate of Designations, extent

(A)from and after the effective time of such Common Stock Change Event, (I) the consideration due upon conversion of any Convertible Preferred Stock will be determined in the same manner as if each reference to any number of shares of Common Stock in this **Section 10** or in **Section 11**, or in any related definitions, were instead a reference to the same number of Reference Property Units; (II) for purposes of **Section 10(c)**, each reference to any number of shares of Common Stock in such Section (or in any related definitions) will instead be deemed to be a reference to the same number of Reference Property Units; and (III) for purposes of the definition of "Change of Control," the terms "Common Stock" and "common equity" will be deemed to mean the common equity (including depositary receipts representing common equity), if any, forming part of such Reference Property; and

(B)for these purposes, the Last Reported Sale Price of any Reference Property Unit or portion thereof that does not consist of a class of securities will be the fair value of such Reference Property Unit or portion thereof, as applicable, determined in good faith by the Company (or, in the case of cash denominated in U.S. dollars, the face amount thereof).

If the Reference Property consists of more than a single type of consideration to be determined based in part upon any form of stockholder election, then the composition of the Reference Property Unit will be deemed to be the weighted average of the types and amounts of consideration actually received, per share of Common Stock, by the holders of Common Stock. The Company will notify the Holders of such weighted average as soon as practicable after such determination is made.

(ii) *Compliance Covenant*. The Company will not become a party to any Common Stock Change Event unless its terms are consistent with this **Section 10(i)**.

that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

(iii) D. Terms of Awards Granted to Non-Employee Directors

1. *Execution of Supplemental Instruments Exercise Price*. On or before The per share exercise price of each option granted to a Non-Employee Director under this Program shall equal the Market Value (as defined in the Equity Plan) of a share of the Company's common stock on the date the Common Stock Change Event becomes effective, the Company and, if applicable, the resulting, surviving or transferee Person (if not the Company) of such Common Stock Change Event (the "**Successor Person**") will execute and deliver such supplemental instruments, if any, as the Company reasonably determines are necessary or desirable to (1) provide for subsequent adjustments to the Conversion Rate pursuant to **Section 10(f)(i)** in a manner consistent with this **Section 10(i)**; and (2) give effect to such other provisions, if any, as the Company reasonably determines are appropriate to preserve the economic interests of the Holders and to give effect to **Section 10(i)(i)**. If the Reference Property includes shares of stock or other securities or assets of a Person other than the Successor Person, then such other Person will also execute such supplemental instrument(s) and such supplemental instrument(s) will contain such additional provisions, if any, that the Company reasonably determines are appropriate to preserve the economic interests of Holders. option is granted.

(iv) 2. *Notice of Common Stock Change Event*. The Company will provide notice of each Common Stock Change Event to Holders no later than the effective date of the Common Stock Change Event.

(j) *Limitation on Share Issuances.* In no event shall the number of shares of Common Stock issuable upon conversion of the Convertible Preferred Stock exceed the Share Cap unless the Requisite Stockholder Approval has been obtained or the Share Cap Fall Away has occurred. If at any time the number of shares of Common Stock issuable upon conversion of the Convertible Preferred Stock, together with the shares of Common Stock previously issued upon conversion of the Convertible Preferred Stock, exceeds the Share Cap, unless the Share Cap Fall Away has occurred, the Company will use its reasonable best efforts to obtain the Requisite Stockholder Approval, including by seeking such approval, if not previously obtained, at each future regular annual meeting of its stockholders and endorsing its approval in the related proxy materials. The Company will promptly notify the Holders if the Requisite Stockholder Approval is obtained. If, prior to the receipt of the Requisite Stockholder Approval or the Share Cap Fall Away, the number of shares of Common Stock issuable upon conversion of the Convertible Preferred Stock, together with the shares of Common Stock previously issued upon conversion of the Convertible Preferred Stock, would exceed the Share Cap, each Holder shall be entitled to convert up to a number of shares of Convertible Preferred Stock that are convertible into its pro rata amount of such Share Cap, calculated based on the number of shares of Convertible Preferred Stock held by each such Holder.

Section 11. CERTAIN PROVISIONS RELATING TO THE ISSUANCE OF COMMON STOCK.

(a) *Equitable Adjustments to Prices*. Whenever this Certificate of Designations requires the Company to calculate the average of the Last Reported Sale Prices, or any function thereof, over a period of multiple days (including to calculate an adjustment to the Conversion Rate), the Company will make appropriate adjustments, if any, to those calculations to account for any adjustment to the Conversion Rate pursuant to **Section 10(f)(i)** that becomes effective, or any event requiring such an adjustment to the Conversion Rate where the Ex-Dividend Date, effective date or Expiration Date, as applicable, of such event occurs, at any time during such period.

(b) *Reservation of Shares of Common Stock*. The Company will reserve, out of its

authorized, unreserved and not outstanding shares of Common Stock, for delivery upon conversion of the Convertible Preferred Stock, a number of shares of Common Stock that would be sufficient to settle the conversion of all shares of Convertible Preferred

Stock then outstanding, if any. To the extent the Company delivers shares of Common Stock held in the Company's treasury in settlement of any obligation under this Certificate of Designations to deliver shares of Common Stock, each reference in this Certificate of Designations to the issuance of shares of Common Stock in connection therewith will be deemed to include such delivery.

(c) *Status of Shares of Common Stock Vesting*. Each share Initial Award shall vest and become exercisable in three (3) substantially equal annual installments following the date of Common Stock delivered upon conversion of grant, such that the Initial Award shall be fully vested on the Convertible Preferred Stock third anniversary of any Holder will be a newly issued or treasury share and will be duly and validly issued, fully paid, non-assessable, free from preemptive rights and free of any lien or adverse claim (except to the extent of any lien or adverse claim created by the action or inaction of such Holder or the Person to whom such share of Common Stock will be delivered). If the Common Stock is then listed on any securities exchange, or quoted on any inter-dealer quotation system, then the Company will cause each such share of Common Stock, when so delivered, to be admitted for listing on such exchange or quotation on such system.

(d) *Taxes Upon Issuance of Common Stock*. The Company will pay any documentary, stamp or similar issue or transfer tax or duty due on the issue of any shares of Common Stock upon conversion of the Convertible Preferred Stock of any Holder, except any tax or duty that is due because such Holder requests those shares to be registered in a name other than such Holder's name.

Section 12. NO PREEMPTIVE RIGHTS. Without limiting the rights of any Holder set forth in this Certificate of Designations (including in connection with the issuance of Common Stock or Reference Property upon conversion of the Convertible Preferred Stock) or the Investment Agreement, the Holders of the Convertible Preferred Stock will not have any preemptive rights to subscribe for or purchase any of the Company's securities.

Section 13. TAX TREATMENT. Notwithstanding anything to the contrary in this Certificate of Designations, for U.S. federal and other applicable state and local income tax purposes, it is intended that the Convertible Preferred Stock will not be treated as "preferred stock" within the meaning of Section 305(b)(4) of Code and Treasury Regulations Section 1.305-5(a). The Company will, and will cause its Subsidiaries and agents to, report consistently with, and take no positions or actions inconsistent with, the foregoing treatment (including by way of withholding) unless otherwise required by a change in law, a determination within the meaning of Section 1313(a) of the Code, or any other settlement on audit that is binding on the Company. Each Holder agrees to provide, at the time it becomes a party hereto and thereinafter upon reasonable request or as required under applicable law (including if such form becomes inaccurate, expired, or obsolete), a valid and duly completed Internal Revenue Service Form W-9.

Section 14. CALCULATIONS.

(a) *Responsibility; Schedule of Calculations*. Except as otherwise provided in this Certificate of Designations, the Company will be responsible for making all calculations called for under this Certificate of Designations or the Convertible Preferred Stock, including determinations

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of the Conversion Rate, the Last Reported Sale Prices and accumulated Regular Dividends on the Convertible Preferred Stock. The Company will make all calculations in good faith, and, absent manifest error, its calculations will be final and binding on all Holders. The Company will provide a schedule of such calculations to any Holder upon written request.

(b) *Calculations Aggregated for Each Holder*. The composition of the Conversion Consideration due upon conversion of the Convertible Preferred Stock of any Holder will be computed based on the total number of shares of Convertible Preferred Stock of such Holder being converted with the same Conversion Date. For these purposes, any cash amounts due to such Holder in respect thereof will be rounded to the nearest cent.

Section 15. NOTICES. The Company will send all notices or communications to Holders pursuant to this Certificate of Designations in writing and delivered personally, by facsimile or e-mail (with confirmation of receipt from the recipient, in the case of

e-mail), or sent by a nationally recognized overnight courier service to the Holders' respective addresses shown on the Register. Notwithstanding anything in the Certificate of Designations to the contrary, any defect in the delivery of any such notice or communication will not impair or affect the validity of such notice or communication and the failure to give any such notice or communication to all the Holders will not impair or affect the validity of such notice or communication to whom such notice is sent.

Section 16. LEGALLY AVAILABLE FUNDS. Without limiting the rights of any Holder (including pursuant to **Section 6**), if the Company does not have sufficient funds legally available to fully pay any cash amount otherwise due on the Convertible Preferred Stock, then the Company will pay the deficiency promptly after funds thereafter become legally available therefor.

Section 17. NO OTHER RIGHTS. The Convertible Preferred Stock will have no rights, preferences or voting powers except as provided in this Certificate of Designations or the Certificate of Incorporation or as required by applicable law.

[***The Remainder of This Page Intentionally Left Blank; Signature Page Follows***]

IN WITNESS WHEREOF, the Company has caused this Amended and Restated Certificate of Designations to be duly executed as of the date first written above.

RHYTHM PHARMACEUTICALS, INC.

By: /s/ Hunter Smith
Name: Hunter Smith
Title: Chief Financial Officer

EXHIBIT A

FORM OF CONVERTIBLE PREFERRED STOCK

[*Insert Restricted Stock Legend, if applicable*]

Rhythm Pharmaceuticals, Inc.

Series A Convertible Preferred Stock

Certificate No.[]

Rhythm Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), certifies that [] is the registered owner of [] shares of the Company's Series A Convertible Preferred Stock (the "**Convertible Preferred Stock**") represented by this certificate (this "**Certificate**"). The special rights, preferences and voting powers of the Convertible Preferred Stock are set forth in the Certificate of

Designations of the Company establishing the Convertible Preferred Stock (the "**Certificate of Designations**"). Capitalized terms used in this Certificate without definition have the respective meanings ascribed to them in the Certificate of Designations.

Additional terms of this Certificate are set forth on the other side of this Certificate.

[***The Remainder of This Page Intentionally Left Blank; Signature Page Follows***]

IN WITNESS WHEREOF, Rhythm Pharmaceuticals, Inc. has caused this instrument to be duly executed as of the date set forth below.

RHYTHM PHARMACEUTICALS, INC.

Date: _____ By: _____
Name:
Title:

Date: _____ By: _____
Name:
Title:

TRANSFER AGENT'S COUNTERSIGNATURE

[*legal name of Transfer Agent*], as Transfer Agent, certifies that this Certificate represents shares of Convertible Preferred Stock referred to in the within-mentioned Certificate of Designations.

Date: _____ By: _____
Authorized Signatory

RHYTHM PHARMACEUTICALS, INC.

Series A Convertible Preferred Stock

This Certificate represents duly authorized, issued and outstanding shares of Convertible Preferred Stock. Certain terms of the Convertible Preferred Stock are summarized below. Notwithstanding anything to the contrary in this Certificate, to the extent that any provision of this Certificate conflicts with the provisions of the Certificate of Designations or the Certificate of Incorporation, the provisions of the of the Certificate of Designations or the Certificate of Incorporation, as applicable, will control.

1. **Method of Payment**. Cash amounts due on the Convertible Preferred Stock represented by this Certificate will be paid in the manner set forth in Section 3(d) of the Certificate of Designations.

2. **Persons Deemed Owners**. The Person in whose name this Certificate is registered will be treated as the owner of the Convertible Preferred Stock represented by this Certificate for all purposes, subject to Section 3(k) of the Certificate of Designations.

3. **Denominations; Transfers and Exchanges**. All shares of Convertible Preferred Stock will be in registered form and in denominations equal to any whole number of shares. Subject to the terms of the Certificate of Designations, the Holder of the Convertible Preferred Stock represented by this Certificate may transfer or exchange this Convertible Preferred Stock by presenting this Certificate to the Company and delivering any required documentation or other materials.

4. **Dividends**. Dividends on the Convertible Preferred Stock will accumulate and will be paid in the manner, and subject to the terms, set forth in Section 5 of the Certificate of Designations.

5. **Liquidation Preference**. The Liquidation Preference per share of Convertible Preferred Stock is initially equal to the Initial Liquidation Preference per share of Convertible Preferred Stock; *provided*, *however*, that the Liquidation Preference is subject to adjustment pursuant to Section 5(a)(ii)(1) of the Certificate of Designations. The rights of Holders upon the Company's liquidation, dissolution or winding up are set forth in Section 6 of the Certificate of Designations.

6. **Right of the Company to Redeem the Convertible Preferred Stock**. The Company will have the right to redeem the Convertible Preferred Stock in the manner, and subject to the terms, set forth in Section 7 of the Certificate of Designations.

7. **Voting Rights**. Holders of the Convertible Preferred Stock have the voting rights set forth in Section 9 of the Certificate of Designations.

8. **Conversion**. The Convertible Preferred Stock will be convertible into Conversion Consideration in the manner, and subject to the terms, set forth in Section 10 of the Certificate of

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Designations.

9. **Countersignature**. The Convertible Preferred Stock represented by this Certificate will not be valid until this Certificate is countersigned by the Transfer Agent.

10. **Abbreviations**. Customary abbreviations may be used in the name of a Holder or its assignee, such as TEN COM (tenants in common), TEN ENT (tenants by the entireties), JT TEN (joint tenants with right of survivorship and not as tenants in common), CUST (custodian), and U/G/M/A (Uniform Gift to Minors Act).

* * *

To request a copy of the Certificate of Designations, which the Company will provide to any Holder at no charge, please send a written request to the following address:

Rhythm Pharmaceuticals, Inc.
222 Berkeley Street, 12th Floor
Boston, MA 02116
Attention: Chief Financial Officer

CONVERSION NOTICE

RHYTHM PHARMACEUTICALS, INC.

Series A Convertible Preferred Stock

Subject to the terms of the Certificate of Designations, by executing and delivering this Conversion Notice, the undersigned Holder of the Convertible Preferred Stock identified below directs the Company to convert (check one):

☐ all of the shares of Convertible Preferred Stock

☐ * shares of Convertible Preferred Stock

identified by Certificate No. .

Date: _____ _____
(Legal Name of Holder)

By: _____
Name:
Title:

Signature Guaranteed:

_____
Participant in a Recognized Signature
Guarantee Medallion Program

By: _____
Authorized Signatory

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* Must be a whole number.

CHANGE OF CONTROL REPURCHASE NOTICE

RHYTHM PHARMACEUTICALS, INC.

Series A Convertible Preferred Stock

Subject to the terms of the Certificate of Designations, by executing and delivering this Change of Control Repurchase Notice, the undersigned Holder of the Convertible Preferred Stock identified below is exercising its Change of Control Repurchase Right with respect to (check one):

☐ all of the shares of Convertible Preferred Stock

☐ [1] shares of Convertible Preferred Stock

identified by Certificate No. .

The undersigned acknowledges that the Certificate identified above, duly endorsed for transfer, must be delivered to the Company before the Change of Control Repurchase Price will be paid.

Date: _____

_____
(Legal Name of Holder)

By: _____
Name:
Title:

Signature Guaranteed:

_____
Participant in a Recognized Signature
Guarantee Medallion Program

By: _____
Authorized Signatory

[1] Must be a whole number.

EXHIBIT B

FORM OF RESTRICTED STOCK LEGEND

THE OFFER AND SALE OF THIS SECURITY AND THE SHARES OF COMMON STOCK ISSUABLE UPON CONVERSION OF THIS SECURITY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND THIS SECURITY AND SUCH SHARES MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED EXCEPT (A) PURSUANT TO A REGISTRATION STATEMENT THAT IS EFFECTIVE UNDER THE SECURITIES ACT; OR (B) PURSUANT TO AN EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT.

Exhibit 10.1

Summary of Non-Employee Director Compensation Policy

Under the Company's non-employee director compensation policy, all non-employee directors will be paid an annual retainer fee of $50,000 and such additional fees as are set forth in the following table. All payments will be made quarterly in arrears.

Non-Employee Director	Annual Fee
Lead Director	$ 35,000
Non-Executive Chair	$ 30,000
Chairman of the audit committee	$ 20,000
Member of the audit committee (other than chairman)	$ 10,000
Chairman of the compensation committee	$ 15,000
Member of the compensation committee (other than chairman)	$ 7,500
Chairman of the governance and nominating committee	$ 10,000
Member of the governance and nominating committee (other than chairman)	$ 5,000

Under the policy, each individual who is initially appointed or elected to the board of directors will be eligible to receive an option to purchase 34,000 shares of our common stock under the 2017 Equity Incentive Plan on the date he or she first becomes a non-employee director. These option grants will vest annually over a three-year period from the date of grant, subject to continued the Non-Employee Director continuing in service as a non-employee director Non-Employee Director through that each such vesting date. In addition, Each Subsequent Award shall vest and become exercisable in a single installment on the date of the annual meeting of stockholders, each continuing non-employee director who has served on the board of directors for a minimum of six months will be eligible to receive an option grant to purchase 14,000 shares of our common stock and 3,000 restricted stock units, both of which will vest in full upon the earlier of the first anniversary of the date of grant or the day immediately prior to the date of the next annual meeting of stockholders. the Company's stockholders occurring after the date of grant, in either case, subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's outstanding Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3.*Term*. The exercise price for maximum term of each stock option granted to a Non-Employee Director under this Program shall be ten (10) years from the date the option is granted.

4. *Black-Scholes Value*. "***Black-Scholes Value***" means, with respect to an option, the per share fair value of the option determined as of the option's date of grant using the Black-Scholes or other option pricing model that the Company most recently applied when valuing grants will be equal of options with service-based vesting conditions for purposes of preparing its (audited or unaudited) consolidated financial statements that have been filed with the Securities Exchange Commission and using as inputs to such model (i) the fair market value Market Value of our a share of the Company's common stock on the date of grant. These new director grants the option is granted and annual grants will (ii) such other assumptions as shall be subject determined by the Company's Chief Accounting Officer on or before the date the option is granted.

4. *Grant Date Fair Value*. "***Grant Date Fair Value***" means (a) with respect to approval by our board of directors at an option, the time of grant. The share numbers set forth herein will be appropriately adjusted for any split or recapitalization Black-Scholes Value of the Company's securities.

Exhibit 10.4

RHYTHM PHARMACEUTICALS, INC.
2017 EQUITY INCENTIVE PLAN

Performance Unit Agreement

This Performance Unit Agreement (this "Agreement"), dated as of [●] (the "Date of Grant"), is between Rhythm Pharmaceuticals, Inc., option and (b) with respect to a corporation organized under restricted stock unit, the laws of the State of Delaware (the "Company") and [●] (the "Participant"). Capitalized terms used in this Agreement without definition shall have the respective meaning ascribed to such capitalized terms in the Rhythm Pharmaceuticals, Inc. 2017 Equity Incentive Plan (as the same may be amended from time to time, the "Plan").

1. Grant of Performance Units. Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants the Participant [●] Performance Units, subject to the restrictions set forth below and in the Plan (the "Stock Units"). The Stock Units shall be eligible to be earned based on the Company's achievement of the performance milestones set forth on Appendix A hereto during the Performance Period (as defined on Appendix A). Each Stock Unit represents the right of the Participant to receive a number of shares of common stock of the Company ("Stock") as determined in accordance with Appendix A hereto, an equivalent amount of cash based on the value Market Value of a share of Stock, or any combination of the foregoing, as determined by the Committee, if and when the specified conditions are met in Section 3 below, and on the applicable settlement date set forth in Section 5 below.

2. No Rights Prior to Settlement. Stock Units represent hypothetical shares of Stock, and not actual shares of Stock. No shares of Stock shall be issued to the Participant at the time the grant of the Stock Units is made, and the Participant shall not be, and shall not have any of the rights or privileges of, a stockholder of the Company with respect to any Stock Units. The Participant shall not have any interest in any fund or specific assets of the Company by reason of this award.

3. Vesting.

a) As of the date of this Agreement, all of the Stock Units shall be unvested and subject to a Risk of Forfeiture pursuant to Section 4 below.

b) Subject to the terms of this Section 3, the Stock Units shall vest in a single installment Company's common stock on the date that the Committee determines the Total Achievement Percentage (as defined in Appendix A hereto) for the Performance Period, provided that the Participant continues his or her employment or other association with the Company or one of its Affiliates from the Date of Grant until such vesting date (the "Vesting Date"). restricted stock unit is granted.

c) In the event a Change of Control occurs before the Vesting Date, 100% of the Stock Units that have not terminated under Section 4 (or, to the extent the Committee determines sufficient milestones set forth on Appendix A have been attained, or if the Committee elects in its discretion to determine that it is probable such milestones will be attained, in either case, so as to result in more than 100% of the Stock Units that have not been terminated being scheduled to vest on the Vesting Date, such larger number of Stock Units as so determined by the Committee) will vest upon the occurrence of the Change of Control, and the Committee may take

such actions as it deems appropriate pursuant to the Plan. This Section 3(c) shall be applied to the Stock Units regardless of and shall supersede any Change of Control vesting terms (including any "double trigger" vesting terms) provided in an employment agreement, offer letter, severance agreement or other contract entered into by and between the Participant and the Company or an Affiliate (in any case, an "Employment Agreement"), except that to the extent such Employment Agreement provides for the Participant to remain eligible to vest in the Stock Units upon a Change in Control that occurs during a period of up to three months following termination of the Participant's employment, the Participant shall remain eligible to vest in Stock Units under this Section 3(c) during such period, subject to any terms or conditions of the Employment Agreement that apply to such Change in Control vesting (including any requirement to timely execute and not revoke a release of claims).

d) Those Stock Units that vest pursuant to this Section 3 or pursuant to any action taken by the Committee pursuant to the Plan shall become free from the termination provisions pursuant to Section 4 below.

4. Termination of Stock Units. If the Participant ceases employment or other association with the Company and its Affiliates for any reason before all of the Stock Units vest, any unvested Stock Units shall automatically terminate and shall be forfeited as of the date of the Participant's termination of employment or other association, unless otherwise provided under Section 3(c) or determined by the Committee. In addition, in the event that the Committee determines that any of the milestones set forth on Exhibit A has not or cannot be achieved during the Performance Period (including at a target or maximum level, as applicable) a number of Stock Units equal to the total number of Stock Units multiplied by the applicable Achievement Percentage for such milestone shall automatically terminate. No settlement or payment shall be made with respect to any Stock Units that terminate as described in this Section 4 or on Appendix A.

5. Settlement of Stock Units and Tax Withholding.

a) If the Stock Units vest in accordance with the provisions of Appendix A and Section 3 above, then, subject to the provisions of this Section 5(a) and Sections 5(b), 5(c) and 12 below, the Company shall issue to the Participant a number of shares equal to (i) the Total Achievement Percentage for the Performance Period multiplied by the total number of Stock Units or (ii) in the event Stock Units vest under Section 3(c), such other number of shares as corresponds to the number of Stock Units vesting under such Section, in any case, rounded down to the nearest whole share, or an equivalent amount of cash based on the value of a share of Stock, or a combination of the foregoing, as determined by the Committee, subject to applicable tax withholding obligations, as soon as reasonably practicable after the Vesting Date applicable to such vested Stock Unit. Notwithstanding anything express or implied in the foregoing provisions of this Section 5(a) to the contrary, in no event shall settlement of a vested Stock Unit occur later than the fifteenth day of the third calendar month following the calendar year in which the Vesting Date applicable to such vested Stock Unit occurs, and in no event shall Participant be permitted, directly or indirectly, to designate the calendar year of payment.

b) All obligations of the Company under this Agreement shall be subject to the right of the Company as set forth in the Plan to collect applicable federal, state, local, foreign or

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other withholding taxes if, when, and to the extent required by law prior to the issuance of shares of Stock or payment in cash. The Company shall satisfy any applicable withholding requirement with respect to the issuance of shares of Stock from proceeds of a sale of a portion of the shares of Stock effected by the Company's designated broker; the Participant's acceptance of the Stock Units shall constitute the Participant's authorization to the broker to effect such sale as promptly as practicable. In the event payment is to be made in a form other than shares of Stock, then the Company shall collect from the Participant the applicable withholding taxes pursuant to such procedures as the Company deems appropriate under the circumstances.

c) The obligation of the Company to deliver Stock shall also be subject to the condition that if at any time the Board shall determine in its discretion that the listing, registration or qualification of any shares of Stock upon any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the issuance of such shares, such shares may not be issued in whole or in part unless such listing, registration, qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Board. The issuance of shares of Stock, if any, to the Participant pursuant to this Agreement is subject to any applicable laws or regulations of the United States or of any state, municipality or other country having jurisdiction thereof.

6. No Stockholder Rights. Neither the Participant, nor any person entitled to receive Stock Units in the event of the Participant's death, shall have any of the rights and privileges of a stockholder with respect to shares of Stock, including voting or dividend rights, until such shares of Stock have been issued upon settlement of Stock Units. The Participant acknowledges that no election under Section 83(b) of the Code is available with respect to Stock Units.

7. Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and settlement of the Stock Units are subject to the provisions of the Plan and to interpretations, regulations and determinations concerning the Plan established from

time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (a) rights and obligations with respect to withholding taxes, (b) the registration, qualification or listing of the shares of Stock, (c) changes in capitalization of the Company and (d) other requirements of applicable law. The Committee shall have the authority to interpret and construe the Stock Units pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

8. No Employment or Other Rights. The grant of the Stock Units shall not confer upon the Participant any right to be retained by or in the employ or service of the Company or any Affiliate and shall not interfere in any way with the right of the Company or any Affiliate to terminate the Participant's employment or other association with the Company and its Affiliates. The right of the Company and any Affiliate to terminate at will the Participant's employment or other association at any time for any reason is specifically reserved.

9. Assignment and Transfers. The Stock Units are not transferable, and shall not be sold, transferred, pledged, assigned, or otherwise alienated or hypothecated, other than by will or

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by the laws of descent and distribution. This Agreement may be assigned by the Company without the Participant's consent.

10. Governing Law; Counterparts. This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware, without regard to the conflict of laws principles thereof. This Agreement may be executed in one or more counterparts all of which together shall constitute but one instrument. In making proof of this Agreement it shall not be necessary to produce or account for more than one such counterpart.

11. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company, at the Company's principal place of business, addressed to the attention of the Company's Treasurer, and any notice to the Participant shall be addressed to such Participant at his or her residence address last filed with the Company. Any notice shall be delivered in accordance with Section 18 of the Plan.

12. Application of Section 409A of the Code. This Agreement is intended to be exempt from or otherwise comply with the provisions of Section 409A of the Code. Notwithstanding the foregoing, if any Stock Units constitute "deferred compensation" under Section 409A of the Code and such Stock Units become vested upon the Participant's termination of employment (or other association), settlement of such vested Stock Units shall be delayed for a period of six (6) months after the Participant's termination of employment (or other association) if the Participant is a "specified employee" as defined under Section 409A of the Code and if required pursuant to Section 409A of the Code. If settlement of any Stock Units is delayed in accordance with the foregoing provisions of this Section 12, such Stock Units shall be settled and paid within thirty (30) days after the date that is six (6) months following the Participant's termination of employment (or other association). To the extent subject to Section 409A of the Code, settlement of the Stock Units may only be made in a manner and upon an event permitted by Section 409A of the Code, and each settlement of the Stock Units shall be treated as a separate payment, and the right to a series of installment payments under the Stock Units shall be treated as a right to a series of separate payments. In no event shall the Participant, directly or indirectly, designate the calendar year of payment. The Company may change or modify the terms of this Agreement without the Participant's consent or signature if the Company determines, in its sole discretion, that such change or modification is necessary for purposes of compliance with or exemption from the requirements of Section 409A of the Code or any regulations or other guidance issued thereunder. Notwithstanding the previous sentence, the Company may also amend the Plan or this Agreement or revoke the Stock Units to the extent permitted by the Plan.

13. French Participants. If the Participant is a French Participant (as defined in the Rules of the Rhythm Pharmaceuticals, Inc. 2017 Equity Incentive Plan for Stock Options, Restricted Stock Units and Performance Units Granted to Participants in France) on the Date of Grant, the terms of the attached Addendum to the Award Agreement Relating to Performance Units Granted to French Participants pursuant to the 2017 Equity Incentive Plan shall apply to this Agreement and the Stock Units granted hereunder.

[The remainder of this page is intentionally left blank. Signature page to follow.]

In Witness Whereof, the parties have executed this Agreement as of the date first above written.* * * * *

RHYTHM PHARMACEUTICALS, INC.	**FIRST_NAME LAST_NAME**
By: Signature	Signature of Participant
Title:	
Participant's Address:	
	ADDRESS_LINE_1 ADDRESS_LINE_2 CITY, STATE ZIPCODE

[Signature Page to Rhythm Pharmaceuticals, Inc. Performance Unit Agreement]

RHYTHM PHARMACEUTICALS, INC.
ADDENDUM TO THE AWARD AGREEMENT RELATING TO PERFORMANCE UNITS GRANTED TO FRENCH PARTICIPANTS PURSUANT TO THE

2017 EQUITY INCENTIVE PLAN

In addition to the terms of the Plan and the Agreement, the grant of Performance Units to the French Participant is subject to the following additional specific terms and conditions (the "Addendum").

Type of Grant. The Performance Units are granted as French-qualified Performance Units and are intended to qualify for the special tax and social security treatment applicable to shares of Stock granted for no consideration under Sections L. 225-197-1 to L. 225-197-5 and Sections L. 22-10-59 to L. 22-10-60 of the French Commercial Code, as amended. The Performance Units are granted subject to the terms and conditions of the Rules of the Rhythm Pharmaceuticals, Inc. 2017 Equity Incentive Plan for Stock Options, Restricted Stock Units and Performance Units Granted to Participants in France (the "French Sub-Plan").

Certain events may affect the status of the Performance Units as French-qualified Performance Units or the underlying Stock, and the Performance Units or the underlying Stock may be disqualified in the future. The Company does not make any undertaking or representation to maintain the qualified status of the French-qualified Performance Units or of the underlying Stock as described in the French Sub-Plan.

Capitalized terms not defined herein, the Agreement or the Plan shall have the meanings ascribed to them in the French Sub-Plan.

Restrictions on Sale or Transfer of Shares.

a) Minimum Vesting/Issuance Period. The Performance Units will vest according to the vesting schedule as set forth in the Agreement, provided, however, that under no circumstances will the Performance Units vest and the shares of Stock underlying the Award be issued and delivered to the French Participant prior to the expiration of such period as is required to comply with the minimum mandatory period applicable to the Performance Units under Section L. 225-197-1 of the French Commercial Code, as amended, the relevant sections of the French Tax Code and/or the relevant sections of the French Social Security Code, as amended, except in the case of the Participant's death. The minimum mandatory vesting period is currently one year from the Date of Grant.

b) Minimum Mandatory Holding Period. The Participant may not sell or transfer the shares of Stock acquired upon vesting of the Performance Units until such time as is required to comply with the minimum mandatory holding period applicable to the Performance Units under Section L. 225-197-1 of the French Commercial Code, as amended, the relevant sections of the French Tax Code and/or the relevant sections of the French Social Security Code, as amended, except in the case of Participant's death or Disability (as defined in the French Sub-Plan). The minimum mandatory holding period is currently two years from the Date of Grant.

Except in the case of the Participant's termination of employment due to death or Disability (as defined in the French Sub-Plan), the minimum mandatory holding period restriction will continue to apply even if the Participant is no longer an Employee or a Managing Corporate Officer of the Company or any Affiliate.

c) Closed Periods. The Participant may not sell any Stock issued upon vesting of the Performance Units during certain Closed Periods, to the extent applicable to the Stock underlying the Performance Units granted by the Company, as described in the French Sub-Plan.

d) Holding Periods for Managing Corporate Officers. If, on the Date of Grant, the Participant qualifies as an executive corporate officer under French law ("*mandataires sociaux*") or any similar official capacity of the Company, the Participant may not sell a portion of the Stock acquired upon vesting of the Performance Units until the termination of such official capacity, as long as this restriction applies to Performance Units.

Termination of Service Due to Death. In the event of the Participant's death, the Participant's heirs may request the issuance of the Stock underlying the Performance Units that have not vested prior to the Participant's death subject to the Award within six months from the date of the Participant's death, as provided for in Section III(c) of the French Sub-Plan and provided that such shares of Stock will not become transferable to the French Participant's heirs unless, until and to the extent milestones relating to the performance-vesting conditions set forth in Appendix A to the Agreement are satisfied. In any case, if the Participant's heirs do not request the shares of Stock within six months from the date of the Participant's death, the Award will be forfeited.

Settlement of RSUs. Subject to Section III(d) of the French Sub-Plan, Settlement of Performance Units will only be in shares of Stock.

Foreign Asset/Account Reporting Information. If the Participant holds cash or shares of Stock outside of France or maintains a foreign bank or brokerage account (including accounts that were opened and closed during the tax year), the Participant is required to report such assets and accounts to the French tax authorities on an annual basis on a specified form, together with the Participant's income tax return. Failure to complete this reporting can trigger significant penalties.

Use of English Language. The Participant acknowledges and agrees that it is the Participant's express wish that this Agreement, as well as all documents, notices and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Utilisation de la langue anglaise. Vous reconnaissez et acceptez qu'il est de votre volonté que le présent accord, ainsi que tout document, toute notification et toute procédure judiciaire conclue, reçue ou intentée en vertu des présentes ou s'y

rapportant directement ou indirectement, soient rédigés en anglais.

Exhibit 10.5

TWO TWENTY-TWO BERKELEY STREET
Boston, MA

Third Amendment to Lease
Rhythm Pharmaceuticals, Inc.

THIS THIRD AMENDMENT TO LEASE (this "Third Amendment") is made as of_____ ____, 2024 (the "Effective Date") by and between 500 BOYLSTON & 222 BERKELEY OWNER (DE) LLC, a Delaware limited liability company ("Landlord"), and RHYTHM PHARMACEUTICALS, INC., a Delaware corporation ("Tenant").

Background

A. Reference is made to that certain Lease dated as of November 25, 2015 by and between Landlord and Tenant (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of April 15, 2016 (the "First Amendment"), as amended by that certain Second Amendment to Lease dated as of August 6, 2018 (the "Second Amendment"; the Original Lease, as amended by the First Amendment and the Second Amendment, the "Lease"), pursuant to which Tenant currently leases from Landlord approximately 13,667 rentable square feet on the twelfth (12th) floor (the "Leased Premises") of the building located at 222 Berkeley Street, Boston, MA (the "Building"), as further set forth in the Lease. Capitalized terms used and not defined herein shall have the respective meanings ascribed to them in the Lease.

B. The Term of the Lease is currently scheduled to expire on July 31, 2025.

C. Landlord and Tenant desire to enter into this Third Amendment to: (i) extend the Term of the Lease, and (ii) amend the Lease in certain other respects, all in accordance with the terms and conditions set forth herein.

Agreement

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained herein, Landlord and Tenant hereby agree to modify and amend the Lease as follows:

1. Lease Extension. The Term of the Lease is hereby extended for a period beginning on August 1, 2025 (the "Extended Term Commencement Date") and, unless sooner terminated in accordance with the Lease, expiring at 11:59 p.m. (Eastern) on July 31, 2030 (the "Extended Term Expiration Date") (such period being referred to herein as the "Extended Term"), on the terms and conditions set forth below. All terms and provisions of the Lease, as amended hereby, shall apply to Tenant's leasing of the Leased Premises during the Extended Term, except to the extent expressly provided otherwise in this Third Amendment, and the "Term Expiration Date" set forth in the Basic Lease Information Sheet of the Original Lease is hereby amended to be the Extended Term Expiration Date.

2. Gross Rent. Tenant shall continue to pay Net Rent due under the Lease for the Leased Premises pursuant to the terms of the Lease through July 31, 2025. Notwithstanding the preceding sentence, provided Tenant is not then in monetary or material non-monetary default of the Lease (continuing beyond any applicable notice and cure period), monthly Net Rent due for

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the months of January 2025, February 2025, March 2025, April 2025, May 2025, June 2025, and July 2025 (only) shall be waived.

Commencing on the Extended Term Commencement Date and continuing thereafter through the Extended Term Expiration Date, Tenant shall pay Net Rent for the Leased Premises in the monthly installments set forth in the following rent chart, in each case at the times and in the manner set forth in the Lease, as amended by this Third Amendment:

Period	Annual Net Rent Rate Per Square Foot of Net Rentable Floor Area	Monthly Net Rent
August 1, 2025 – July 31, 2026	$80.00	$91,180.00
August 1, 2026 – July 31, 2027	$81.60	$93,003.60
August 1, 2027 – July 31, 2028	$83.23	$94,863.67
August 1, 2028 – July 31, 2029	$84.90	$96,760.95
August 1, 2029 – July 31, 2030	$86.59	$98,696.16

Tenant shall continue to pay Tenant's Proportionate Share of Estimated Operating Cost, Tenant's Proportionate Share of Estimated Impositions, electricity charges, and all other payments due under the Lease on account of the Leased Premises, in each case at the times and in the manner set forth in the Lease, as amended by this Third Amendment.

3. "As Is" Condition. Notwithstanding anything contained in the Lease to the contrary, Tenant shall lease the Leased Premises for the Extended Term "as-is, where is," and in all respects in the condition in which the Leased Premises are in as of the Effective Date set forth above, without any obligation on the part of Landlord to prepare or construct the Leased Premises for Tenant's occupancy, or to construct any additional work or improvements therein or in the Building, or to provide any contributions, allowances or inducements of any kind whatsoever (except as expressly set forth below in this Section 3 of this Third Amendment), and without any representation or warranty (express or implied) on the part of Landlord as to the condition of the Leased Premises.

Landlord shall provide Tenant with a tenant improvement allowance in the amount of Two Hundred Seventy-Three Thousand Five Hundred Forty and 00/100 Dollars ($273,540.00) (the "Extended Term Allowance") for design and construction costs of refurbishments, alterations, and installations hereafter to be made by Tenant (the "Extended Term Work") in the Leased Premises from and after the Effective Date set forth above (collectively, the "Extended Term Refurbishment Costs"). All design, construction, and other costs for the Extended Term Work in excess of the Extended Term Allowance shall be paid for entirely by Tenant, and Landlord shall not provide any reimbursement for any such excess. The Extended Term Allowance shall be disbursed as requisitioned by Tenant but in no more than four (4) disbursements. Tenant may not requisition a disbursement of the Extended Term Allowance more than once per calendar month. For each disbursement, Tenant shall submit a requisition package to Landlord prior to the first day of a calendar month, with an itemization of the costs being requisitioned, a certificate by an officer of Tenant that all such costs are Extended Term Refurbishment Costs and have been incurred and paid for by Tenant, and appropriate back-up documentation including, without limitation,

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customary AIA forms of progress payment certifications and partial lien waivers (in a customary, recordable form provided or reasonably approved by Landlord), and copies of paid invoices and bills. If the total Extended Term Refurbishment Costs are reasonably estimated to exceed the Extended Term Allowance, Landlord reserves the right to make pro-rata disbursements of the Extended Term Allowance for each requisition in the ratio that the Extended Term Allowance bears to the total estimated Extended Term Refurbishment Costs, subject to a final reconciliation of the Extended Term Allowance upon completion of the Extended Term Work. Landlord further reserves the right to fund the final ten percent (10%) of the Extended Term Allowance within thirty (30) days after Tenant's submission to Landlord of the ET Close-Out Materials. The "ET Close-Out Materials" shall mean the requisition package for the final amount of the Extended Term Allowance as provided above, together with (i) a final AIA certificate from Tenant's architect evidencing substantial completion of the Extended Term Work in accordance with the construction documents for the Extended Term Work approved by Landlord, (ii) a set of "as built" or final record plans for the Extended Term Work, (iii) final lien waivers (in a customary, recordable form provided or reasonably approved by Landlord) for the Extended Term Work from all contractors, subcontractors, vendors, suppliers, and materialmen who would be entitled to a lien on the Property if not paid, (iv) a

certificate of occupancy for the Leased Premises after the performance of the Extended Term Work, and (v) any other items required under Landlord's construction rules and regulations. Tenant may, upon prior Tenant's written request, apply all or any portion of the Extended Term Allowance as a credit against the next monthly installment(s) of Net Rent, Estimated Operating Cost, and Estimated Impositions then due for the Leased Premises; provided, however, that any remaining amount of the Extended Term Allowance not requisitioned or applied by Tenant prior to the six (6) month anniversary of the Extended Term Commencement Date shall thereafter be automatically applied by Landlord as a credit against the next monthly installment(s) of Net Rent, Estimated Operating Cost, and Estimated Impositions then due for the Leased Premises until fully amortized. Notwithstanding the foregoing, Landlord shall have no obligation to disburse or credit any portion of the Extended Term Allowance at any time when Tenant is in monetary or material non-monetary default of the Lease (continuing beyond any applicable notice and cure period).

Tenant shall perform all work under this Section 3 in accordance with all applicable laws, statutes, codes, ordinances, rules, by-laws, and regulations, Landlord's construction rules and regulations, and all terms and conditions of the Lease, including, without limitation, Section 4.07 of the Original Lease and Schedule C-2 to the Second Amendment. Notwithstanding the preceding sentence, neither the provisions of Exhibit B to the Original Lease nor the provisions of Exhibit B to the Second Amendment shall apply to the Extended Term Work. Landlord shall not be responsible for any aspects of the design or construction of the Extended Term Work, the correction of any defects therein, or any delays in the completion thereof, and Landlord's approval of the construction documents for the Extended Term Work shall not result in any responsibility of Landlord concerning compliance of the Extended Term Work with applicable, laws, statutes, ordinances, regulations, codes, rules, and by-laws, coordination of any aspect of the Extended Term Work with any component or system of the Building, or the feasibility of constructing the Extended Term Work without damage or harm to the Building, all of which shall be the sole responsibility of Tenant. After Landlord has approved the construction documents for the Extended Term Work, any change in the work shown thereon, whether material or not, shall be made only after Tenant shall have submitted revised construction documents to Landlord for its review and approval. If the Extended Term Work includes any structural or other specialty items, Tenant shall reimburse Landlord for the reasonable, out-of-pocket, third-party costs incurred by

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Landlord in reviewing such items. Tenant shall pay to Landlord or its managing agent a fee for Landlord's administrative oversight or coordination of the Extended Term Work in an amount equal to two percent (2%) of the total cost of the Extended Term Work, which Landlord may deduct from the Extended Term Allowance. Notwithstanding the immediately preceding sentence, if Tenant elects to apply the entire Extended Term Allowance as a credit against the next monthly installment(s) of Net Rent, Estimated Operating Cost, and Estimated Impositions then due for the Leased Premises as provided in this Section 3, then no administrative oversight or coordination fee shall be due to Landlord. In addition, Tenant shall pay to Landlord the costs of Building services or facilities (such as electricity, HVAC, fire alarm plug-ins/outs, freight elevator usage, and cleaning) used by Tenant in connection with its performance of the Extended Term Work, in each case at Building standard rates charged to Building tenants generally. All such costs shall constitute Extended Term Refurbishment Costs that may be requisitioned from time to time from the Extended Term Allowance as provided in this Section 3.

4. Letter of Credit. The parties hereby acknowledge that Landlord is currently holding a security deposit in the form of the Letter of Credit with a face amount of $75,000.00 pursuant to Section 4.17 of the Lease, and will continue to hold the Letter of Credit throughout the Term. The Letter of Credit shall not be subject to reduction during the Term of the Lease.

5. Exhibit D to the Second Amendment. The second paragraph of Exhibit D to the Second Amendment is hereby deleted in its entirety and replaced by the following: "For purposes of this Exhibit D, all references herein to the "Premises" shall be deemed to refer to the Leased Premises, and all references herein to the "Term" shall be deemed to refer to the Extended Term, as set forth in the Third Amendment." Section 1 of Exhibit D to the Second Amendment is hereby deleted and of no further force or effect. Notwithstanding anything to the contrary in this Third Amendment, the reference to the "Relocation Premises" in the first sentence of Section 2 of said Exhibit D shall remain unchanged.

6. Extension Term. The second sentence of Section 3 of Exhibit D to the Second Amendment is hereby deleted in its entirety and replaced by the following: "For the avoidance of doubt, as used herein, references to the "initial Term" shall be deemed

to refer to the Extended Term set forth in Section 1 of the Third Amendment." All other terms of said Section 3 shall continue to apply.

7. Miscellaneous

(a) Brokerage. Landlord and Tenant each represent and warrant to the other that it has not dealt with any real estate broker or agent in connection with this Third Amendment except for CBRE, Inc. ("Tenant's Broker"). Tenant shall indemnify and hold Landlord and its trustees, managers, members, principals, beneficiaries, partners, officers, directors, employees, mortgagees, and agents harmless from all claims of any brokers, agents, or finders claiming to have represented Tenant in connection with this Third Amendment other than Tenant's Broker. Landlord shall pay the commission due to Tenant's Broker with respect to this Third Amendment pursuant to a separate agreement. The provisions of this Section 7(a) shall survive the expiration or earlier termination of the Lease.

(b) Tenant Confirmations. Tenant represents and warrants to Landlord that (i) Landlord is not in default of its obligations under the Lease, nor do circumstances exist which,

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with the giving of notice or passage of time, or both, would constitute a default by Landlord under the Lease, (ii) the person executing this Third Amendment to Lease on behalf of Tenant is duly authorized and has full power and authority to execute and deliver this Third Amendment, (iii) Tenant has no claim, offset, or defense against the enforcement of the Lease in accordance with its terms, and (iv) Tenant is not acting, directly or indirectly, for or on behalf of any person, group, entity, or nation named by any Executive Order or the United States Treasury Department as a terrorist, "Specially Designated National and Blocked Person," or other banned or blocked person, group, entity, nation, or transaction pursuant to any law, order, rule, or regulation that is enforced or administered by the Office of Foreign Assets Control and that it is not engaged in this transaction, directly or indirectly, on behalf of, or instigating or facilitating this transaction, directly or indirectly, on behalf of any such person, group, entity, or nation.

(c) General. The submission of this Third Amendment to Tenant or a summary of some or all of its provisions for examination does not constitute a reservation of or option for the Leased Premises or an offer to lease any space, and no legal obligations shall arise with respect to the Leased Premises hereunder or other matters herein unless and until such time as this Third Amendment is executed by both parties. This Third Amendment may be executed in one or more counterparts and, when executed by each party, shall constitute an agreement binding on all parties notwithstanding that all parties are not signatories to the original or the same counterpart provided that all parties are furnished a copy or copies thereof reflecting the signature of all parties. Transmission of a facsimile or by email of a pdf copy of the signed counterpart of this Third Amendment shall be deemed the equivalent of the delivery of the original, and any party so delivering a facsimile or pdf copy of the signed counterpart of this Third Amendment by email transmission shall in all events deliver to the other party an original signature promptly upon request. This Third Amendment may be signed and/or transmitted by electronic mail of a .PDF document or electronic signature (e.g., DocuSign or similar electronic signature technology) and thereafter maintained in electronic form, and such electronic record shall be valid and as effective to bind the party so signing as a paper copy bearing such party's handwritten signature. The electronic signatures appearing on this Third Amendment shall be treated, for purpose of validity, enforceability, and admissibility, the same as handwritten signatures.

(d) Entire Amendment. This Third Amendment contains all of the agreements of the parties with respect to the subject matter hereof and supersedes all prior dealings between the parties with respect to such subject matter. All references in the Lease to the "Lease" or "this Lease" or "the Lease" or "herein" or "hereunder" or similar terms or to any section thereof shall mean the Lease, or such section thereof, as amended by this Third Amendment.

(e) Binding Amendment. This Third Amendment shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and permitted assigns.

(f) Governing Law. This Third Amendment shall be governed by the laws of the Commonwealth of Massachusetts without regard to conflict of laws principles.

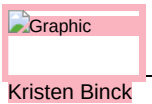
(g) Ratification. Except as expressly modified by this Third Amendment, the Lease is hereby ratified and confirmed and shall remain in full force and effect.

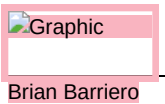
[*signature page immediately follows*]

IN WITNESS WHEREOF, Landlord and Tenant have entered into this Third Amendment as a sealed Massachusetts instrument as of the Effective Date set forth above.

LANDLORD:

500 BOYLSTON & 222 BERKELEY OWNER (DE) LLC, a Delaware limited liability company

By: 
Name: Kristen Binck
Title: Vice President

By: 
Name: Brian Barriero
Title: Vice President

TENANT:

RHYTHM PHARMACEUTICALS, INC., a Delaware corporation

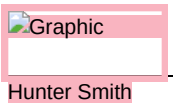
By: 
Name: Hunter Smith
Title: CFO

Exhibit 31.1

CERTIFICATION

I, David P. Meeker, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 7, 2024 August 6, 2024

/s/ David P. Meeker, M.D.

Name: David P. Meeker, M.D.

Title: President and Chief Executive Officer
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION

I, Hunter C. Smith, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 7, 2024 August 6, 2024

/s/ Hunter C. Smith

Name: Hunter C. Smith

Title: Chief Financial Officer and Treasurer

(*Principal Financial Officer*)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, David P. Meeker, M.D., certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge, the Quarterly Report on Form 10-Q of Rhythm Pharmaceuticals, Inc. for the fiscal quarter ended March 31, 2024 June 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Rhythm Pharmaceuticals, Inc.

/s/ David P. Meeker, M.D.

Name: David P. Meeker, M.D.

Title: President and Chief Executive Officer

(*Principal Executive Officer*)

May 7, August 6, 2024

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Hunter C. Smith, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge, the Quarterly Report on Form 10-Q of Rhythm Pharmaceuticals, Inc. for the fiscal quarter ended March 31, 2024 June 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Rhythm Pharmaceuticals Inc.

/s/ Hunter C. Smith

Name: Hunter C. Smith
Title: Chief Financial Officer and Treasurer
(*Principal Financial Officer*)

May 7, August 6, 2024

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