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

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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: 001-36510

LARIMAR THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-3857670**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Three Bala Plaza East, Suite 506	**19004**
Bala Cynwyd, PA	**(Zip Code)**
(Address of principal executive offices)	

(844) 511-9056

(Registrant's telephone number, including area code)

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, par value $0.001 per share	LRMR	The 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 ☒

As of May 7, 2024, there were 63,802,017 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q that are not statements of historical or current facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements discuss our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “potential,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” or similar statements reflect our beliefs and opinions on the relevant subject only. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- uncertainties in obtaining successful non-clinical or clinical results that reliably and meaningfully demonstrate safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration (“FDA”), European Medicines Agency ("EMA") and other comparable regulatory authorities for marketing approval for nomlabofusp (nomlabofusp is the International Nonproprietary Name and the United States Adopted Name for CTI-1601) or any other product candidates that we may develop in the future and unexpected costs that may result therefrom;

- our ability to continue to successfully execute our ongoing open label extension study (“OLE”), including the timing of site initiations and rate of patient enrollment, and our ability to pursue dose escalation;

- uncertainties associated with the clinical development and regulatory approval for nomlabofusp, including potential delays in the commencement, enrollment and completion of clinical trials, the timing of a potential Biologics License Application (“BLA”) submission for accelerated approval, including our ability to supply to the FDA all required data for the FDA to review and accept an accelerated application, or any other product candidates that we may develop in the future;

- the difficulties and expenses associated with obtaining and maintaining regulatory approval for nomlabofusp or any other product candidates we may develop in the future, and the indication and labeling under any such approval;

- how long we can continue to fund our operations with our existing cash, cash equivalents and marketable securities and our estimates regarding future results of operations, financial position, research and development costs, capital requirements and our access and needs for additional financing;

- our expectations regarding the use of proceeds from recent and future financings, if any;

- our ability, and the ability of third-party manufacturers we engage, to optimize and scale nomlabofusp or any other product candidate’s manufacturing process and to manufacture sufficient quantities of clinical supplies, and, if approved, commercial supplies of nomlabofusp or any other product candidates that we may develop in the future and our ability to maintain our relationships and contracts with our key vendors and to identify and contract with alternate or secondary key vendors;

- our ability to realize any value from nomlabofusp and/or any other product candidates we may develop in the future in light of inherent risks and difficulties involved in successfully bringing product

candidates to market and the risk that the product candidates, if approved, will not achieve broad market acceptance;

•our ability to comply with regulatory requirements applicable to our business and other regulatory developments in the United States and other countries;

•the size and growth of the potential markets for nomlabofusp, if approved, or any other product candidates that we may develop in the future, the rate and degree of market acceptance of nomlabofusp or any other product candidate, if approved, that we may develop in the future and our ability to serve those markets;

•given competing therapies and products for the treatment of FA, our ability to obtain and maintain designations or eligibility for expedited regulatory programs, and to commercialize current and future product candidates, if approved, (including the impact of potential barriers to entry if a competitor is able to establish a strong market position before we are able to commercialize our products);

•our ability to obtain and maintain patent protection and defend our intellectual property rights against third parties;

•the performance and compliance with the rules and regulations of the FDA (and all other regulatory authorities) of third parties upon which we depend, including third-party contract research organizations ("CROs"), consultants, and third-party suppliers, manufacturers, distributors, and logistics providers;

•our ability to recruit and retain key scientific, technical, commercial, and management personnel and to retain our executive officers;

•our ability to maintain proper functionality and security of our internal computer and information systems and prevent or avoid cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption;

•the extent to which geopolitical tensions, including regional conflicts around the world, adverse macroeconomic events, including those due to inflationary pressures, rising interest rates, banking instability, economic slowdowns or recessions, health epidemics, unforeseen emergencies and other outbreaks of communicable diseases could disrupt our operations, the operations of third parties on which we rely or the operations of regulatory agencies we interact with in the development of nomlabofusp and any other product candidates that we may develop;

•the potential impact of healthcare reform in the United States, including the Inflation Reduction Act of 2022, and measures being taken worldwide designed to reduce healthcare costs and limit the overall level of government expenditures.

These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements may not be achieved or occur at all. The factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K filed on March 14, 2024. All forward-looking statements are applicable only as of the date on which they were made and, except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of any unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

Larimar Therapeutics, Inc.

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PART I-FINANCIAL INFORMATION

Item 1. Financial Statements

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 110,125	$ 26,749
Short-term marketable securities	117,171	60,041
Prepaid expenses and other current assets	3,657	3,385
Total current assets	230,953	90,175
Long-term marketable securities	11,711	—
Property and equipment, net	604	684
Operating lease right-of-use assets	2,920	3,078
Restricted cash	1,339	1,339
Other assets	678	659
Total assets	$ 248,205	$ 95,935
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,918	$ 1,283
Accrued expenses	10,098	7,386
Operating lease liabilities, current	825	837
Total current liabilities	12,841	9,506
Operating lease liabilities	4,520	4,709
Total liabilities	17,361	14,215
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 63,800,017 and 43,909,069 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	64	43
Additional paid-in capital	434,013	270,150
Accumulated deficit	(203,208)	(188,554)
Accumulated other comprehensive gain (loss)	(25)	81
Total stockholders' equity	230,844	81,720
Total liabilities and stockholders' equity	$ 248,205	$ 95,935

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

LARIMAR THERAPEUTICS, 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
Operating expenses:		
Research and development	$ 12,939	$ 4,562
General and administrative	3,795	3,075
Total operating expenses	16,734	7,637
Loss from operations	(16,734)	(7,637)
Other income, net	2,080	1,111
Net loss	$ (14,654)	$ (6,526)
Net loss per share, basic and diluted	$ (0.27)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	53,553,707	43,897,603
Comprehensive loss:		
Net loss	$ (14,654)	$ (6,526)
Other comprehensive gain (loss):		
Unrealized gain (loss) on marketable securities	(106)	31
Total other comprehensive gain (loss)	(106)	31
Total comprehensive loss	$ (14,760)	$ (6,495)

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

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
Balances as of December 31, 2023	43,909,069	$ 43	$ 270,150	$ (188,554)	$ 81	$ 81,720
Issuance of common stock, net	19,736,842	20	161,736	—	—	161,756
Vesting of restricted stock units	153,750	1	(1)	—	—	—
Exercise of stock options	356	—	—	—	—	—
Stock-based compensation expense	—	—	2,128	—	—	2,128
Unrealized loss on marketable securities	—	—	—	—	(106)	(106)
Net loss	—	—	—	(14,654)	—	(14,654)
Balances as of March 31, 2024	63,800,017	$ 64	$ 434,013	$ (203,208)	$ (25)	$ 230,844

	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
Balances as of December 31, 2022	43,269,200	$ 43	$ 262,496	$ (151,605)	$ (31)	$ 110,903
Stock-based compensation expense	—	—	1,833	—	—	1,833
Unrealized gain on marketable securities	—	—	—	—	31	31
Net loss	—	—	—	(6,526)	—	(6,526)
Balances as of March 31, 2023	43,269,200	$ 43	$ 264,329	$ (158,131)	$ —	$ 106,241

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

LARIMAR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (14,654)	$ (6,526)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,128	1,833
Lease expense	(43)	(24)
Depreciation expense	80	78
Amortization of premium on marketable securities	(583)	(616)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(272)	371
Accounts payable	290	(991)
Accrued expenses	2,662	(1,682)
Other assets	(19)	6
Net cash used in operating activities:	(10,411)	(7,551)
Cash flows from investing activities:		
Purchase of marketable securities	(84,864)	—
Maturities and sales of marketable securities	16,500	92,250
Net cash provided by (used in) investing activities	(68,364)	92,250
Cash flows from financing activities:	—	—
Proceeds from issuance of equity securities, net of issuance costs	162,151	—
Net cash provided by financing activities	162,151	—
Net increase in cash, cash equivalents and restricted cash	83,376	84,699
Cash, cash equivalents and restricted cash at beginning of period	28,088	28,164
Cash, cash equivalents and restricted cash at end of period	$ 111,464	$ 112,863
Supplemental disclosure of non-cash investing and financing activities:		
Offering costs included in accounts payable and accrued expense	$ 395	$ —

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

LARIMAR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1.Description of Business and Basis of Presentation

Larimar Therapeutics, Inc., together with its subsidiary (the “Company” or “Larimar”), is a clinical-stage biotechnology company focused on developing treatments for patients suffering from complex rare diseases using its novel cell penetrating peptide technology platform. Larimar's lead product candidate, nomlabofusp (nomlabofusp is the International Nonproprietary Name and the United States Adopted Name for CTI-1601), is a subcutaneously administered, recombinant fusion protein intended to deliver human frataxin ("FXN"), an essential protein, to the mitochondria of patients with Friedreich’s ataxia ("FA"). FA is a rare, progressive and fatal disease in which patients are unable to produce sufficient FXN due to a genetic abnormality.

The Company has completed two phase 1 studies of nomlabofusp, a Phase 2 dose exploration study, and recently initiated an open label extension study (“OLE”) in patients with FA.

In May 2021, after reporting positive top-line data from the Company’s Phase 1 FA program, the U.S. Food and Drug Administration (“FDA”) placed a clinical hold on the Company’s nomlabofusp clinical program after the Company notified the FDA of mortalities at the highest dose levels of a 26-week non-human primate toxicology study that was designed to support extended dosing of patients with nomlabofusp. In August 2022, the Company submitted a complete response to the clinical hold following a Type C Meeting with the FDA, and proposed as nomlabofusp's next clinical trial a Phase 2, four-week, dose exploration study in FA patients starting at the lower dose levels tested in the Company’s Phase 1 multiple-ascending dose clinical trial. In September 2022, the FDA lifted its full clinical hold on the nomlabofusp program and imposed a partial clinical hold.

In May 2023, the Company announced top-line data from its completed 25 mg cohort of a Phase 2, four-week, dose exploration trial of nomlabofusp in patients with FA and provided a complete response to the FDA in June 2023, which included unblinded safety, pharmacokinetic ("PK"), and pharmacodynamic ("PD") data from the Phase 2 trial’s completed 25 mg cohort.

In June 2023, the Company met with the FDA. Following that meeting, the Company submitted a complete response to the FDA’s partial clinical hold that included unblinded safety, PK and frataxin data from the Phase 2 trial’s completed 25 mg cohort.

In July 2023, following the FDA’s review of the Company's complete response to the partial clinical hold, the FDA cleared initiation of a second cohort at 50 mg of our four-week, placebo-controlled, Phase 2 dose exploration trial and initiation of an OLE study with daily dosing of 25 mg.

In February 2024, the Company reported positive top-line data and successful completion of their four-week, placebo-controlled Phase 2 dose exploration study of nomlabofusp in participants with FA. Nomlabofusp was generally well tolerated throughout the four-week treatment periods, had a predictable pharmacokinetic profile and let to dose dependent increases in FXN levels in all evaluated tissues (skin and buccal cells) after daily dosing of 14 days followed by every other day dosing until day 28 in the 25 mg and 50 mg cohorts. Participants in the 25 mg (n=13) and 50 mg (n=15) cohorts were randomized 2:1 to receive subcutaneous injections of nomlabofusp or placebo. The initiation of additional U.S. clinical trials evaluating nomlabofusp are contingent on FDA review of data under the partial clinical hold.

In January 2024, the Company initiated the OLE trial, discussed above, evaluating daily subcutaneous injections of 25 mg of nomlabofusp self-administered or administered by a caregiver, with the first patient dosed in March 2024. Additional patients continue to be enrolled and dosed and additional clinical sites added. Participants who completed treatment in the Phase 2 dose exploration study, or who previously completed a prior clinical trial of nomlabofusp, are potentially eligible to screen for the OLE study. The OLE study will evaluate the safety and tolerability, pharmacokinetics, and frataxin levels in peripheral tissues as well as other exploratory pharmacodynamic markers (lipid profiles and gene expression data) following long-term subcutaneous administration of nomlabofusp. Dose escalation in the OLE study is contingent on the FDA’s review of data from the 50 mg cohort of the Phase 2 study and available data from the OLE study, due to the continued partial clinical hold. Interim data is expected in the fourth quarter of 2024. In addition, clinical assessments collected during the study will be compared to data from a matched control arm derived from participants in the Friedreich’s Ataxia Clinical Outcome Measures Study (FACOMS) database.

The Company is subject to risks and uncertainties common to pre-commercial companies in the biotechnology industry, including, but not limited to, development and commercialization by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with governmental regulations, failure to secure regulatory approval for its drug candidates or any other product candidates and the

ability to secure additional capital to fund its operations. Product candidates under development will require extensive non-clinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, it will realize significant revenue from product sales.

Basis of Presentation

The condensed consolidated financial statements include the accounts of Larimar and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated. The accompanying condensed consolidated financial statements have been prepared in conformity with Generally Accepted Accounting Principles ("GAAP").

The condensed consolidated balance sheet as of December 31, 2023 was derived from the Company's audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements as of March 31, 2024 and for the three months ended March 31, 2024 and 2023, have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2024.

In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of March 31, 2024, condensed consolidated results of operations for the three months ended March 31, 2024 and condensed consolidated statement of cash flows for the three months ended March 31, 2024 have been made. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

Liquidity and Capital Resources

The Company's condensed consolidated financial statements have been presented on the basis that it will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since its inception, the Company has incurred significant recurring operating losses and negative cash flows from operations. The Company has incurred net losses of $14.7 million and $6.5 million for the three months ended March 31, 2024 and 2023, respectively. In addition, as of March 31, 2024, the Company had an accumulated deficit of $203.2 million. The Company expects to continue to generate operating losses for the foreseeable future. As of March 31, 2024, the Company had approximately $239.0 million of cash, cash equivalents and marketable securities available for use to fund its operations and capital requirements.

The Company has funded its operations to date primarily with proceeds from sales of common stock and proceeds from the sale of prefunded warrants for the purchase of common stock, the acquisition in 2020 of cash, cash equivalents and marketable securities upon the merger with Zafgen, Inc. ("Zafgen") and, prior to the 2020 merger with Zafgen, capital contributions from Chondrial Holdings, LLC.

In February 2024, the Company completed an underwritten public offering in which the Company issued and sold 19,736,842 shares of its common stock at a public offering price of $8.74 per share. The Company received net proceeds of approximately $161.8 million after deducting underwriting discounts, commissions and other offering expenses.

In accordance with Accounting Standards Update ("ASU") No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are issued. As of the issuance date of these condensed consolidated financial statements, the Company expects its cash, cash equivalents and marketable securities, including its net proceeds from the February 2024 public offering, will be sufficient to fund its forecasted operating expenses and capital expenditure requirements into 2026. If the timing

of the Company's clinical assumptions are delayed or if there are other forecasted assumption changes that negatively impact its operating plan, the Company would reduce expenditures in order to further extend cash resources.

The Company has not yet commercialized any products and does not expect to generate revenue from the commercial sale of any products for several years, if at all. The Company expects that its research and development and general and administrative expenses will continue to increase and, as a result, that it will need additional capital to fund its future operating and capital requirements. Unless and until the Company can generate substantial revenue, management continuously evaluates different strategies to obtain the required funding for future operations. These strategies include seeking additional funding through a combination of public or private equity offerings, debt or royalty financings, collaborations and licensing arrangements, strategic partnerships with pharmaceutical and/or larger biotechnology companies, or other sources. The incurrence of indebtedness would result in increased fixed payment obligations and the Company may be required to agree to certain restrictive covenants, such as limitations on its ability to incur additional debt, limitations on its ability to acquire, sell or license intellectual property rights, minimum required cash balances and other operating restrictions that could adversely impact the Company's ability to conduct its business. Any additional fundraising efforts may divert the Company's management from their day-to-day activities, which may adversely affect its ability to develop and commercialize its product candidates.

There can be no assurance that the Company will be able to raise sufficient additional capital on acceptable terms, if at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, or if the Company does not have sufficient authorized shares, the Company may be required to delay, limit, or eliminate the development of business opportunities and its ability to achieve its business objectives, its competitiveness, and its business, financial condition, and results of operations will be materially adversely affected. The Company could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and it may be required to relinquish rights to some of its technologies or product candidates or otherwise agree to terms unfavorable to it, any of which may have a material adverse effect on the Company's business, operating results and prospects. In addition, geopolitical tensions, volatility of capital markets, and other adverse macroeconomic events, including those due to inflationary pressures, rising interest rates, bank instability and the ability of the U.S. government to manage federal debt limits as well as the potential impact of other health crises on the global financial markets may reduce the Company's ability to access capital, which could negatively affect its liquidity and ability to continue as a going concern.

If the Company is unable to obtain sufficient funding when needed and/or on acceptable terms, the Company may be required to significantly curtail, delay or discontinue one or more of its research and development programs, the manufacture of clinical and commercial supplies, product portfolio expansion, pre commercialization efforts and/or commercial operations, which could adversely affect its business prospects, or the Company may be unable to continue operations.

2.Summary of Significant Accounting Policies

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. This process involves reviewing open contracts and purchase orders, communicating with our personnel and outside vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expense, the recording as prepaid expense of payments made in advance of the actual provision of goods or services, valuation of stock-based awards and valuation of leases. Due to inherent uncertainty involved in making estimates, actual results reported in future periods may be affected by changes in these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions.

Research and Development Costs

Costs associated with internal research and development and external research and development services, including drug development, clinical studies and non-clinical studies, are expensed as incurred. Research and

development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation, stock-based compensation, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, non-clinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company recognizes external research and development costs based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its key service providers.

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. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments, milestone payments and annual maintenance fees under license agreements are currently expensed in the period in which they are incurred.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-Based Compensation

The Company measures all stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. Compensation expense of those awards is recognized over the requisite service period, which is the vesting period of the respective award. Typically, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

Prior to May 28, 2020, the Company had been a private company and lacked company-specific historical and implied volatility information for its common stock. Prior to January 1, 2023, the Company estimated its expected common stock price volatility solely based on the historical volatility of publicly traded peer companies. Beginning on January 1, 2023, based on the availability of sufficient historical trading data of the Company's own common stock on the Nasdaq Global Market to calculate accurately its volatility, the Company began blending its volatility starting from June 2020 (following its merger with Zafgen in 2020) to the date of each stock-based award, and weighing the volatility of its peer group for the amount of time from May 31, 2020 backwards so that the blended volatility equals the expected term of the related stock-based award. The expected term of the Company’s stock options has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield considers the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Prior to August 11, 2023, basic shares outstanding includes the weighted average effect of the Company’s prefunded warrants issued in June 2020, the exercise of which requires little or no consideration for the delivery of shares of common stock. These prefunded warrants were exercised on August 11, 2023 and the Company received cash proceeds of less than $0.1 million. Accordingly, the 628,403 shares were issued upon the exercise of these warrants and are included in issued and outstanding common stock.

Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares, including potentially dilutive common stock equivalents assuming the dilutive effect of outstanding stock options, outstanding restricted stock units, and unvested restricted common shares, as determined using the treasury stock method. For periods in which the Company has reported net losses (all periods since inception), diluted net loss per common share

attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, since dilutive common stock equivalents are not assumed to have been issued if their effect is antidilutive.

The Company excluded 6,555,145 and 4,974,521 common stock equivalents outstanding as of March 31, 2024 and 2023, respectively, from the computation of diluted net loss per share for the three months ended March 31, 2024 and 2023 because they had an anti-dilutive impact due to the net loss incurred for the periods presented.

Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting guidance is issued by the FASB or other standard setting bodies that is adopted by us as of the effective date or, in some cases where early adoption is permitted, in advance of the effective date. We have assessed the recently issued guidance that is not yet effective and believe the new guidance will not have a material impact on the condensed consolidated results of operations, cash flows or financial position.

3.Fair Value Measurements and Marketable Securities

Fair Value Measurements

The Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2024 and December 31, 2023 are measured in accordance with the standards of ASC 820, "*Fair Value Measurements and Disclosures"*, which establishes a three-level valuation hierarchy for measuring fair value and expands financial statement disclosures about fair value measurements. The valuation hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:

Level – 1	Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level – 2	Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.
Level – 3	Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The Company's financial instruments consist primarily of cash, cash equivalents, marketable securities, accounts payable and accrued liabilities. For accounts payable and accrued liabilities, the carrying amounts of these financial instruments as of March 31, 2024 and December 31, 2023 were considered representative of their fair values due to their short term to maturity.

The following tables summarize the Company's cash equivalents and marketable securities as of March 31, 2024 and December 31, 2023:

	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
March 31, 2024				
Cash equivalents:				
Money market funds invested in government securities	$ 69,905	$ 69,905	$ —	$ —
U.S. Treasury Bills	39,813	39,813	—	—
Total cash equivalents	109,718	109,718	—	—
Marketable securities:				
U.S. Treasury Bills	23,058	23,058	—	—
U.S. Government securities	79,835	—	79,835	—
Corporate bonds	25,989	—	25,989	—
Total marketable securities	128,882	23,058	105,824	—
Total cash equivalents and marketable securities	$ 238,600	$ 132,776	$ 105,824	$ —
December 31, 2023				
Cash equivalents:				
Money market funds invested in government securities	$ 24,701	$ 24,701	$ —	$ —
Total cash equivalents	24,701	24,701	—	—
Marketable securities:				
U.S. Treasury Bills	17,334	17,334	—	—
U.S. Government securities	35,719	—	35,719	—
Corporate bonds	6,988	—	6,988	—
Total marketable securities	60,041	17,334	42,707	—
Total cash equivalents and marketable securities	$ 84,742	$ 42,035	$ 42,707	$ —

The accrued interest receivable related to the Company's investments was $1.1 million and $0.3 million as of March 31, 2024 and December 31, 2023, respectively, and is included in prepaid expenses and other current assets on the condensed consolidated balance sheet.

The Company classifies its money market funds and U.S. treasury bills, which are valued based on quoted market prices in active markets with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The Company classifies its investments in U.S. government and agency securities, corporate commercial paper, and corporate bonds, if any, as Level 2 assets within the fair value hierarchy. The fair values of these investments are estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

As of March 31, 2024 and December 31, 2023, the unrealized losses for available-for-sale investments were non-credit related, and the Company does not intend to sell the investments that were in an unrealized loss position, nor will it be required to sell those investments before recovery of their amortized cost basis, which may be maturity. As of March 31, 2024 and December 31, 2023, no allowances for credit losses for the Company's

investments were recorded. During the three months ended March 31, 2024 and 2023, the Company did not recognize any impairment losses related to investments.

Marketable securities

The following table summarizes the Company's marketable securities as of March 31, 2024 and December 31, 2023.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
March 31, 2024				
Assets:				
U.S. Treasury Bills	$ 23,061	$ —	$ (3)	$ 23,058
U.S. Government securities	79,849	6	(20)	79,835
Corporate bonds	25,997	3	(11)	25,989
Total marketable securities	$ 128,907	$ 9	$ (34)	$ 128,882
December 31, 2023				
Assets:				
U.S. Treasury Bills	$ 17,330	$ 4	$ —	$ 17,334
U.S. Government securities	35,653	66	—	35,719
Corporate bonds	6,977	11	—	6,988
Total marketable securities	$ 59,960	$ 81	$ —	$ 60,041

No marketable securities held as of March 31, 2024 or December 31, 2023, had remaining maturities greater than two years.

As of March 31, 2024 and December 31, 2023, the Company held no investments that have been in a continuous loss position for 12 months or longer.

4.Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	March 31, 2024	December 31, 2023
	(in thousands)	
Prepaid research and development expenses	$ 1,786	$ 1,994
Interest receivable	1,079	332
Prepaid insurance	448	682
Other prepaid expenses and other assets	344	377
	$ 3,657	$ 3,385

5.Fixed Assets

Fixed assets, net consisted of the following:

	Useful Life	March 31, 2024	December 31, 2023
		(in thousands)	
Computer equipment	5 years	$ 117	$ 117
Lab equipment	5 years	1,192	1,192
Furniture and fixtures	7 years	555	555
Leasehold improvements	lease term	45	45
		1,909	1,909
Less: Accumulated depreciation		(1,305)	(1,225)
		$ 604	$ 684

Depreciation expense was $0.1 million for each of the three months ended March 31, 2024 and 2023. In addition, for the three months ended March 31, 2024 and 2023, there was less than $0.1 million of depreciation related to sublet assets recorded as other expense.

6.Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2024	December 31, 2023
	(in thousands)	
Accrued research and development expenses	$ 8,804	$ 4,594
Accrued payroll and related expenses	788	2,365
Accrued other	506	427
	$ 10,098	$ 7,386

7.Stockholders' Equity and Stock Options

Common Stock and Prefunded Warrants

On May 28, 2020, the Company entered into a securities purchase agreement with certain accredited investors (the "Purchasers") for the sale by the Company in a private placement of 6,105,359 shares of the Company's common stock and prefunded warrants to purchase an aggregate of 628,403 shares of the Company's common stock, for a price of $11.88 per share of the common stock and $11.87 per prefunded warrant. The prefunded warrants were exercisable at an exercise price of $0.01 and were exercisable indefinitely. In August 2023, the 628,403 shares of prefunded warrants were exercised and the Company received cash proceeds of six thousand two hundred and eighty-four dollars. The private placement closed on June 1, 2020. The aggregate gross proceeds for the issuance and sale of the common stock and prefunded warrants were $80.0 million, transaction costs totaled $4.6 million and resulted in net proceeds of $75.4 million. The Company's Registration Statement on Form S-3, filed with the SEC on June 26, 2020, registered the resale of 6,105,359 shares of common stock sold and the 628,403 shares of common stock underlying the prefunded warrants. MTS Health Partners served as placement agent to the Company in connection with the private placement. As partial compensation for these services, the Company issued MTS Health Partners 35,260 shares of common stock.

As of March 31, 2024,the Company's Ninth Amended and Restated Certificate of Incorporation, as amended, authorized the Company to issue up to 115,000,000 shares of common stock, par value $0.001 per share, of which 63,800,017 shares were issued and outstanding, and up to 5,000,000 shares of undesignated preferred stock, par value $0.001 per share, of which no shares were issued or outstanding. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors of the Company (the "Board"), if any. No cash dividends have been declared or paid to date.

In February 2024, the Company completed an underwritten public offering in which the Company issued and sold 19,736,842 shares of its common stock at a public offering price of $8.74 per share. The Company received net proceeds of approximately $161.8 million after deducting underwriting discounts, commissions and other offering expenses.

ATM Agreement

In November 2022, the Company entered into a Sales Agreement (the "2022 ATM Agreement") with a Guggenheim Securities, LLC as a sales agent in connection with the establishment of an "at-the-market" offering program under which the Company could sell up to an aggregate of $50.0 million of shares of common stock (the "2022 ATM Shares") from time to time. In February 2024, in connection with the underwritten public offering described above, the Company terminated the 2022 ATM Agreement. No ATM Shares were ever sold pursuant to the 2022 ATM Agreement.

In May 2024, the Company entered into a sales agreement (the "ATM Agreement") with a Guggenheim Securities, LLC in connection with the establishment of an "at-the-market" offering program under which the Company could sell up to an aggregate of $100.0 million of shares of common stock (the "ATM Shares") from time to time.

2020 Equity Incentive Plan

The Board adopted the 2020 Equity Incentive Plan (the "2020 Plan") on July 16, 2020 and the stockholders of the Company approved the 2020 Plan on September 29, 2020. The 2020 Plan replaced the predecessor plans (the "Prior Plans") that the Company assumed following its merger with Zafgen in May 2020. Options outstanding under the Prior Plans will remain outstanding, unchanged, and subject to the terms of the Prior Plans and the respective award agreements, and no further awards will be made under the Prior Plans. However, if any award previously granted under the Prior Plans, expires, terminates, is canceled, or is forfeited for any reason after the approval of the 2020 Plan, the shares subject to that award will be added to the 2020 Plan share pool so that they can be utilized for new grants under the 2020 Plan.

The 2020 Plan provides for the grant of incentive stock options (“ISOs”), nonstatutory stock options (“NSOs”), stock appreciation rights, restricted stock awards, restricted stock unit awards, and cash or other stock-based awards. ISOs may be granted only to the Company’s employees, including the Company’s officers, and the employees of the Company’s affiliates. All other awards may be granted to the Company’s employees, including the Company’s officers, the Company’s non-employee directors and consultants, and the employees and consultants of the Company’s affiliates.

The maximum number of shares that may be issued in respect of any awards under the 2020 Plan is the sum of: (i) 1,700,000 shares plus (ii) an annual increase on January 1, 2021 and each anniversary of such date thereafter through January 1, 2030, equal to the lesser of (A) 4% of the shares issued and outstanding on the last day of the immediately preceding fiscal year, or (B) such smaller number of shares as determined by the Board (collectively, the “Plan Limit”). The maximum aggregate number of shares that may be issued under the 2020 Plan is 8,000,000 over the ten-year term of the 2020 Plan.

As permitted by the 2020 Plan, the Company added 1,756,363 and 1,730,768 shares available for grant to the 2020 Plan on January 1, 2024 and January 1, 2023, respectively. As of March 31, 2024, 1,222,219 shares of common stock were available for grant under the 2020 Plan.

During the twelve months ended December 31, 2023, options to purchase 224,437 shares issued under the Prior Plans were cancelled and became available for grant under the 2020 Plan. No such options were cancelled in the three months ended March 31, 2024.

Stock Option Valuation

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to employees:

	March 31, 2024
Risk-free interest rate	4.06%
Expected term (in years)	6.25
Expected volatility	96%
Dividend yield	0.00%

Stock Options

The following table summarizes the Company's stock option activity for the three months ended March 31, 2024 (amounts in millions, except for share, contractual term, and per share data):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (a) (in millions)
Outstanding as of December 31, 2023	4,273,502	$ 9.06	7.8	
Options granted	1,580,377	4.42		
Options exercised	(356)	2.95		
Options forfeited/expired	(5,000)	11.38		
Outstanding as of March 31, 2024	5,848,523	$ 7.81	8.1	$ 11.0
Exercisable as of March 31, 2024	2,419,698	$ 11.39	6.7	$ 1.5
Vested and expected to vest as of March 31, 2024	5,848,523	$ 7.81	8.1	$ 11.0

(a)The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were "in the money" at March 31, 2024.

Option Grants

During the three months ended March 31, 2024, the Company granted options to purchase 1,580,377 shares of common stock to employees under the 2020 Plan. The options have an exercise price equal to the closing stock price as of the grant date, and vest over four years, with 25% vesting on the first anniversary of the grant and the remainder vesting in equal monthly installments thereafter. The weighted-average grant date fair value of options granted under the 2020 Plan during the three months ended March 31, 2024 was $3.52.

As of March 31, 2024, total unrecognized compensation expense related to unvested stock options granted under the 2020 Plan was $12.5 million, which is expected to be recognized over a weighted average period of 2.57 years.

Inducement Stock Option Grant

There were no inducement awards granted in the three months ended March 31, 2024.

As of March 31, 2024, total unrecognized compensation expense related to unvested inducement options granted was $1.0 million, which is expected to be recognized over a weighted average period of 3.03 years.

Restricted Stock Units

In January 2024, RSUs were granted under the 2020 Plan to certain of the Company's employees in order to maintain retention of key employees. The value of an RSU award is based on the Company's stock price on the date of grant. The shares underlying the RSUs are not issued until the RSUs vest.

Activity with respect to the Company's RSUs during the three months ended March 31, 2024 was as follows (in millions, except share, contractual term, and per share data):

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (a) (in millions)
Outstanding as of December 31, 2023	615,000	$ 4.94	1.6	
Restricted stock units granted	245,372	4.21		
Restricted stock units vested	(153,750)	4.94		
Outstanding as of March 31, 2024	706,622	$ 4.69	2.0	$ 5.4
Unvested and expected to vest as of March 31, 2024	706,622	$ 4.69	2.0	$ 5.4

Restricted Stock Unit Grants

During the three months ended March 31, 2024, the Company granted 245,372 shares of RSUs to employees under the 2020 Plan. The RSUs vest annually over four years and have a weighted-average grant date fair value of $4.21 per unit.

As of March 31, 2024, total unrecognized compensation expense for RSUs was $3.1 million, which is expected to be recognized over a weighted-average period of 3.14 years.

Stock-Based Compensation

Stock-based compensation expense was classified in the condensed consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 911	$ 743
General and administrative	1,217	1,090
	$ 2,128	$ 1,833

8.Commitments and Contingencies

Intellectual Property Licenses

The Company is party to an exclusive License Agreement (the “WFUHS License”), dated November 30, 2016, as amended, with Wake Forest University Health Sciences (“WFUHS”) and an exclusive License Agreement (the “IU License”), dated November 30, 2016, as amended, with Indiana University (“IU”). Such agreements provide for a transferable, worldwide license to certain patent rights regarding technology used by the Company with respect to the development of nomlabofusp. Both agreements continue from their effective date through the last to date of expiration of the licensed patents, unless earlier terminated by either party in accordance with their terms.

In partial consideration for the right and license granted under these agreements, the Company will pay each of WFUHS and IU a royalty of a low single digit percentage of net sales of licensed products depending on whether there is a valid patent covering such products. As additional consideration for these agreements, the Company is obligated to pay each of WFUHS and IU certain milestone payments of up to $2.6 million in the aggregate upon the achievement of certain developmental milestones, which commenced with the enrollment of the first patient in a Phase 1 clinical trial. The Company enrolled the first patient in its SAD trial on December 11, 2019 and paid WFUHS and IU less than $0.1 million. The Company will also pay each of WFUHS and IU sublicensing fees ranging from a high-single digit to a low double-digit percentage of sublicense consideration depending on the Company's achievement of certain regulatory milestones as of the time of receipt of the sublicense consideration. The Company is also obligated to reimburse WFUHS and IU for patent-related expenses. In the event that the Company disputes the validity of any of the licensed patents, the royalty rate would be tripled during such dispute. The Company is also obligated to pay to IU a minimum annual royalty of less than $0.1 million per annum.

In the event that the Company is required to pay IU consideration, then the Company may deduct 20% of such IU consideration on a dollar-for-dollar basis from the consideration due to WFUHS. In the event that the Company is required to pay WFUHS consideration, then the Company may deduct 60% of such WFUHS consideration on a dollar-for-dollar basis from the consideration due to IU.

In October 2022, the Company initiated dosing of a Phase 2 study. Pursuant to the terms of both the WFUHS License and the IU License, the company recognized milestone expense of $0.3 million within research and development expenses.

Both agreements continue from their effective date through the last date of expiration of the licensed patents, unless earlier terminated by either party in accordance with their terms.

Leases

Bala Cynwyd Office Space

On August 8, 2019, the Company entered into an operating lease for office space in Bala Cynwyd, Pennsylvania, effective as of December 15, 2019, for a period of three years and six months with an option to extend the lease for three additional years. Due to required tenant improvements to be completed by the landlord, the Company did not take immediate possession of the leased property and the lease term commenced on February 15, 2020.

On March 9, 2023, the Company executed a lease extension agreement on its original 4,642 square footage of office space in Bala Cynwyd, Pennsylvania (which was set to expire in August 2023) and agreed to lease an additional 3,462 square feet of office space from the same landlord.

The lease extension on the original 4,642 square footage commenced on September 1, 2023 and the Company recorded a right of use asset and lease liability of $0.5 million as of that date.

The new lease on 3,462 additional square footage commenced on October 1, 2023 and the Company recorded a right of use asset and lease liability of $0.3 million as of that date.

The right of use assets and lease liabilities with both these leases are reflected in the financial statements for three months ended March 31, 2024 as are the right of use asset and lease liability of the Company's Boston office space discussed below.

Boston Office Lease

In connection with the Company's 2020 merger with Zafgen described in footnote 1, on May 28, 2020, the Company acquired a non-cancellable operating lease for approximately 17,705 square feet of office space (the “Premises”). The lease expires on October 30, 2029. As part of the agreement, the Company is required to maintain a letter of credit, which upon signing was $1.3 million and is classified as restricted cash within the condensed consolidated financial statements. In addition to the base rent, the Company is also responsible for its share of operating expenses, electricity and real estate taxes, which costs are not included in the determination of the leases’ right-of-use assets or lease liabilities. The right-of-use asset is being amortized to other income/(expense) over the remaining lease term as a result of the sublease described below.

On October 27, 2020, the Company entered into a sublease agreement (the “Sublease”) with Massachusetts Municipal Association, Inc. (the “Subtenant”), whereby the Company sublet the entire Premises to the Subtenant. The initial term of the Sublease commenced on December 4, 2020 and continues until October 30, 2029. In connection with the Sublease, the Company evaluated the need for impairment under ASC 360 "Impairment Testing: Long-Lived Assets Classified as Held and Used," and determined there was no impairment.

The Sublease provided for an initial annual base rent of $0.8 million, which increases annually up to a maximum annual base rent of $1.0 million. The Subtenant also is responsible for paying to the Company future increases in operating costs (commencing on January 1, 2022), future increases in annual tax costs (commencing July 1, 2021) and all utility costs (commencing March 1, 2021) attributable to the Premises during the term of the Sublease. As part of the Sublease, the subtenant deposited a letter of credit in the amount of $0.8 million to assure their performance under the sublease. If there are no uncured events of default under the sublease, the amount of this security deposit decreases over time to $0.4 million on the sixth anniversary of the Sublease. The Company records sublease income on this sublease on a straight-line basis as a component of other income/(expense).

Lab Space

On November 5, 2018, the Company entered into an operating lease for office and lab space in Philadelphia, Pennsylvania, effective as of January 1, 2019, and expiring on December 31, 2020 with an option to extend the lease for two additional years. On August 4, 2020, the Company executed the first option to extend the lease for an additional year, expiring on December 31, 2021. On August 9, 2021, the Company executed the remaining option to extend the lease for an additional year, expiring on December 31, 2022. In January 2023, the Company executed an extension of this lease for an additional year, expiring on December 31, 2023. The Company has determined this lease extension qualifies as a short-term lease and have applied the accounting policy election to not record the related right-of-use asset and lease liabilities.

On October 16, 2023, the Company entered into an operating lease for lab space in King of Prussia, Pennsylvania for a period of four years. Due to required tenant improvements to be completed by the landlord, the Company did not take immediate possession of the leased property and the lease term is expected to commence in the second quarter of 2024. The Company will not record a right of use asset or lease liability until the lease commencement date.

Lease Expense

Expense arising from operating leases was $0.1 million during each of the three months ended March 31, 2024 and 2023. For operating leases, the weighted-average remaining lease term for leases at March 31, 2024 and December 31, 2023 was 5.2 and 5.5 years, respectively. For operating leases, the weighted average discount rate for leases at March 31, 2024 and December 31, 2023 was 11.0%. The Company has not entered into any financing leases.

Maturities of lease liabilities due under these lease agreements as of March 31, 2024 are as follows:

(in thousands)		Operating Leases
Nine months ending December 31, 2024	$	1,036
Year ended December 31, 2025		1,403
Year ended December 31, 2026		1,328
Year ended December 31, 2027		1,118
Year ended December 31, 2028		1,136
Thereafter		959
Total lease payments		6,980
Less: imputed interest		(1,635)
Present value of lease liabilities	$	5,345

Legal Proceedings

The Company is not currently a party to any litigation, nor is management aware of any pending or threatened litigation against the Company, that it believes would materially affect the Company's business, operating results, financial condition or cash flows.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (“Quarterly Report”), and the audited consolidated financial statements and notes thereto and management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2023 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 14, 2024 (the "2023 Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties, and assumptions. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause our actual results to differ materially from anticipated results. We undertake no obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. You should read the “Risk Factors” section included in our 2023 Annual Report, in addition to the "Risk Factors" and “Cautionary Note Regarding Forward-Looking Statements” sections of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company focused on developing treatments for patients suffering from complex rare diseases using our novel cell penetrating peptide ("CPP") technology platform. Our lead product candidate, nomlabofusp (nomlabofusp is the International Nonproprietary Name and the United States Adopted Name for CTI-1601), is a subcutaneously administered, recombinant fusion protein intended to deliver tissue frataxin ("FXN"), an essential protein, to the mitochondria of patients with Friedreich's ataxia (“FA”). FA is a rare, progressive, and fatal disease in which patients are unable to produce sufficient FXN due to a genetic abnormality. Currently, there are no treatment options that address the core deficit of FA, low levels of FXN. Nomlabofusp represents the first potential therapy designed to increase FXN levels in patients with FA.

We believe that our CPP platform, which enables a therapeutic molecule to cross a cell membrane in order to reach intracellular targets, has the potential to enable the treatment of other rare and orphan diseases. We intend to use our proprietary platform to target additional orphan indications characterized by deficiencies in or alterations of intracellular content or activity.

Since our inception, we have devoted substantially all of our resources to developing nomlabofusp, building our intellectual property portfolio, developing third-party manufacturing capabilities, business planning, raising capital, and providing general and administrative support for such operations.

Nomlabofusp Program Update

Clinical Trials

We have completed two Phase 1 clinical trials, a Phase 2 dose exploration trial, and recently initiated an open label extension study (“OLE”) in patients with FA.

In May 2021, after reporting positive top-line data from our Phase 1 FA program, the U.S. Food and Drug Administration (“FDA”) placed a clinical hold on the our nomlabofusp clinical program after we notified the FDA of mortalities at the highest dose levels of a 26-week non-human primate toxicology study that was designed to support extended dosing of patients with nomlabofusp. In August 2022, we submitted a complete response to the clinical hold following a Type C Meeting with the FDA, and proposed as nomlabofusp's next clinical trial a Phase 2, four-week, dose exploration study in FA patients starting at the lower dose levels tested in our Phase 1 multiple-ascending dose clinical trial. In September 2022, the FDA lifted its full clinical hold on the nomlabofusp program and imposed a partial clinical hold.

In May 2023, we announced top-line data from its completed 25 mg cohort of a Phase 2, four-week, dose exploration trial of nomlabofusp in patients with FA and provided a complete response to the FDA in June 2023, which included unblinded safety, pharmacokinetic ("PK"), and pharmacodynamic ("PD") data from the Phase 2 trial’s completed 25 mg cohort.

In June 2023, we met with the FDA. Following that meeting, we submitted a complete response to the FDA’s partial clinical hold that included unblinded safety, PK and frataxin data from the Phase 2 trial’s completed 25 mg cohort.

In July 2023, following the FDA's review of our complete response to the partial clinical hold, the FDA cleared initiation of a second cohort at 50 mg of our four-week, placebo-controlled, Phase 2 dose exploration trial and initiation of an OLE study with daily dosing of 25 mg.

In February 2024, we reported positive top-line data and successful completion of their four-week, placebo-controlled Phase 2 dose exploration study of nomlabofusp in participants with FA. Nomlabofusp was generally well tolerated throughout the four-week treatment periods, had a predictable pharmacokinetic profile and let to dose dependent increases in FXN levels in all evaluated tissues (skin and buccal cells) after daily dosing of 14 days followed by every other day dosing until day 28 in the 25 mg and 50 mg cohorts. Participants in the 25 mg (n=13) and 50 mg (n=15) cohorts were randomized 2:1 to receive subcutaneous injections of nomlabofusp or placebo. The initiation of additional U.S. clinical trials evaluating nomlabofusp are contingent on FDA review of data under the partial clinical hold.

In January 2024, we initiated the OLE trial, discussed above, evaluating daily subcutaneous injections of 25 mg of nomlabofusp self-administered or administered by a caregiver, with the first patient dosed in March 2024. Additional patients continue to be enrolled and dosed and additional clinical sites added. Participants who completed treatment in the Phase 2 dose exploration study, or who previously completed a prior clinical trial of nomlabofusp, are potentially eligible to screen for the OLE study. The OLE study will evaluate the safety and tolerability, pharmacokinetics, and frataxin levels in peripheral tissues as well as other exploratory pharmacodynamic markers (lipid profiles and gene expression data) following long-term subcutaneous administration of nomlabofusp. Dose escalation in the OLE study is contingent on the FDA's review of data from the 50 mg cohort of the Phase 2 study and available data from the OLE study, due to the continued partial clinical hold. Interim data is expected in the fourth quarter of 2024. In addition, clinical assessments collected during the study will be compared to data from a matched control arm derived from participants in the Friedreich's Ataxia Clinical Outcome Measures Study (FACOMS) database.

Recently, we had discussions with the FDA regarding the use of tissue FXN levels as a novel surrogate endpoint. The FDA has acknowledged that frataxin deficiency appears to be critical to the pathogenic mechanism of FA, and that there continues to be an unmet need for treatments for FA patients that address the underlying disease pathophysiology. We intend to pursue an accelerated approval using FXN levels, supportive PD and clinical information, and safety data from the OLE study, along with additional non-clinical pharmacology information needed to support the novel surrogate endpoint approach. We are beginning to plan for a confirmatory study and are targeting a BLA submission in the second half of 2025.

Nomlabofusp has been granted Orphan Drug (U.S. and Europe), Rare Pediatric Disease (U.S.), Fast Track (U.S.), and PRIME (Europe) designations for FA. We have also begun to engage with regulators and investigators outside the U.S. as we prepare to expand our clinical program to additional geographies. With approximately 75% of individuals with FA living outside the U.S., establishing global clinical trial capabilities is important for addressing the pressing unmet needs of the FA community.

Financing Activities, including Recent Material Financings

We have funded our operations to date primarily with proceeds from sales of common stock, proceeds from the sale of prefunded warrants for the purchase of common stock, the acquisition in 2020 of cash, cash equivalents, marketable securities and restricted cash upon the merger with Zafgen, Inc. ("Zafgen") and, prior to the 2020 merger with Zafgen, capital contributions from Chondrial Holdings, LLC.

In February 2024, we completed an underwritten public offering in which we issued and sold 19,736,842 shares of our common stock at a public offering price of $8.74 per share. We received net proceeds of approximately $161.8 million after deducting underwriting discounts, commissions and other offering expenses.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amount of assets, liabilities, costs and expenses, and related disclosures. We believe that the estimates and assumptions involved in the accounting policies described below may have the greatest potential impact on our condensed consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate these estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

Research and Development Expense

Costs for certain research and development activities, such as manufacturing, non-clinical studies and clinical trials are generally recognized based on the evaluation of the progress of completion of specific tasks using information and data provided by our vendors and collaborators, and accordingly, are considered an area of significant judgment and management's review of manufacturing, non-clinical and clinical expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel and outside vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. We work with vendors and suppliers to ensure that our estimates of our research and development expenses are reasonable. We expect to increase our investment in research and development in order to advance nomlabofusp through additional clinical trials. As a result, we expect that our research and development expenses will increase in the foreseeable future as we pursue clinical development of nomlabofusp and/or any other product candidates we develop.

Stock Compensation Expense

We measure all stock-based awards granted to employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. The assumptions used in our option-pricing model represent management's best estimates. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment, and thus are inherently subjective. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Prior to May 28, 2020, we were a private company and lacked company-specific historical and implied volatility information for our common stock. Prior to January 1, 2023, the Company estimated its expected common stock price volatility solely based on the historical volatility of publicly traded peer companies with comparable characteristics including enterprise value, risk profiles and position within the industry. Beginning on January 1, 2023, the Company began blending its historical data starting in June 2020 (following its merger with Zafgen in 2020) with its historical peer group. We regularly evaluate our peer group to assess changes in circumstances where identified companies may no longer be similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation. We expect to continue to do so until we have full historical data regarding the volatility of our own traded stock price.

The expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield considers the fact that we have never paid cash dividends on common stock and do not expect to pay any cash dividends in the foreseeable future.

Compensation expense of those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Typically, we issue awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We account for forfeitures as they occur.

We classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales, and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for our product candidates, we may generate revenue from those product candidates or collaborations.

Operating Expenses

The majority of our operating expenses since inception have consisted primarily of research and development activities, and general and administrative costs.

Research and Development Expenses

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- third-party contract costs relating to research, formulation, manufacturing, non-clinical studies and clinical trial activities;
- employee related costs, including salaries, benefits and stock-based compensation expenses for employees engaged in scientific research and development functions;
- external costs of outside consultants and vendors;
- payments made under our third-party licensing agreements;
- sponsored research agreements;
- laboratory consumables; and
- allocated facility-related costs.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the clinical and commercial development of nomlabofusp, or any other product candidates we develop. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. The duration, costs, and timing of clinical trials and development of nomlabofusp or any other product candidates we develop will depend on a variety of factors, including:

- the scope, rate of progress and expense of clinical trials and other research and development activities;
- clinical trial results;
- uncertainties in clinical trial enrollment rate or design;
- significant and changing government regulation;
- the timing and receipt of any regulatory approvals;
- the influence of the FDA or other regulatory authorities on our clinical trial design and timing;
- establishing manufacturing capabilities or making arrangements with third-party manufacturers and risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- our ability to obtain and maintain patent and trade secret protection and regulatory exclusivity for our product candidates; and
- our ability to recruit and retain key research and development personnel.

A change in the outcome of one or more of these variables with respect to the development of a product candidate could significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct additional non-clinical or clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, consisting of salaries, related benefits and stock-based compensation, costs related to our executive, finance, information technology, and costs related to other administrative functions. General and administrative expenses also include insurance expenses and professional fees for auditing, tax, and legal services, including legal expenses to pursue patent protection for our intellectual property. We expect that our general and administrative expenses will increase in the foreseeable future as we hire additional employees to implement, improve and scale our operational, financial, commercial and management systems.

Results of Operations

Comparison of three months ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,		
	2024	2023	Increase (Decrease)
		(in thousands)	
Statement of Operations Data:			
Operating expenses:			
Research and development	$ 12,939	$ 4,562	$ 8,377
General and administrative	3,795	3,075	720
Total operating expenses	16,734	7,637	9,097
Loss from operations	(16,734)	(7,637)	(9,097)
Other income (expense), net	2,080	1,111	969
Net loss	$ (14,654)	$ (6,526)	$ (8,128)

Research and development expenses

Research and development expenses for the three months ended March 31, 2024 increased $8.4 million compared to the three months ended March 31, 2023. The increase in research and development expenses was primarily driven by an increase of $5.7 million in nomlabofusp manufacturing costs, an increase of $1.0 million in clinical costs primarily associated with the OLE study which began dosing patients in the first quarter of 2024, an increase of $1.0 million in personnel expense due to increased headcount, an increase of $0.3 million in consulting fees and an increase of $0.2 million in stock compensation expense associated with grants made in the first quarter of 2024.

General and administrative expenses

General and administrative expenses for the three months ended March 31, 2024 increased $0.7 million compared to the three months ended March 31, 2023. The increase in general and administrative expenses was primarily driven by an increase of $0.2 million in personnel expense, an increase of $0.2 million in legal fees, an increase of $0.1 million in stock compensation expense associated with grants made in the first quarter of 2024.

Other income (expense), net

Other income (expense), net was $2.1 million income in the first quarter of 2024 compared to $1.1 million income in the first quarter of 2023. The first quarter of 2024 primarily relates to interest income which increased as compared to the first quarter of 2023 due to a higher investment base and higher interest rates on that base.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from our operations. We have devoted substantially all of our resources to developing nomlabofusp, building our intellectual property portfolio, developing third-party manufacturing capabilities, business planning, capital raising, and providing general and administrative support for such operations.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented below:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (10,411)	$ (7,551)
Net cash provided by (used in) investing activities	(68,364)	92,250
Net cash provided by financing activities	162,151	—
Net increase in cash, cash equivalents and restricted cash	$ 83,376	$ 84,699

Net cash used in operating activities

During the three months ended March 31, 2024, operating activities used $10.4 million of cash, resulting from our net loss of $14.7 million, adjusted for noncash expenses of $1.6 million and changes in our operating assets and liabilities resulting in a source of cash of $2.7 million. Our net loss was primarily attributed to research and development activities related to our nomlabofusp program and our general and administrative expenses as described above. Noncash expenses are primarily stock-based compensation expenses. The change in operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses.

During the three months ended March 31, 2023, operating activities used $7.6 million of cash, resulting from our net loss of $6.5 million, adjusted for noncash expenses of $1.3 million and changes in our operating assets and liabilities resulting in a source of cash of $2.3 million. Our net loss was primarily attributed to research and development activities related to our nomlabofusp program and our general and administrative expenses as described above. Noncash expenses are primarily stock-based compensation expenses. The change in operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses.

Net cash provided by (used in) investing activities

During the three months ended March 31, 2024, investing activities used $68.4 million of cash to purchase $84.9 million of marketable securities, partially offset by $16.5 million of cash provided by maturities of marketable securities.

During the three months ended March 31, 2023, investing activities provided $92.3 million of cash from maturities of marketable securities.

Net cash provided by financing activities

During the three months ended March 31, 2024, financing activities provided $162.2 million of cash flows primarily from an offering of common stock.

During the three months ended March 31, 2023, there were no financing activities.

Operating Capital Requirements

We have not yet commercialized any products and do not expect to generate revenue from the commercial sale of any products for several years, if at all.

We have to date incurred net losses. We incurred net losses of approximately $14.7 million and $6.5 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $203.2 million and cash and cash equivalents of $239.0 million, excluding restricted cash of $1.3 million.

Losses have resulted principally from costs incurred in connection with research and development activities, and general and administrative costs associated with the development of nomlabofusp and our operations. We expect to incur significant expenses and operating losses for the foreseeable future as we expect to continue to incur expenses in connection with our ongoing activities, if and as we:

- continue to advance the development of nomlabofusp through additional clinical trials, including related manufacturing costs;
- seek to identify and advance development of additional product candidates into clinical development and identify additional indications for our product candidates;
- seek to obtain regulatory approvals for nomlabofusp and other potential product candidates;
- identify, acquire or in-license other product candidates and technologies;
- maintain, leverage and expand our intellectual property portfolio; and
- expand our operational, financial, commercial and management systems and personnel, including personnel to support our clinical development and future commercialization efforts and our operations as a public company.

In February 2024, we completed an underwritten public offering in which we issued and sold 19,736,842 shares of our common stock and received net proceeds of approximately $161.8 million after deducting underwriting discounts, commissions and other offering expenses. We anticipate that our current cash, cash equivalents and marketable securities will fund operations into 2026. If we encounter unexpected delays in our clinical trials or if there are other unanticipated changes to our operating plan from our current assumptions that negatively impact our operations, we may reduce expenditures in order to further extend our existing cash resources. Until we can generate substantial revenue, if ever, we expect to seek additional funding through a combination of public or private equity offerings, debt/royalty financings, collaborations, strategic alliances and licensing arrangements or other sources. 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, minimum cash balances, 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. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, if at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, or we do not have sufficient authorized shares, we may be required to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition, and results of operations will be materially adversely affected. We could also be required to seek funds through arrangements with collaborative partners, strategic alliances or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, geopolitical tensions, volatility of capital markets, and other adverse macroeconomic events, including those due to inflationary pressures, rising interest rates, bank instability and the ability of the U.S. government to manage federal debt limits, as well as the potential impact of health crises on the global financial markets may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern.

If we are unable to obtain sufficient funding when needed and/or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research and development programs, the manufacture of clinical and commercial supplies, product portfolio expansion and/or pre commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. 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. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Off-Balance Sheet Arrangements

During the periods presented we did not have, and we currently do not have, any off-balance sheet arrangements, as defined under applicable SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Recently Issued Accounting Pronouncements

Please read Note 2 to our condensed consolidated financial statements included in Part I of Item 1 of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our business, if any.

Other Company Information

None.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and are not required to provide the information under this item.

Item 4. Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended March 31, 2024, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control Over Financial Reporting

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 ended March 31, 2024 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are subject to claims in legal proceedings arising in the normal course of business. To our knowledge, during the three months ended March 31, 2024, there were no, and as of the date of this Quarterly Report, there are no, threatened or pending legal actions that could reasonably be expected to have a material adverse effect on our business, financial condition, results of operations or cash flows.

Item 1A. Risk Factors

You should carefully consider the risk factors described in our 2023 Annual Report under the caption "Item 1A. Risk Factors." The risks described in our 2023 Annual Report are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

2024 "At-the-Market" Offering Agreement

On May 9, 2024, we entered into a Sales Agreement with Guggenheim Securities, LLC as sales agent (the "Agent"), in connection with the establishment of an "at-the-market" offering program under which we may sell shares of our common stock (the "ATM Shares") from time to time through the Agent (the "ATM Agreement").

Under the ATM Agreement, we will set the parameters for the sale of ATM Shares, including the number of ATM Shares to be issued, the time period during which sales are requested to be made, limitations on the number of ATM Shares that may be sold in any one trading day and any minimum price below which sales may not be made. Sales of the ATM Shares, if any, pursuant to the ATM Agreement may be made in transactions that are deemed to be "at-the-market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. We will pay the Agent a commission of up to 3.0% of the gross proceeds of any ATM Shares sold through the Agent under the ATM Agreement and have agreed to reimburse the Agent for certain specified expenses. The ATM Agreement contains customary representations, warranties and agreements by us, indemnification obligations of us and the Agent, other obligations of the parties and termination provisions. We have no obligation to sell any of the ATM Shares, and may at any time suspend offers under the ATM Agreement.

The ATM Shares will be offered and sold pursuant to our Registration Statement on Form S-3 filed by the Company on May 9, 2024 (the "Registration Statement") and the sales agreement prospectus that forms a part of such Registration Statement, following such time, if ever, as the Registration Statement is declared effective by the Securities and Exchange Commission.

The foregoing description of the ATM Agreement is not complete and is qualified in its entirety by reference to the ATM Agreement, a copy of which is filed as exhibit 10.1 to this Quarterly Report.

This Quarterly Report shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the ATM Shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Rule 10b5-1 Trading Arrangements

During the quarter ended March 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) 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).

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report are set forth on the Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

Exhibit No.	Description
10.1*	Sales Agreement, dated as of May 9, 2024, by and between the Company and Guggenheim Securities, LLC.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tag re embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

LARIMAR THERAPEUTICS, INC.

Date: May 9, 2024

By: /s/ Carole S. Ben-Maimon, M.D.
Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2024

By: /s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial and Accounting Officer)

LARIMAR THERAPEUTICS, INC.

SALES AGREEMENT

May 9, 2024

Guggenheim Securities, LLC
330 Madison Avenue
New York, NY 10017

Ladies and Gentlemen:

As further set forth in this agreement (this ***"Agreement"***), Larimar Therapeutics, Inc., a Delaware corporation (the ***"Company"***), proposes to issue and sell from time to time through Guggenheim Securities, LLC (the ***"Agent"***), as sales agent, shares of the Company's common stock, par value $0.001 per share (the ***"Common Stock"***, and such shares of Common Stock to be sold pursuant to this Agreement, the ***"Shares"***), on terms set forth herein. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in Section 2 of this Agreement on the number of shares of Shares issued and sold under this Agreement shall be the sole responsibility of the Company, and the Agent shall have no obligation in connection with such compliance.

The Company hereby confirms its agreement with the Agent with respect to the sale of the Shares.

1.Representations and Warranties of the Company.

(a)The Company represents and warrants to, and agrees with, the Agent that, unless such representation or warranty specifies otherwise, as of the date of this Agreement, each Representation Date (as defined in Section 3(o) below), each date on which a Placement Notice (as defined in Section 2(a)(i) below) is given (each, a "***Notice Date***"), each date on which Shares are sold hereunder (each, an "***Applicable Time***"), and each Settlement Date (as defined in Section 2(a)(vii) below) as follows:

(i)*Registration Statement and Prospectus*. The Company will file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the ***"Securities Act"***), with the Securities and Exchange Commission (the ***"Commission"***) one or more registration statements on Form S-3, including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the ***"Exchange Act"***). The Company has prepared or will prepare a prospectus included as part of such registration statement or a prospectus supplement to be filed with the Commission together with the prospectus included as part of such registration statement, in each case specifically relating to the Shares (the ***"Sales Prospectus"***). The Company has furnished to the Agent, for use by the Agent, copies of the Sales Prospectus included as part of such registration statement or filed with

the Commission, as supplemented by any prospectus supplement, relating to the Shares. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable (which shall be a Sales Prospectus), with respect to the Shares. Except where the context otherwise requires, each such registration statement, as amended when it becomes effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) under the Securities Act, is herein called the ***"Registration Statement."*** The Sales Prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by any prospectus supplement, in the form in which the Sales Prospectus, as supplemented by any prospectus supplement, if applicable, has most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any "***issuer free writing prospectus***," as defined in Rule 433 under the Securities Act (***"Rule 433"***), relating to the Shares, if any, that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g), is herein called the ***"Prospectus."*** Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant the Electronic Data Gathering Analysis and Retrieval System ("***EDGAR"***).

(ii)*Continuing Effectiveness of Registration Statement*. The Registration Statement and any Rule 462(b) Registration Statement will have been declared effective by the Commission under the Securities Act. The Company will have complied, to the Commission's satisfaction, with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement shall be in effect and no proceedings for such purpose shall have been instituted, be pending or, to the knowledge of the Company, be contemplated or threatened by the Commission. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Shares hereunder meets the requirements of General Instruction I.B.1. or I.B.6 of Form S-3.

(iii)*No Material Misstatements or Omissions*. The Prospectus when filed, and as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it becomes effective or its date, as applicable, and as of each Settlement Date (as defined in Section 2(a)(vii) below), complied in all material respects with the Securities Act, and as of each effective date and each Settlement Date, will not contain any untrue statement of a material fact or omit to state

a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, and, as of each Settlement Date, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.

(iv)*Eligible Issuer*. The Company is not an "ineligible issuer" (as defined in Rule 405 under the Securities Act) as of the eligibility determination date for purposes of Rules 164 and 433 under the Securities Act with respect to the offering of the Shares contemplated by the Registration Statement; the parties hereto agree and understand that the content of any and all "road shows" (as defined in Rule 433 under the Securities Act) related to the offering of the Shares contemplated hereby is solely the property of the Company.

(v)Reserved.

(vi)*Financial Statements*. The historical financial statements (including the related notes and supporting schedules) to be included or incorporated by reference, in the Registration Statement, and the Prospectus comply as to form in all material respects with the requirements of Regulation S-X under the Securities Act (***"Regulation S-X"***) and present fairly in all material respects the financial condition, results of operations and cash flows of the entities purported to be shown thereby at the dates and for the periods indicated and have been prepared in conformity with generally accepted accounting principles in the United States applied on a consistent basis throughout the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto, or (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes and are subject to normal and recurring year-end adjustments that are not reasonably expected to be material in amount). All disclosures contained in the Registration Statement and Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Act, to the extent applicable. There are no financial statements (historical or pro forma) that are required to be included in the Registration Statement or the Prospectus that are not so included as required. The interactive data in eXtensible Business Reporting Language (***"XBRL"***) included or incorporated by reference in the Registration Statement and the Prospectus fairly present the information called for in all material respects and have been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(vii)*No Off-Balance Sheet Transactions*. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structural finance, special purpose or limited purpose entity (each, an "

Off-Balance Sheet Transaction") that could reasonably be expected to affect materially the Company's liquidity or the availability of or requirements for its capital resources, including those Off Balance Sheet Transactions described in the Commission's Statement about Management's Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), and are required to be described in the Prospectus, which have not been described as required.

(viii)*Auditor Independence.* PricewaterhouseCoopers LLP, who have certified certain financial statements of the Company and its consolidated subsidiary (the ***"Subsidiary"***), whose report appears in the Registration Statement and the Prospectus, are independent public accountants as required by the Securities Act and the Public Accounting Oversight Board.

(ix)*No Material Adverse Effect*. The Company and its Subsidiary (as listed in Schedule 4 hereto) have been duly organized, and are validly existing as a corporation and in good standing under the laws of their respective jurisdictions of organization. The Company and its Subsidiary are, and will be, duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. "***Material Adverse Effect***" shall mean any material adverse change or effect on or affecting (i) the business, earnings, assets, liabilities, prospects, condition (financial or otherwise), operations, general affairs, management, financial position, stockholders' equity or results of operations of the Company and the Subsidiary taken as a whole, or (ii) the ability of the Company to perform its obligations under this Agreement, including this issuance and sale of the Shares, or to consummate the transactions contemplated by this Agreement. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiary listed in Exhibit 21.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 except for subsidiaries that in the aggregate would not constitute a "significant subsidiary" (as defined in Rule 405 under the Securities Act). The Subsidiary is not a ***"significant subsidiary"*** (as defined in Rule 405 under the Securities Act).

(x)*Capitalization*. The Company has an authorized capitalization as set forth in each of the Registration Statement and the Prospectus, and all of the issued shares of the Company have been duly authorized and validly issued, are fully paid and non-assessable, conform in all material respects to the description thereof contained in the Registration Statement and the Prospectus and were not issued in violation of any preemptive right, resale right, right of first refusal or similar right. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's capital stock have been duly authorized and validly issued, and conform in all material respects to the description thereof contained in the Registration Statement and the Prospectus. All of the issued shares of capital stock or other ownership interest of the Company's subsidiary have been duly authorized and validly issued, are fully paid and non-assessable and are owned directly or indirectly by the Company, free and

clear of all liens, encumbrances, equities or claims, except for such liens, encumbrances, equities or claims as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xi)*Due Authorization, Valid Issuance and Non-Assessiblity of Shares*. The Shares to be issued and sold by the Company to the Agent hereunder have been duly authorized and, upon payment and delivery in accordance with this Agreement, will be validly issued, fully paid and non-assessable, will conform in all material respects to the description thereof contained in the Registration Statement and the Prospectus, will be issued in compliance with federal and state securities laws and will be free of statutory and contractual preemptive rights, rights of first refusal and similar rights.

(xii)*Authority to Enter into this Agreement*. The Company has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement. This Agreement has been duly and validly authorized, executed and delivered by the Company.

(xiii)*Non-Contravention*. The issue and sale of the Shares, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby and the application of the proceeds from the sale of the Shares as described under “Use of Proceeds” in the Registration Statement and the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, impose any lien, charge or encumbrance upon any property or assets of the Company and its subsidiary, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which the Company or its subsidiary is a party or by which the Company or its subsidiary is bound or to which any of the property or assets of the Company or its subsidiary is subject; (ii) result in any violation of the provisions of the certificate of incorporation or by-laws (or similar organizational documents) of the Company or its subsidiary; or (iii) result in any violation of any statute or any judgment, order, decree, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or its subsidiary or any of their properties or assets, except, with respect to clauses (i) and (iii), for such conflicts, breaches, violations, liens, charges, encumbrances or defaults that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xiv)*No Consent or Approval Required*. No consent, approval, authorization or order of, or filing, registration or qualification with, any court or governmental agency or body having jurisdiction over the Company or its subsidiary or any of their properties or assets is required for the issue and sale of the Shares, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby, the application of the proceeds from the sale of the Shares as described under “Use of Proceeds” in the Registration Statement and the Prospectus, except for (i) the registration of the Shares under the Securities Act; (ii) such consents, approvals, authorizations, orders, filings, registrations or qualifications as may be required under the Exchange Act, and applicable state or foreign securities laws and/or the bylaws and rules of the Financial Industry Regulatory Authority (the ***“FINRA”***) in connection with the sale of the Shares by the Agent; and (iii) the inclusion of the Shares on the Nasdaq Global Market (the ***“Exchange”***).

(xv)*Internal Controls*. The Company and its subsidiary maintain a system of "internal controls over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorization, (ii) transactions are recorded as necessary to permit preparation of the Company's financial statements in conformity with generally accepted accounting principles in the United States and to maintain accountability for its assets, (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization, (iv) the recorded accountability for the Company's assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences, and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly present the information called for in all material respects and are prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as disclosed in the Registration Statement or the Prospectus, as of the date of the most recent balance sheet of the Company and its consolidated subsidiary audited by PricewaterhouseCoopers LLP, there were no "material weaknesses" (as defined by the Public Company Accounting Oversight Board) in the Company's internal controls over financial reporting, or any fraud, whether or not material, that involves management or other employees of the Company and its subsidiary who have a significant role in the Company's internal controls; and since the end of the latest audited fiscal year, there has been no change in the Company's internal control over financial reporting (whether or not remediated) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company's board of directors has, subject to the exceptions, cure periods and the phase in periods specified in the Exchange rules ("***Exchange Rules***"), validly appointed an audit committee to oversee internal accounting controls whose composition satisfies the applicable requirements of the Exchange Rules and the Company's board of directors and/or the audit committee has adopted a charter that satisfies the requirements of the Exchange Rules.

(xvi)*Disclosure Controls*. Except as disclosed in the Registration Statement or the Prospectus, the Company and its subsidiary maintain "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that comply with the requirements of the Exchange Act and that have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company and its subsidiary have carried out evaluations of the effectiveness of their disclosure controls and procedures as required by Rule 13a-15 of the Exchange Act.

(xvii)*Critical Accounting Policies*. The section entitled "Critical Accounting Policies and Significant Judgments and Estimates" incorporated by reference in the Registration Statement and the Prospectus accurately describes in all material respects (i) the accounting policies that the Company believes are the most important in the portrayal of the

Company's financial condition and results of operations and that require management's most difficult, subjective or complex judgments ("***Critical Accounting Policies***"); (ii) the judgments and uncertainties affecting the application of Critical Accounting Policies; and (iii) the likelihood that materially different amounts would be reported under different conditions or using different assumptions, and an explanation thereof.

(xviii)*Sarbanes-Oxley Compliance*. There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith that are applicable to the Company or its directors or officers in their capacities as directors or officers of the Company.

(xix)*Exceptions*. Except as would not, in the aggregate, reasonably be expected to have a Material Adverse Effect, since the date of the latest audited financial statements included in the Registration Statement and the Prospectus, and, except as disclosed in the Registration Statement and the Prospectus, neither the Company nor its subsidiary has (i) sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, (ii) issued or granted any securities (other than pursuant to employee benefit plans, qualified stock option plans or other equity compensation plans or arrangements existing on the date hereof and disclosed in the Registration Statement and the Prospectus (the ***"Specified Equity Plans"***)), (iii) incurred any material liability or obligation, direct or contingent, other than liabilities and obligations that were incurred in the ordinary course of business, (iv) entered into any material transaction not in the ordinary course of business, or (v) declared or paid any dividend on its share capital; and since such date, except as disclosed in the Registration Statement and the Prospectus, there has not been any change in the share capital, long-term debt, net current assets or short-term debt of the Company or its subsidiary or any adverse change, or any development involving a prospective adverse change, in or affecting the condition (financial or otherwise), results of operations, shareholders' equity, properties, management, business or prospects of the Company and its subsidiary taken as a whole.

(xx)*Valid Title*. The Company and its subsidiary have good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by them, that are material to the business of the Company, in each case free and clear of all liens, encumbrances and defects, except such liens, encumbrances and defects as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiary. All assets held under lease by the Company and its subsidiary, that are material to the business of the Company, are held by them under valid, subsisting and enforceable leases, with such exceptions as do not materially interfere with the use made and proposed to be made of such assets by the Company and its subsidiary.

(xxi)*Intellectual Property*. The Company and its subsidiary owns, possesses, or can acquire on reasonable terms, all Intellectual Property necessary for the conduct of the Company's and its subsidiary's business as now conducted or as proposed to be conducted, as described in the Registration Statement and the Prospectus. Furthermore, (A) to

the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any such Intellectual Property; (B) there is no pending or, to the knowledge of the Company, threatened, action, suit, proceeding or claim by others challenging the Company's or its subsidiary's rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (C) the Intellectual Property owned by the Company and its subsidiary, and to the knowledge of the Company, the Intellectual Property licensed to the Company and its subsidiary, in each case that is necessary for the conduct of the Company's and its subsidiary's business as now conducted or as proposed to be conducted, has not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property and the Company is unaware of any facts which would form a reasonable basis for any such claim; (D) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company or its subsidiary infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, and neither the Company nor its subsidiary has received any written notice of such claim and the Company is unaware of any other fact which would form a reasonable basis for any such claim; (E) to the Company's knowledge, no employee of the Company or its subsidiary is in or has ever been in material violation of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company nor its subsidiary or actions undertaken by the employee while employed with the Company or its subsidiary; (F) with respect to the Intellectual Property that is necessary for the conduct of the Company's and its subsidiary's business as now conducted or as proposed to be conducted, there is no prior art or public or commercial activity of which the Company is aware that may render any patent included with respect to such Intellectual Property invalid or that would preclude the issuance of any patent on any patent application included in such Intellectual Property, which has not been disclosed to the U.S. Patent and Trademark Office or the relevant foreign patent authority, as the case may be; (G) to the Company's knowledge, the issued patents included in the Intellectual Property that is necessary for the conduct of the Company's and its subsidiary's business as now conducted or as proposed to be conducted are valid and enforceable and the Company is unaware of any facts that would preclude the issuance of a valid and enforceable patent on any pending patent application included in such Intellectual Property; (H) with respect to the Intellectual Property that is necessary for the conduct of the Company's and its subsidiary's business as now conducted or proposed to be conducted and that is owned or purported to be owned by the Company, the Company has taken reasonable steps necessary to secure the interests of the Company in such Intellectual Property from all employees, consultants, agents or contractors that developed (in whole or in part) such Intellectual Property; (I) no government funding, facilities or resources of a university, college, other educational institution or research center was used in the development of any Intellectual Property necessary for the conduct of the Company's and its subsidiary's business as now conducted or proposed to be conducted and that is owned or purported to be owned by the Company that would confer upon any governmental agency or body, university, college, other educational institution or research center any claim or right in or to any such Intellectual Property; and (J) to the Company's knowledge, none of the technology employed by the Company has been obtained or is being used by the Company in violation of

the rights of any entity. "***Intellectual Property***" shall mean all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, domain names, technology, know-how and other intellectual property in the United States and foreign jurisdictions.

(xxii)*Health Care Authorizations*. The Company has submitted and possesses, or qualifies for applicable exemptions to, such valid and current registrations, listings, approvals, clearances, licenses, certificates, authorizations or permits and supplements or amendments thereto issued or required by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their business ("***Permits***"), including, without limitation, all such Permits required by the U.S. Food and Drug Administration (the "***FDA***"), the U.S. Department of Health and Human Services ("***HHS***"), the U.S. Centers for Medicare & Medicaid Services ("***CMS***"), the European Medicines Agency ("***EMA***"), Health Canada or any other comparable state, federal or foreign agencies or bodies to which it is subject, and the Company has not received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Permit, except for such Permits, the lack of which would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(xxiii)*Compliance with Health Care Laws*. The Company and, to the Company's knowledge, its directors, employees and agents (while acting in such capacity) are and at all times have been in material compliance with, all health care laws applicable to the Company, or any of its products or activities, including, but not limited to, the federal Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. Section 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. Section 3729 et seq.), the administrative False Claims Law (42 U.S.C. Section 1320a-7b(a)), the Stark law (42 U.S.C. Section 1395nn), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), the exclusion laws (42 U.S.C. Section 1320a-7), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), the Controlled Substances Act (21 U.S.C. Section 801 et seq.), the Public Health Service Act (42 U.S.C. Section 201 et seq.), the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Section 263a), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, the regulations promulgated pursuant to such laws, and any other state, federal or foreign law, accreditation standards, regulation, memorandum, opinion letter, or other issuance which imposes legally binding requirements on manufacturing, development, testing, labeling, advertising, marketing, promotion, distribution, reporting, kickbacks, patient or program charges, recordkeeping, claims process, documentation requirements, medical necessity, referrals, the hiring of employees or acquisition of services or supplies from those who have been excluded from government health care programs, quality, safety, privacy, security, licensure, accreditation or any other aspect of providing health care, clinical laboratory or diagnostics products or services (collectively, "***Health Care Laws***"). The Company has not received any notification, correspondence or any other written or oral communication, including notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority, including, without limitation, the FDA, the EMA, Health Canada, the U.S. Federal Trade Commission, the U.S. Drug Enforcement Administration ("***DEA***"), CMS, HHS's Office of

Inspector General, the U.S. Department of Justice and state Attorneys General or similar agencies of potential or actual non-compliance by, or liability of, the Company under any Health Care Laws, except, with respect to any of the foregoing, such as would not, individually or in the aggregate, result in a Material Adverse Effect. To the Company's knowledge, there are no facts or circumstances that would reasonably be expected to give rise to material liability of the Company under any Health Care Laws. The statements with respect to Health Care Laws and the Company's compliance therewith included in the Registration Statement and in the Prospectus fairly summarize the matters therein described.

(xxiv)*Clinical Trials*. The studies, tests and preclinical and clinical trials conducted by or on behalf of, or sponsored by, the Company, or in which the Company has participated, that are described in the Registration Statement or the Prospectus, or the results of which are referred to in the Registration Statement or the Prospectus, were and, if still pending, are being conducted in all material respects in accordance with protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company and all applicable statutes, rules and regulations of the FDA, the EMA, Health Canada and other comparable regulatory agencies outside of the U.S. to which they are subject, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, 312, and 812; the descriptions of the results of such studies, tests and trials contained in the Registration Statement or the Prospectus do not contain any misstatement of a material fact or omit a material fact necessary to make such statements not misleading; the Company has no knowledge of any studies, tests or trials not described in the Registration Statement or the Prospectus the results of which reasonably call into question in any material respect the results of the studies, tests and trials described in the Registration Statement or Prospectus; and the Company has not received any notices or other correspondence from the FDA, EMA, Health Canada or any other foreign, state or local governmental body exercising comparable authority or any Institutional Review Board or comparable authority requiring or threatening the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of, or sponsored by, the Company or in which the Company has participated, and, to the Company's knowledge, there are no reasonable grounds for the same. Except as disclosed in the Registration Statement and the Prospectus, there has not been any violation of law or regulation by the Company in its respective product development efforts, submissions or reports to any regulatory authority that could reasonably be expected to require investigation, corrective action or enforcement action.

(xxv)*Absence of Settlement Agreements or Undertakings*. Except as disclosed in the Registration Statement and the Prospectus, the Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental authority.

(xxvi)*Absence of Legal or Governmental Proceedings.* Except as disclosed in the Registration Statement and the Prospectus, there are no legal or governmental proceedings pending to which the Company or its subsidiary is a party or of which any property or assets of the Company or its subsidiary is the subject that, if determined adversely to the Company, would, in the aggregate, reasonably be expected to have a Material Adverse Effect; and to the Company's knowledge, no such proceedings are threatened in writing by governmental authorities or others.

(xxvii)*Material Contracts*. There are no contracts or other documents required to be described in the Registration Statement or filed as exhibits to the Registration Statement that are not described and filed as required. The statements made in the Registration Statement and Prospectus, insofar as they purport to constitute summaries of the terms of the contracts and other documents described and filed, constitute accurate summaries of the terms of such contracts and documents in all material respects. Except as disclosed in the Registration Statement and the Prospectus, neither the Company nor its subsidiary has knowledge that any other party to any such contract or other document has any intention not to render full performance as contemplated by the terms thereof.

(xxviii)*Insurance*. The Company and its subsidiary maintain insurance from insurers of recognized financial responsibility in such amounts and covering such risks is commercially reasonable in accordance with customary practices for companies engaged in similar businesses and similar industries for the conduct of their respective businesses and the value of their respective properties and as is customary for companies engaged in similar businesses in similar industries. All policies of insurance of the Company and its subsidiary are in full force and effect; the Company and its subsidiary are in compliance with the terms of such policies in all material respects; neither the Company nor its subsidiary has received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance; there are no material claims by the Company or its subsidiary under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; and neither the Company nor any such subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

(xxix)*Related Party Disclosure*. No relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, shareholders, customers or suppliers of the Company, on the other hand, that is required to be described in the Registration Statement or the Prospectus which is not so described.

(xxx)*No Labor Dispute*. No labor disturbance by or dispute with the employees of the Company or its subsidiary exists or, to the knowledge of the Company, is imminent that could reasonably be expected to have a Material Adverse Effect.

(xxxi)*No Violation or Default*. Except as disclosed in the Registration Statement and the Prospectus, neither the Company nor its subsidiary (i) is in violation of its certificate of incorporation or by-laws (or similar organizational documents), (ii) is in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant, condition or other obligation contained in any indenture, mortgage, deed of trust, loan agreement, license or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, or (iii) is in violation of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over it or its property or assets or has failed to obtain any license, permit, certificate, franchise or other governmental authorization or permit necessary to the ownership of its property or to the conduct of its

business, except in the case of clauses (ii) and (iii), to the extent any such conflict, breach, violation or default would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xxxii)*Environmental Laws*. Except as disclosed in the Registration Statement and the Prospectus, the Company and its subsidiary (i) are, and at all times prior hereto were, in compliance with all laws, regulations, ordinances, rules, orders, judgments, decrees, permits or other legal requirements of any governmental authority, including without limitation any international, foreign, national, state, provincial, regional, or local authority, relating to pollution, the protection of human health or safety, the environment, or natural resources, or to use, handling, storage, manufacturing, transportation, treatment, discharge, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants (***"Environmental Laws"***) applicable to such entity, which compliance includes, without limitation, obtaining, maintaining and complying with all permits and authorizations and approvals required by Environmental Laws to conduct their respective businesses, and (ii) have not received written notice or otherwise have knowledge of any actual or alleged violation of Environmental Laws, or of any actual or potential liability for or other obligation concerning the presence, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except in the case of clauses (i) and (ii), to the extent any such non-compliance, violation, liability or other obligation would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as described in the Registration Statement and the Prospectus, (x) there are no proceedings that are pending, or to the Company's knowledge, threatened, against the Company or its subsidiary under Environmental Laws in which a governmental authority is also a party, other than such proceedings regarding which it is reasonably believed no monetary sanctions of $100,000 or more will be imposed, (y) the Company and its subsidiary are not aware of any issues regarding compliance with Environmental Laws, including any pending or proposed Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would reasonably be expected to have a Material Adverse Effect, and (z) none of the Company and its subsidiary anticipates material capital expenditures relating to Environmental Laws.

(xxxiii)*Taxes*. The Company and its subsidiary have filed all federal, state, local and foreign tax returns required to be filed through the date hereof, subject to permitted extensions, and have paid all taxes due except where the failure to file or pay would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and no tax deficiency has been determined adversely to the Company or its subsidiary, nor does the Company have any knowledge of any tax deficiencies that have been, or would reasonably be expected to be asserted against the Company, that would, in the aggregate, reasonably be expected to have a Material Adverse Effect.

(xxxiv)*ERISA Compliance*. (i) Each "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Security Act of 1974, as amended (***"ERISA"***)) for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the ***"Code"***)) would have any liability (each a ***"Plan"***) has been maintained in compliance in all material respects with its

terms and with the requirements of all applicable statutes, rules and regulations including ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) with respect to each Plan subject to Title IV of ERISA (A) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur that would result in a material loss to the Company, (B) no "accumulated funding deficiency" (within the meaning of Section 302 of ERISA or Section 412 of the Code), whether or not waived, has occurred or is reasonably expected to occur, (C) the fair market value of the assets under each Plan that is required to be funded exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan), and (D) neither the Company or any member of its Controlled Group has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(c)(3) of ERISA); and (iv) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, to the Company's knowledge, whether by action or by failure to act, which would cause the loss of such qualification.

(xxxv)*Accuracy of Statistical and Market Data*. The statistical and market-related data included in the Registration Statement and the Prospectus and the consolidated financial statements of the Company and its subsidiary included or incorporated by reference in the Registration Statement and the Prospectus are based on or derived from sources that the Company believes to be reliable in all material respects.

(xxxvi)*Not an Investment Company*. Neither the Company nor its subsidiary is, and as of the applicable Settlement Date and, after giving effect to the offer and sale of the Shares and the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement and the Prospectus, none of them will be, (i) an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the ***"Investment Company Act"***), and the rules and regulations of the Commission thereunder, or (ii) a "business development company" (as defined in Section 2(a)(48) of the Investment Company Act).

(xxxvii)*Accuracy of Certain Summaries and Statements*. The statements set forth or incorporated by reference, as applicable, in each of the Registration Statement and the Prospectus under the captions "Description of Capital Stock," "Legal Proceedings" and "Certain Relationships and Related Transactions, and Director Independence", insofar as they purport to summarize the provisions of the laws and documents referred to therein, are accurate summaries in all material respects.

(xxxviii)*Registration Rights*. Except as disclosed in the Registration Statement and the Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person. There are no contracts, agreements or understandings to

require the Company to include any such securities in the securities proposed to be offered pursuant to this Agreement, except as have been waived.

(xxxix)*No Other Brokers*. Neither the Company nor its subsidiary is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against any of them or the Agent for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.

(xl)*No Integration*. The Company has not sold or issued any securities that would be integrated with the offering of the Shares contemplated by this Agreement pursuant to the Securities Act or the interpretations thereof by the Commission.

(xli)*Absence of Stabilization or Manipulation*. The Company and its affiliates have not taken, directly or indirectly, any action designed to or that has constituted or that could reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company in connection with the offering of the Shares.

(xlii)*Exchange Act Registration and Listing of the Common Stock*. The shares of Common Stock are registered pursuant to Section 12(b) of the Exchange Act and listed on the Exchange; the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing.

(xliii)*Offering Material*. The Company has not distributed and prior to any Settlement Date, will not distribute any offering material in connection with any Placement (as defined in Section 2(a)(i) below), other than the Prospectus and any Permitted Free Writing Prospectus to which the Agent has consented.

(xliv)*Compliance with Labor Laws*. Neither the Company nor any subsidiary is in violation of or has received notice of any violation with respect to any federal or state law relating to discrimination in the hiring, promotion or pay of employees, nor any applicable federal or state wage and hour laws, nor any state law precluding the denial of credit due to the neighborhood in which a property is situated, the violation of any of which could reasonably be expected to have a Material Adverse Effect.

(xlv)*No Unlawful Payments*. Neither the Company nor its subsidiary, nor, to the knowledge of the Company, any director, officer, agent, employee or other person acting on behalf of the Company or its subsidiary, has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, the Organization for Economic Co-operation and Development Convention on Bribery of Foreign Public Officials in International Business Transactions, and the rules and regulations thereunder and any other similar foreign or domestic law or regulation; or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment. The Company has instituted and maintains policies and procedures designed

to ensure continued compliance with the laws and regulations referenced in clause (iii) of this paragraph.

(xlvi)*Anti-Money Laundering Compliance*. The operations of the Company and its subsidiary are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any applicable related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the ***"Money Laundering Laws"***) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xlvii)*OFAC*.

(A)Neither the Company nor its subsidiary, nor any or their directors, officers or employees, nor, to the Company's knowledge, any agent, affiliate or representative of the Company or its subsidiary, is an individual or entity that is, or is owned or controlled by an individual or entity that is:

(1)the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, His Majesty's Treasury, or other relevant sanctions authority (collectively, "***Sanctions***"), nor

(2)located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Cuba, Iran, North Korea, Sudan, Syria and the Crimea region of Ukraine claimed by Russia).

(B)Neither the Company nor its subsidiary will, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity:

(1)to fund or facilitate any activities or business of or with any individual or entity or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(2)in any other manner that will result in a violation of Sanctions by any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(C)For the past five years, neither the Company nor its subsidiary has knowingly engaged in, and is not now knowingly engaged in, any dealings or transactions with any individual or entity, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(xlviii)*Not a Passive Foreign Investment Company*. Subject to the qualifications and assumptions set forth in the Registration Statement, the Company is not, and upon the sale of the Shares contemplated by this Agreement does not expect to become, a "passive foreign investment company" (as defined in Section 1297 of the Code, and the regulations promulgated thereunder).

(xlix)*No Taxes or Fees Due Upon Issuance*. No stamp, issue, registration, documentary, transfer or other similar taxes and duties, including interest and penalties, are payable on or in connection with the issuance and sale of the Shares by the Company or the execution and delivery of this Agreement.

(l)*No Immunity*. Neither the Company nor its subsidiary, nor any of their respective properties or assets, has any immunity from the jurisdiction of any court or from any legal process (whether through service or notice, attachment to prior judgment, attachment in aid of execution or otherwise) under the laws of any jurisdiction in which it is organized, headquartered or doing business.

(li)*No Legal, Accounting or Tax Advice*. The Company has not relied upon the Agent or legal counsel for the Agent for any legal, tax or accounting advice in connection with the offering and sale of the Shares.

(lii)*Certificate as Representation and Warranty*. Any certificate signed by any officer of the Company and delivered to the Agent or the Agent's counsel in connection with the offering of the Shares shall be deemed a representation and warranty by the Company to the Agent as to the matters covered thereby.

(liii)*Cybersecurity.* The Company and its subsidiary's information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "***IT Systems***") are adequate for, and operate and perform in all material respects as required in connection with the operation of the business of the Company and its subsidiary as currently conducted, free and clear of all material bugs, errors, defects, Trojan horses, time bombs, malware and other corruptants. The Company and its subsidiary have implemented and maintained commercially reasonable physical, technical and administrative controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and data, including "Personal Data," used in connection with their businesses. "***Personal Data***" means (i) a natural person's name, street address, telephone number, e-mail address, photograph, social security number or tax identification number, driver's license number, passport number, credit card number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "personal data" as defined by GDPR (as defined below); (iv) any information which would qualify as "protected health information" under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "***HIPAA***"); and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. There have been no breaches, violations,

outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and its subsidiary are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification.

(liv)*Compliance with Data Privacy Laws.* The Company and its subsidiary are, and at all prior times were, in material compliance with all applicable state and federal data privacy and security laws and regulations, including without limitation HIPAA, and the Company and its subsidiary have taken commercially reasonable actions to prepare to comply with, and since May 25, 2018, have been and currently are in compliance with, the European Union General Data Protection Regulation ("***GDPR***") (EU 2016/679) (collectively, the "***Privacy Laws***"). To ensure compliance with the Privacy Laws, the Company and its subsidiary have in place, comply with, and take appropriate steps reasonably designed to ensure compliance in all material respects with their policies and procedures relating to data privacy and security and the collection, storage, use, disclosure, handling, and analysis of Personal Data (the "***Policies***"). The Company and its subsidiary have at all times made all disclosures to users or customers required by applicable laws and regulatory rules or requirements, and none of such disclosures made or contained in any Policy have, to the knowledge of the Company, been inaccurate or in violation of any applicable laws and regulatory rules or requirements in any material respect. The Company further certifies that neither it nor any subsidiary: (i) has received notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposes any obligation or liability under any Privacy Law.

(lv)*eXtensible Business Reporting Language*. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(lvi)*No Shutdowns or Prohibitions*. The Company has not had any product, clinical laboratory or manufacturing site (whether Company-owned or, to the Company's knowledge, that of a third party manufacturer for the Company's products) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company's products, processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action.

(lvii)*No Safety Notices*. (i) Except as disclosed in the Registration Statement and the Prospectus, there have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company's products ("Safety Notices") and (ii) to the Company's knowledge, there are no facts that would be reasonably likely to result in (x) a Safety Notice with respect to the Company's products or services, (y) a change in labeling of any of the Company's respective products or services, or (z) a termination or suspension of marketing or testing of any of the Company's products or services.

2.Purchase, Sale and Delivery of Shares.

(a)*At-the-Market Sales.* On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell through the Agent as sales agent, and the Agent agrees to use its commercially reasonable efforts to sell for and on behalf of the Company, the Shares on the following terms and conditions; *provided*, *however*, that any obligation of the Agent to use such commercially reasonable efforts shall be subject to the continuing accuracy of the representations and warranties of the Company herein, the performance by the Company of its covenants and obligations hereunder and the continuing satisfaction of the additional conditions specified in Section 4 of this Agreement. The Company acknowledges and agrees that (i) there can be no assurance that the Agent will be successful in selling Shares, and (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Shares as required under this Section 2.

(i)Each time that the Company wishes to issue and sell the Shares hereunder (each, a ***"Placement"***), it will notify the Agent by email notice (or other method mutually agreed to in writing by the parties) (a ***"Placement Notice"***) containing the parameters in accordance with which it desires the Shares to be sold, which shall at a minimum include the number of shares of Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Shares that may be sold in any one Trading Day (as defined below) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 2 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 2, as such Schedule 2 may be amended from time to time. The Placement Notice shall be effective upon receipt by the Agent unless and until (i) in accordance with the notice requirements set forth in Section 2(a)(iii) of this Agreement, the Agent declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Shares subject to the Placement Notice or set forth on the Sales Prospectus have been sold, (iii) the Company suspends or terminates the Placement Notice in accordance with the notice requirements set forth in Section 2(a)(iii) below, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of Section 7. The amount of any commission or other compensation to be paid by the Company to the Agent in connection with

the sale of the Shares shall be calculated in accordance with the terms set forth in Section 2(a)(v) below. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of the Placement Notice, the terms of the Placement Notice will control. For the purposes hereof, ***"Trading Day"*** means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

(ii)The Shares are to be sold by the Agent on a daily basis or otherwise as shall be agreed to by the Company and the Agent on any day that is a Trading Day for the Exchange (other than a day on which the Exchange is scheduled to close prior to its regular weekday closing time). The gross sales price of the Shares sold under this Section 2(a) shall be the market price for the Company's Common Stock sold by the Agent under this Section 2(a) at the time of such sale.

(iii)Notwithstanding the foregoing, the Company may instruct the Agent by telephone (confirmed promptly by email) not to sell the Shares if such sales cannot be effected at or above the price designated by the Company in any such instruction. Furthermore, the Company shall not authorize the issuance and sale of, and the Agent shall not be obligated to use its commercially reasonable efforts to sell, any Share at a price lower than the minimum price therefor designated from time to time by the Company's board of directors and notified to the Agent in writing. In addition, the Company or the Agent may, upon notice to the other party hereto by telephone (confirmed promptly by email), suspend the offering of the Shares, whereupon the Agent shall so suspend the offering of Shares until further notice is provided to the other party to the contrary; *provided*, *however*, that such suspension or termination shall not affect or impair the parties' respective obligations with respect to the Shares sold hereunder prior to the giving of such notice. Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and the Agent agree that (i) no sale of Shares will take place, (ii) the Company shall not request the sale of any Shares, and (iii) the Agent shall not be obligated to sell or offer to sell any Shares.

(iv)Subject to the terms of the Placement Notice, the Agent may sell the Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) under the Securities Act, including sales made directly on or through the Exchange. Subject to the terms of any Placement Notice, the Agent may also sell Shares in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law, subject to the prior written consent of the Company.

(v)The compensation to the Agent for sales of the Shares, as an agent of the Company, shall be up to 3.0% of the gross sales price of the Shares sold pursuant to this Section 2(a), payable in cash (the ***"Sales Commission"***); *provided that* the combined Sales Commission and reimbursement of the Agent for its out-of-pocket expenses pursuant to Section 3(g), including the reasonable and documented fees and disbursements of the Agent's counsel, shall not exceed 8.0% of the gross sales price of the Shares. The remaining proceeds, after

further deduction for any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales, and reimbursement of expenses that the Agent may be entitled to pursuant to Section 3(g), shall constitute the net proceeds to the Company for such Shares (the "***Net Proceeds***").

(vi)The Agent will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on Schedule 2), no later than the opening of the Trading Day immediately following the Trading Day on which it has made sales of Shares hereunder, setting forth the number of Shares sold on such day, the volume-weighted average price of the Shares sold, and the Net Proceeds payable to the Company.

(vii)All Shares sold pursuant to this Section 2(a) will be delivered by the Company to the Agent for the account of the Agent, against payment of the Net Proceeds therefor, by wire transfer of same-day funds payable to the order of the Company at the offices of Guggenheim Securities, LLC, 330 Madison Avenue, New York, NY 10017, fax no. 212-658-9689, or such other location as may be mutually acceptable, at 9:00 a.m. New York City time on the second full business day following the date on which such Shares are sold, or at such other time and date as the Agent and the Company determine pursuant to Rule 15c6-1(a) under the Exchange Act, each such time and date of delivery being herein referred to as a "***Settlement Date***." If the Agent so elects, delivery of the Shares may be made by credit through full fast transfer to an account or accounts at The Depository Trust Company designated by the Agent. On each Settlement Date, the Agent will deliver the Net Proceeds in same day funds to an account designated by the Company on, or prior to, such Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to timely deliver duly authorized Shares on a Settlement Date, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 5 hereto, it will (i) hold the Agent harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company, (ii) reimburse the Agent for any losses incurred by the Agent attributable, directly or indirectly, to such default and (iii) pay to the Agent any commission or other compensation to which the Agent would otherwise have been entitled absent such default.

(b)*Maximum Amount*. Under no circumstances shall the aggregate number or aggregate value of the Shares sold pursuant to this Agreement exceed: (i) the aggregate number and aggregate dollar amount of shares of Common Stock available for issuance under the currently effective Registration Statement, (ii) the aggregate number of authorized but unissued shares of Common Stock that are available for issuance under the Company's certificate of incorporation or certificate of designation, (iii) the aggregate dollar amount of shares of Common Stock permitted to be sold under the Company's effective Registration Statement (including any limit set forth in General Instruction I.B.6 thereof, if applicable) or (iv) the aggregate number or aggregate dollar amount of shares of Common Stock for which the Company has filed any Sales Prospectus in connection with the Shares (the lesser of (i), (ii), (iii) and (iv), the *"**Maximum Amount***").

(c)*No Association or Partnership*. Nothing herein contained shall constitute the Agent as an unincorporated association or partner with the Company.

(d)*Duration*. Under no circumstances shall any Shares be sold pursuant to this Agreement after the date which is three years after the Registration Statement is first declared effective by the Commission.

(e)*Market Transactions by Agent*. The Company acknowledges and agrees that the Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act, the Exchange Act and this Agreement, purchase and sell shares of Common Stock for its own account while this Agreement is in effect, *provided, that* (i) no sale for its own account shall take place while a Placement Notice is in effect (except to the extent the Agent may engage in sales of Shares purchased or deemed purchased from the Company as a "riskless principal" or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent. The Company consents to the Agent trading in the Common Stock for the account of any of its clients at the same time as sales of the Shares occur pursuant to this Agreement.

3.Covenants of the Company. The Company covenants and agrees with the Agent as follows:

(a)*Amendments to Registration Statement and Prospectus*. After the date of this Agreement and during any period in which a Prospectus relating to any Shares is required to be delivered by the Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company agrees that it will: (i) notify the Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference or amendments not related to the Shares, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus related to the Shares has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement (insofar as it relates to the transactions contemplated hereby) or Prospectus or for additional information; (ii) prepare and file with the Commission, promptly upon the Agent's request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agent's reasonable opinion, may be necessary or advisable in connection with the sale of the Shares by the Agent (*provided, however*, that the failure of the Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement); (iii) not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Shares or a security convertible into the Shares unless a copy thereof has been submitted to the Agent within a reasonable period of time before the filing and the Agent has not reasonably objected thereto (*provided, however*, that (A) the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement), (B) the Company has no obligation to provide the Agent any advance copy of such filing or to provide the Agent an opportunity to object to such filing if the filing does not name the Agent or does not relate to a Placement or other transaction contemplated hereunder, and (C) the only remedy that the Agent shall have with respect to the failure by the Company to provide the Agent with such copy or the filing of such amendment or supplement despite the Agent's objection shall be to cease making sales under this Agreement; (iv) not file any new Registration Statement or new Prospectus relating to the Shares or a security convertible into the Shares

without the prior written consent of the Agent; (v) furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (vi) cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act.

(b)*Stop Order*. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose, and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c)*Continuing Amendments*. During any period in which a Prospectus relating to the Shares is required to be delivered by the Agent under the Securities Act with respect to any Placement or pending sale of the Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports (taking into account any extensions available under the Exchange Act) and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(d)*Qualification of the Shares*. The Company shall take or cause to be taken all necessary action to qualify the Shares for sale under the securities laws of such jurisdictions as the Agent reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Shares, except that the Company shall not be required in connection therewith to qualify as a foreign corporation or to execute a general consent to service of process in any state. The Company shall promptly advise the Agent of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for offer or sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose.

(e)*Copies of Registration Statement and Prospectus*. The Company will furnish to the Agent and counsel for the Agent copies of the Registration Statement (which will include three complete manually signed copies of the Registration Statement and all consents and exhibits filed therewith), the Prospectus and all amendments and supplements to such

documents, in each case as soon as available and in such quantities as the Agent may from time to time reasonably request; provided, however, that the Company's obligations to provide such copies shall not apply to any filing available via EDGAR.

(f)*Section 11(a)*. The Company will make generally available to its security holders as soon as practicable an earnings statement (which need not be audited) covering a 12-month period that shall satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 promulgated thereunder.

(g)*Expenses*. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, will pay or cause to be paid (i) all expenses (including stock or transfer taxes and stamp or similar duties allocated to the respective transferees) incurred in connection with the registration, issue, sale and delivery of the Shares, (ii) all expenses and fees (including, without limitation, fees and expenses of the Company's accountants and counsel) in connection with the preparation, printing, filing, delivery, and shipping of the Registration Statement (including the financial statements therein and all amendments, schedules, and exhibits thereto), the Shares, the Prospectus and any amendment thereof or supplement thereto, and the producing, word-processing, printing, delivery, and shipping of this Agreement and other transaction documents or closing documents, including Blue Sky Memoranda (covering the states and other applicable jurisdictions) and including the cost to furnish copies of each thereof to the Agent, (iii) all filing fees, (iv) all fees and disbursements of the Agent's counsel incurred in connection with the qualification of the Shares for offering and sale by the Agent or by dealers under the securities or blue sky laws of the states and other jurisdictions which the Agent shall designate, (v) the fees and expenses of any transfer agent or registrar, (vi) the filing fees and reasonable, actual and documented fees and disbursements of the Agent's counsel incident to any required review and approval by FINRA of the terms of the sale of the Shares, (vii) listing fees, if any, (viii) the cost and expenses of the Company relating to investor presentations or any "roadshow" undertaken in connection with marketing of the Shares, and (ix) all other costs and expenses incident to the performance of its obligations hereunder that are not otherwise specifically provided for herein. In addition to (iv) and (vi) above, the Company shall reimburse the Agent for the out-of-pocket reasonable and documented expenses, including reasonable fees and disbursements of the Agent's counsel (actually incurred in an amount which, taken together with the fees and disbursements of Agent's counsel incurred pursuant to (iv) and (vi) above do not exceed $50,000).

(h)*Use of Proceeds*. The Company will apply the net proceeds from the sale of the Shares in the manner disclosed in the Prospectus.

(i)*Restrictions on Future Sales*. During the period beginning on the third Trading Day immediately prior to the date on which any Placement Notice is delivered to the Agent hereunder and ending on the third Trading Day immediately following the earlier of (x) the Settlement Date with respect to Shares sold pursuant to such Placement Notice and (y) the termination or suspension by the Company of such Placement Notice, the Company will not, without the prior written consent of the Agent, offer for sale, sell, contract to sell, pledge, grant any option for the sale of, enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition of Common Stock (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any

affiliate, or otherwise issue or dispose of, directly or indirectly (or publicly disclose the intention to make any such offer, sale, pledge, grant, issuance or other disposition), any Common Stock or any securities convertible into or exchangeable for, or any options or rights to purchase or acquire, Common Stock, or permit the registration under the Securities Act of any Common Stock, such securities, options or rights, except for: (i) the registration of the Shares and the sales through the Agent pursuant to this Agreement, (ii) sales of shares through any dividend reinvestment and stock purchase plan of the Company, (iii) sales of shares of restricted stock, restricted stock units and options granted pursuant to employee benefit plans existing as of the date hereof, and the Common Stock issuable upon the exercise of such outstanding options or vesting of such restricted stock units, (iv) grants made pursuant to Nasdaq Listing Rule 5635(c)(4), (v) the issuance of shares pursuant to the exercise of warrants, options or other derivative securities, (vi) the filing of registration statements on Form S-8, and (vii) the filing of a registration statement pursuant to any registration rights granted prior to the date hereof as disclosed in the Registration Statement.

(j)*No Stabilization or Manipulation*. The Company has not taken and will not take, directly or indirectly, any action designed to, or which might reasonably be expected to cause or result in, or which constitutes: (i) the stabilization or manipulation of the price of the Common Stock or any other security of the Company to facilitate the sale or resale of the Shares, (ii) a violation of Regulation M. The Company shall notify the Agent of any violation of Regulation M by the Company or its subsidiary or any of their respective officers or directors promptly after the Company has received notice or obtained knowledge of any such violation. The Company shall not invest in futures contracts, options on futures contracts or options on commodities, unless the Company is exempt from the registration requirements of the Commodity Exchange Act, as amended (the ***"Commodity Act"***), or otherwise complies with the Commodity Act. The Company will not engage in any activities bearing on the Commodity Act, unless such activities are exempt from the Commodity Act or otherwise comply with the Commodity Act.

(k)*No Other Broker*. Except as contemplated by this Agreement, the Company will not incur any liability for any finder's or broker's fee or agent's commission in connection with the execution and delivery of this Agreement, or the consummation of the transactions contemplated hereby.

(l)*Timely Securities Act and Exchange Act Reports*. During any prospectus delivery period, the Company will use its commercially reasonable efforts to file on a timely basis with the Commission such periodic and special reports as required by the Securities Act and the Exchange Act.

(m)*Internal Controls*. The Company and its subsidiary will maintain such controls and other procedures, including without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act and the applicable regulations thereunder, that are designed to provide reasonable assurances that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is

accumulated and communicated to the Company's management, including its principal executive officer and its principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, to ensure that material information relating to Company, including its subsidiary, is made known to them by others within those entities.

(n)*Permitted Free Writing Prospectus*. The Company represents and agrees that, unless it obtains the prior written consent of the Agent, and the Agent severally represents and agrees that, unless it obtains the prior written consent of the Company, it has not made and will not make any offer relating to the Shares that would constitute an "issuer free writing prospectus," as defined in Rule 433 under the Securities Act, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405 under the Securities Act, required to be filed with the Commission. Any such free writing prospectus consented to by the Company and the Agent is hereinafter referred to as a ***"Permitted Free Writing Prospectus."*** The Company represents that it has treated or agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely Commission filing where required, legending and record keeping.

(o)*Representation Date and Opinions of Counsel*. On or prior to the date of the first Placement Notice, and thereafter during the term of this Agreement, each time the Company (A) files an amendment to the Registration Statement or Prospectus (other than relating solely to the offering of securities other than the Shares), (B) files an Annual Report on Form 10-K under the Exchange Act or files its Quarterly Reports on Form 10-Q under the Exchange Act; and (C) files a report on Form 8-K containing amended financial statements (other than an earnings release) under the Exchange Act, (each of the dates in (A), (B) and (C) are referred to herein as a "***Representation Date***"), the Company shall cause:

(i)Goodwin Procter LLP, counsel for the Company, to furnish to the Agent the opinion and negative assurance letter of such counsel, dated as of such date and addressed to the Agent, in form and substance reasonably satisfactory to the Agent; provided however, the opinion of such counsel shall be required only prior to the date of the first Placement Notice and only a negative assurance letter of such counsel shall be required for each Representation Date.

(ii)McCarter & English, LLP, intellectual property and patent counsel for the Company, to furnish to the Agent the opinion of such counsel, dated as of such date and addressed to the Agent, in form and substance reasonably satisfactory to the Agent; provided however, the opinion of counsel shall only be required for the first Settlement Date.

Notwithstanding the foregoing and Sections 3(p), 3(q) and 3(v) hereof, the requirement to provide counsel opinions, a comfort letter, certificates and documents under this Section 3 shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the date the Company delivers a Placement Notice to the Agent. Notwithstanding the foregoing, if the Company subsequently decides to sell Shares following a Representation Date when the Company relied on such waiver and did not provide the Agent with the opinions, comfort letter, certificates and documents under this Section 3, then

before the Agent sells any Shares pursuant to Section 2(a), the Company shall cause the opinions (including the opinion pursuant to Section 3(o) if not delivered on the date of the prior Form 10-K), comfort letter, certificates and documents that would be delivered on a Representation Date to be delivered.

(p)*Representation Date and Comfort Letter*. On or prior to the date of the first Placement Notice and thereafter during the term of this Agreement, on each Representation Date to which a waiver does not apply, the Company shall cause PricewaterhouseCoopers LLP, or other independent accountants reasonably satisfactory to the Agent (the "***Accountants***"), to deliver to the Agent a letter, dated as of such date and addressed to the Agent, confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualifications of accountants under Rule 2-01 of Regulation S-X of the Commission, and stating the conclusions and findings of said firm with respect to the financial information and other matters covered by its letter in form and substance satisfactory to the Agent of the same tenor as the first such letter received hereunder.

(q)*Representation Date and Representation Certificate*. On or prior to the date of the First Placement Notice and thereafter during the term of this Agreement, on each Representation Date to which a waiver does not apply, the Company shall furnish to the Agent a certificate (the ***"Representation Certificate"***), substantially in the form of Schedule 3 hereto and dated as of such date, addressed to the Agent and signed by the chief executive officer and by the chief financial officer of the Company.

(r)*Disclosure of Shares Sold*. The Company shall disclose in its Quarterly Reports on Form 10-Q and in its Annual Report on Form 10-K the number of the Shares sold through the Agent under this Agreement, the net proceeds to the Company and the compensation paid by the Company with respect to sales of the Shares pursuant to this Agreement during the relevant quarter.

(s)*Continued Listing of Shares*. The Company shall use its commercially reasonable efforts to maintain the listing of the Common Stock on the Exchange.

(t)*Notice of Changes*. At any time during the term of this Agreement, as supplemented from time to time, the Company shall advise the Agent as soon as practicable after it shall have received notice or obtain knowledge thereof, of any information or fact that would alter or affect any opinion, certificate, letter and other document provided to the Agent pursuant to this Section 3.

(u)*Maximum Amount*. The Company will not instruct the Agent to sell or otherwise attempt to sell Shares pursuant to this Agreement in excess of the Maximum Amount.

4.Conditions of Agent's Obligations. The obligations of the Agent hereunder are subject to (i) the accuracy, as of the date of this Agreement, each Representation Date, each Notice Date, each Applicable Time, and each Settlement Date (in each case, as if made at such date) of and compliance with all representations, warranties and agreements of the Company contained herein, (ii) the performance by the Company of its obligations hereunder and (iii) the following additional conditions:

(a)*Continuing Amendments; No Stop Order*. If filing of the Prospectus, or any amendment or supplement thereto, or any Permitted Free Writing Prospectus, is required under the Securities Act, the Company shall have filed the Prospectus (or such amendment or supplement) or such Permitted Free Writing Prospectus with the Commission in the manner and within the time period so required (without reliance on Rule 424(b)(8) or Rule 164(b) under the Securities Act); the Registration Statement shall be effective; no stop order suspending the effectiveness of the Registration Statement or any part thereof, any registration statement filed pursuant to Rule 462(b) under the Securities Act, or any amendment thereof, nor suspending or preventing the use of the Prospectus shall have been issued; no proceedings for the issuance of such an order shall have been initiated or threatened; and any request of the Commission for additional information (to be included in the Registration Statement, the Prospectus or otherwise) shall have been complied with to the Agent's satisfaction.

(b)*Absence of Certain Events*. None of the following events shall have occurred and be continuing: (i) receipt by the Company or its subsidiary of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c)*No Material Misstatement or Omission*. The Agent shall not have advised the Company that the Registration Statement or the Prospectus, contains an untrue statement of fact which, in the Agent's opinion, is material, or omits to state a fact which, in the Agent's opinion, is material and is required to be stated therein or necessary to make the statements therein not misleading.

(d)*No Adverse Changes*. Except as disclosed in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus, neither the Company nor its subsidiary shall have incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock; and there shall not have been any material change in the capital stock (other than a change in the number of outstanding shares of Common Stock due to the issuance of shares of Common Stock upon the exercise of outstanding

options or warrants), or any material change in the short-term or long-term debt of the Company, or any issuance of options, warrants, convertible securities or other rights to purchase the capital stock of the Company or its subsidiary, or any development involving a prospective Material Adverse Effect (whether or not arising in the ordinary course of business), or any loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, incurred by the Company or its subsidiary, the effect of which, in any such case described above, in the Agent's judgment, makes it impractical or inadvisable to offer or deliver the Shares on the terms and in the manner contemplated in the Prospectus.

(e)*No Rating Downgrade*. On or after each Applicable Time (i) no downgrading shall have occurred in the rating accorded any of the Company's securities by any "nationally recognized statistical organization," as that term is defined by the Commission for purposes of Rule 436(g)(2) under the Securities Act, and (ii) no such organization shall have publicly announced that it has under surveillance or review, with possible negative implications, its rating of any of the Company's securities.

(f)*Compliance with Certain Obligations*. The Company shall have performed each of its obligations under Sections 3(o) – 3(q) and Section 3(v).

(g)*Opinion of Agent Counsel*. On each Representation Date to which a waiver does not apply, there shall have been furnished to the Agent the opinion and negative assurance letter of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Agent, dated as of such Representation Date and addressed to the Agent, in a form reasonably satisfactory to the Agent, and such counsel shall have received such papers and information as they request to enable them to pass upon such matters; provided however, the opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. shall only be required prior to the first Placement Notice, and thereafter, only a negative assurance letter of such counsel shall be required for each subsequent Representation Date.

(h)*Representation Certificate*. On or prior to the first Placement Notice, the Agent shall have received the Representation Certificate substantially in the form of Schedule 3 hereto.

(i)*No Objection by FINRA*. FINRA shall have raised no objection to the fairness and reasonableness of the compensation terms and arrangements.

(j)*Timely Filing of Prospectus*. All filings with the Commission required by Rule 424 under the Securities Act to have been filed by the Settlement Date, as the case may be, shall have been made within the applicable time period prescribed for such filing by Rule 424 under the Securities Act.

(k)*Additional Documents and Certificates*. The Company shall have furnished to the Agent and the Agent's counsel such additional documents, certificates and evidence as they may have reasonably requested.

All opinions, certificates, letters and other documents described in this Section 4 will be in compliance with the provisions hereof only if they are reasonably satisfactory in form and substance to the Agent and the Agent's counsel. The Company will furnish the Agent with such

conformed copies of such opinions, certificates, letters and other documents as the Agent shall reasonably request.

5.Indemnification and Contribution.

(a)*Company Indemnification*. The Company agrees to indemnify and hold harmless the Agent, its affiliates, and their respective directors, officers, agents and employees, and each person, if any, who controls the Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any losses, claims, damages or liabilities, joint or several, to which the Agent may become subject, under the Securities Act or otherwise (including in settlement of any litigation), insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon, in whole or in part:

(i)an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including the Rule 430B Information (as defined below) and at any subsequent time pursuant to Rules 430A and 430B promulgated under the Securities Act, and any other information deemed to be part of the Registration Statement at the time of effectiveness, and at any subsequent time pursuant to the Securities Act or the Exchange Act, and the Prospectus, or any amendment or supplement thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference into the Prospectus), any Permitted Free Writing Prospectus, or any roadshow as defined in Rule 433(h) under the Securities Act (a ***"road show"***), or an omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading,

(ii)any inaccuracy in the representations and warranties of the Company contained herein;

(iii)any investigation or proceeding by any governmental authority, commenced or threatened (whether or not the Agent is a target of or party to such investigation or proceeding); or

(iv)any failure of the Company to perform its respective obligations hereunder or under law;

and will reimburse the Agent for any legal or other expenses reasonably incurred by it in connection with investigating or defending against such loss, claim, damage, liability or action; *provided, however,* that the Company shall not be liable in any such case of (i) through (iv) to the extent that any such loss, claim, damage, liability or action arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Prospectus, or any such amendment or supplement, in reliance upon and in conformity with written information furnished to the Company by the Agent specifically for use in the preparation thereof. "***Rule 430B Information***," as used herein, means information with respect to the Shares and the offering thereof permitted to be omitted from the Registration Statement when it becomes effective pursuant to Rule 430B.

In addition to its other obligations under this Section 5(a), the Company agrees that, as an interim measure during the pendency of any claim, action, investigation, inquiry or other proceeding arising out of or based upon any statement or omission, or any alleged statement or

omission, described in this Section 5(a), it will reimburse the Agent on a monthly basis for all reasonable, actual and documented legal fees or other expenses incurred in connection with investigating or defending any such claim, action, investigation, inquiry or other proceeding, notwithstanding the absence of a judicial determination as to the propriety and enforceability of the Company's obligation to reimburse the Agent for such expenses and the possibility that such payments might later be held to have been improper by a court of competent jurisdiction. Any such interim reimbursement payments which are not made to the Agent within 30 days of a request for reimbursement shall bear interest at the WSJ Prime Rate (as published from time to time by the Wall Street Journal).

(b)*Agent Indemnification*. The Agent will indemnify and hold harmless the Company against any losses, claims, damages or liabilities to which the Company may become subject, under the Securities Act or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Agent), but only insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Prospectus, any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in conformity with written information furnished to the Company by the Agent specifically for use in the preparation thereof, it being understood and agreed that the only information furnished by the Agent for use in the Registration Statement or the Prospectus consists of the statements set forth in the seventh and ninth paragraphs under the caption "Plan of Distribution" in the Prospectus, and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending against any such loss, claim, damage, liability or action.

(c)*Notice and Procedures*. Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof; but the omission so to notify the indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party except to the extent such indemnifying party has been materially prejudiced by such failure. In case any such action shall be brought against any indemnified party, and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of the indemnifying party's election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation; *provided*, *however*, that if, in the sole judgment of the Agent, it is advisable for the Agent to be represented by separate counsel, the Agent shall have the right to employ a single counsel to represent the Agent, in which event the reasonable fees and expenses of such separate

counsel shall be borne by the indemnifying party or parties and reimbursed to the Agent as incurred (in accordance with the provisions of the second paragraph in subsection (a) above).

The indemnifying party under this Section 5 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by this Section 5, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into, and (iii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent (a) includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and (b) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d)*Contribution; Limitations on Liability; Non-Exclusive Remedy*. If the indemnification provided for in this Section 5 is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other from the offering of the Shares, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Agent on the other in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Agent on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total commissions received by the Agent (before deducting expenses) from the sale of the Shares. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this subsection (d) were to be determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this subsection (d). The amount paid or payable by an indemnified party as a result

of the losses, claims, damages or liabilities referred to in this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending against any action or claim which is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

6.Representations and Agreements to Survive Delivery. All representations, warranties, and agreements of the Company herein or in certificates delivered pursuant hereto, including but not limited to the agreements of the Agent and the Company contained in Section 5 hereof, shall remain operative and in full force and effect regardless of any investigation made by or on behalf of the Agent or any controlling person thereof, or the Company or any of its officers, directors, or controlling persons, and shall survive delivery of, and payment for, the Shares to and by the Agent hereunder.

7.Termination of this Agreement.

(a)The Company shall have the right, by giving ten (10) days' written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that (i) with respect to any pending sale, through the Agent for the Company, the obligations of the Company, including in respect of compensation of the Agent, shall remain in full force and effect notwithstanding the termination and (ii) the provisions of Section 3(g), Section 5 and Section 6 of this Agreement shall remain in full force and effect notwithstanding such termination.

(b)The Agent shall have the right, by giving written notice as hereinafter specified, to terminate the provisions of this Agreement relating to the solicitation of offers to purchase the Shares in its sole discretion at any time. Any such termination shall be without liability of any party to any other party except that the provisions of Section 3(g), Section 5 and Section 6 of this Agreement shall remain in full force and effect notwithstanding such termination.

(c)Unless earlier terminated pursuant to this Section 7, this Agreement shall automatically terminate upon issuance and sale of all of the Shares through the Agent on the terms and subject to the conditions set forth herein, except that the provisions of Section 3(g), Section 5 and Section 6 of this Agreement shall remain in full force and effect notwithstanding such termination.

(d)This Agreement shall remain in full force and effect unless terminated pursuant to Sections 7(a), (b) or (c) above or otherwise by mutual agreement of the parties; provided that any such termination by mutual agreement shall in all cases be deemed to provide that Section 3(g), Section 5 and Section 6 shall remain in full force and effect.

(e)Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of the Shares, such sale shall settle in accordance with the provisions of Section 2(a)(vii) of this Agreement.

8.Default by the Company. If the Company shall fail at any Settlement Date to sell and deliver the number of Shares which it is obligated to sell hereunder, then this Agreement shall terminate without any liability on the part of the Agent or, except as provided in Section 3(g) hereof, any non-defaulting party. No action taken pursuant to this Section shall relieve the Company from liability, if any, in respect of such default, and the Company shall (A) hold the Agent harmless against any loss, claim or damage arising from or as a result of such default by the Company and (B) pay the Agent any commission to which it would otherwise be entitled absent such default.

9.Notices. Except as otherwise provided herein, all communications under this Agreement shall be in writing and, if to the Agent, shall be delivered via overnight delivery services to (i) Guggenheim Securities, LLC, 330 Madison Avenue, New York, NY 10017, fax no. 212-658-9689, Attention: Head of Equity Capital Markets, with a copy to Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., One Financial Center, Boston, Massachusetts 02111, Attention: William Hicks, Esq.; and (ii) the Company at Larimar Therapeutics, Inc. Three Bala Plaza East, Suite 506, Bala Cynwyd, PA 19004, Attention: Chief Financial Officer, with a copy to its counsel at Goodwin Procter LLP, One Commerce Square, 2005 Market Street, 32nd Floor, Philadelphia, PA 19103, Attention: Rachael Bushey, Esq. and Jennifer Porter, Esq.; or in each case to such other address as the person to be notified may have requested in writing. Any party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose.

10.Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns and the controlling persons, officers and directors referred to in Section 5. Nothing in this Agreement is intended or shall be construed to give to any other person, firm or corporation any legal or equitable remedy or claim under or in respect of this Agreement or any provision herein contained. The term “successors and assigns” as herein used shall not include any purchaser, as such purchaser, of any of the Shares from the Agent.

11.Absence of Fiduciary Relationship. The Company, having been advised by counsel, acknowledges and agrees that: (a) the Agent has been retained solely to act as a sales agent in connection with the sale of the Shares and that no fiduciary, advisory or agency relationship between the Company (including any of the Company’s affiliates (including directors), equity holders, creditors, employees or agents, hereafter, ***“Company Representatives”***), on the one hand, and the Agent on the other, has been created or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Agent has advised or is advising the Company on other matters and irrespective of the use of the defined term “Agent;” (b) neither the Agent nor any of its affiliates (including directors), equity holders, creditors, employees or agents, hereafter, ***“Agent Representatives”***) shall have any duty or obligation to the Company or any Company Representative except as set

forth in this Agreement; (c) the price and other terms of any Placement executed pursuant to this Agreement, as well as the terms of this Agreement, are deemed acceptable to the Company and its counsel, following discussions and arms-length negotiations with the Agent; (d) the Company is capable of evaluating and understanding, and in fact has evaluated, understands and accepts the terms, risks and conditions of any Placement Notice to be executed pursuant to this Agreement, and any other transactions contemplated by this Agreement; (e) the Company has been advised that the Agent and the Agent Representatives are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Agent and the Agent Representatives have no obligation to disclose any such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship, or otherwise; (f) the Company has been advised that the Agent is acting, in respect of any Placement and the transactions contemplated by this Agreement, solely for the benefit of the Agent, and not on behalf of the Company; and (g) the Company and the Company Representatives waive, to the fullest extent permitted by law, any claims that they may have against the Agent or any of the Agent Representatives for breach of fiduciary duty or alleged breach of fiduciary duty in respect of any Placement or any of the transactions contemplated by this Agreement and agree that the Agent and the Agent Representatives shall have no liability (whether direct or indirect, in contract, tort or otherwise) to the Company or any of the Company Representatives in respect of any person asserting any claim of breach of any fiduciary duty on behalf of or in right of the Company or any of the Company Representatives.

12.Recognition of the U.S. Special Resolution Regimes.

(a)In the event that the Agent qualifies as a Covered Entity and becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from the Agent of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b)In the event that the Agent qualifies as a Covered Entity and becomes subject, or a BHC Act Affiliate of the Agent becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against the Agent are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

(c)As used in this section:

"***BHC Act Affiliate***" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k);

"***Covered Entity***" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b);

"***Default Right***" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and

"***U.S. Special Resolution Regime***" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

13.Governing Law and Waiver of Jury Trial. This Agreement and any transaction contemplated by this Agreement and any claim, controversy or dispute arising under or related thereto shall be governed by and construed in accordance with the laws of the State of New York without regard to principles of conflict of laws that would results in the application of any other law than the laws of the State of New York. THE COMPANY (ON ITS OWN BEHALF AND ON BEHALF OF ITS STOCKHOLDERS AND AFFILIATES) HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

14.Submission to Jurisdiction, Etc. Each party hereby submits to the exclusive jurisdiction of the U.S. federal and New York state courts sitting in the Borough of Manhattan, City of New York, in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. The parties hereby irrevocably and unconditionally waive any objection to the laying of venue of any lawsuit, action or other proceeding in such courts, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such lawsuit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

15.Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

16.Construction. The section and exhibit headings herein are for convenience only and shall not affect the construction hereof. References herein to any law, statute, ordinance, code, regulation, rule or other requirement of any governmental authority shall be deemed to refer to such law, statute, ordinance, code, regulation, rule or other requirement of any governmental authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules and regulations promulgated thereunder.

[Signature Pages Follow]

Please sign and return to the Company the enclosed duplicates of this letter whereupon this letter will become a binding agreement between the Company and the Agent in accordance with its terms.

Very truly yours,

LARIMAR THERAPEUTICS, INC.

By: /s/ Michael Celano
Name: Michael Celano
Title: Chief Financial Officer

Confirmed as of the date first above mentioned.

GUGGENHEIM SECURITIES, LLC

By: /s/ Jordan Bliss
Name: Jordan Bliss
Title: Senior Managing Director

SCHEDULE 1

FORM OF PLACEMENT NOTICE

SCHEDULE 2

NOTICE PARTIES

Company:

Carole Ben-Maimon, M.D.
Michael Celano

Guggenheim Securities, LLC:

Jordan Bliss
Eric Guzman
James Lee
Michael Jiang
Marguerite O'Brien

SCHEDULE 3

FORM OF REPRESENTATION CERTIFICATE

PURSUANT TO SECTION 3(Q) OF THE AGREEMENT

[Date]

Guggenheim Securities, LLC
330 Madison Avenue
New York, New York 10017

Sir:

The undersigned, the duly qualified and elected Chief Executive Officer and the duly qualified and elected Chief Financial Officer of Larimar Therapeutics, Inc., a Delaware corporation (the "**Company**"), do each hereby certify in such capacity, and not in their individual capacities, and on behalf of the Company, pursuant to Section 3(q) of the Sales Agreement, dated May 9, 2024 (the "**Sales Agreement**"), between the Company and Guggenheim Securities, LLC, that to the best of the knowledge of each the undersigned:

(i) The representations and warranties of the Company in this Sales Agreement are true and correct, in all material respects, as if made at and as of the date of the certificate, and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the date of the certificate;

(ii) No stop order or other order suspending the effectiveness of the Registration Statement or any part thereof or any amendment thereof or the qualification of the Shares for Registration Statement, nor suspending or preventing the use of the base prospectus, the Prospectus or any Permitted Free Writing Prospectus, has been issued, and no proceeding for that purpose has been instituted or, to the best of the Company's knowledge, is contemplated by the Commission or any state or regulatory body;

(iii) The Shares have been duly and validly authorized by the Company and that all corporate action required to be taken for the authorization, issuance and sale of the Shares has been validly and sufficiently taken;

(iv) The signers of this certificate have carefully examined the Registration Statement, the base prospectus, the Prospectus and any Permitted Free Writing Prospectus, and any amendments thereof or supplements thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference into the base prospectus, the Prospectus and any Permitted Free Writing Prospectus),

(A) each part of the Registration Statement and the Prospectus, and any amendments thereof or supplements thereto (including any documents filed under the Exchange Act and deemed to be incorporated by reference into the Prospectus) contain, and contained when such part of the Registration Statement (or such amendment) became effective, all statements and information required to be included therein, each part of the Registration

Statement, or any amendment thereof, does not contain, and did not contain, when such part of the Registration Statement (or such amendment) became effective, any untrue statement of a material fact or omit to state, and did not omit to state when such part of the Registration Statement (or such amendment) became effective, any material fact required to be stated therein or necessary to make the statements therein not misleading, and the Prospectus, as amended or supplemented, does not include and did not include as of its date, or the time of first use within the meaning of the Securities Act, any untrue statement of a material fact or omit to state and did not omit to state as of its date, or the time of first use within the meaning of the Securities Act, a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading,

(B) at no time during the period that begins on the earlier of the date of such base prospectus, Prospectus, or Permitted Free Writing Prospectus and the date such base prospectus, Prospectus, or Permitted Free Writing Prospectus was filed with the Commission and ends on the date of this certificate did such base prospectus, Prospectus, or Permitted Free Writing Prospectus, as then amended or supplemented, include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading,

(C) since the date of the Sales Agreement, there has occurred no event required to be set forth in an amended or supplemented prospectus which has not been so set forth, and there has been no document required to be filed under the Exchange Act that upon such filing would be deemed to be incorporated by reference into the base prospectus, the Prospectus or any Permitted Free Writing Prospectus that has not been so filed,

(D) except as stated in the Prospectus or any Permitted Free Writing Prospectus, the Company has not incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions, not in the ordinary course of business, or declared or paid any dividends or made any distribution of any kind with respect to its capital stock, and except as disclosed in the base prospectus, the Prospectus, and any Permitted Free Writing Prospectus, there has not been any material change in the capital stock (other than a change in the number of outstanding Common Stock due to sales of Shares pursuant to the Sales Agreement and the issuance of shares of Common Stock upon the exercise of equity awards or warrants), or any material change in the short term or long term debt, or any Material Adverse Effect or any development involving a prospective Material Adverse Effect (whether or not arising in the ordinary course of business), or any loss by strike, fire, flood, earthquake, accident or other calamity, whether or not covered by insurance, incurred by the Company, and

(E) except as stated in the base prospectus, the Prospectus, and any Permitted Free Writing Prospectus, there is not pending, or, to the knowledge of the Company, threatened or contemplated, any action, suit or proceeding to which the Company is a party before or by any court or governmental agency, authority or body, or any arbitrator, which might result in a Material Adverse Effect.

Capitalized terms used herein without definition shall have the meanings given to such terms in the Sales Agreement.

LARIMAR THERAPEUTICS, INC.

By: _
Name: _
Title: _

By: _
Name: _
Title: _

SCHEDULE 4

SUBSIDIARIES

Zafgen Australia Pty Limited

Exhibit 31.1

CERTIFICATION

I, Carole S. Ben-Maimon, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Larimar Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

1. 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;

2. 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;

3. 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

4. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

1. 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

2. 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 9, 2024

/s/ Carole S. Ben-Maimon, M.D.

Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Michael Celano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Larimar Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

1. 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;

2. 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;

3. 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

4. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

1. 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

2. 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 9, 2024

/s/ Michael Celano

Michael Celano
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

CERTIFICATION
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Larimar Therapeutics, Inc. (the "Company"), does hereby certify, to the best of such officer's knowledge, that:

(1)The Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 9, 2024

/s/ Carole S. Ben-Maimon, M.D.
Carole S. Ben-Maimon, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2024

/s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial and Accounting Officer)