UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2023

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: 001-39334

Biora Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-3950390**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4330 La Jolla Village Drive, Suite 300, San Diego, CA	**92122**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (833) 727-2841

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BIOR	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, 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 November 6, 2023, the registrant had 23,703,672 shares of common stock, par value $0.001 per share, outstanding.

Table of Contents

EXPLANATORY NOTE

All share and per share information included in this Quarterly Report on Form 10-Q has been retroactively adjusted to reflect a 1-for-25 reverse stock split effected on January 3, 2023.

TRADEMARKS

Biora Therapeutics™, BIOJET™, NAVICAP™, and GITRAC™ are trademarks of Biora Therapeutics, Inc. Any other brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BIORA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 12,569	$ 30,486
Income tax receivable	818	828
Prepaid expenses and other current assets	3,351	4,199
Current assets of disposal group held for sale	2,509	2,603
Total current assets	19,247	38,116
Property and equipment, net	1,236	1,654
Right-of-use assets	1,834	1,482
Other assets	6,314	6,201
Goodwill	6,072	6,072
Total assets	$ 34,703	$ 53,525
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,905	$ 3,606
Accrued expenses and other current liabilities	24,314	16,161
Warrant liabilities	41,325	3,538
Total current liabilities	69,544	23,305
Convertible notes, net of unamortized discount of $2,347 and $4,914 as of September 30, 2023 and December 31, 2022, respectively	80,378	127,811
Other long-term liabilities	3,567	4,696
Total liabilities	$ 153,489	$ 155,812
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock – $0.001 par value; 164,000,000 shares authorized; 24,147,645 and 9,098,844 shares issued as of September 30, 2023 and December 31, 2022, respectively; 23,411,013 and 8,928,498 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	21	8
Additional paid-in capital	835,817	743,626
Accumulated deficit	(935,545)	(826,843)
Treasury stock – at cost; 736,632 and 170,346 shares as of September 30, 2023 and December 31, 2022, respectively	(19,079)	(19,078)
Total stockholders' deficit	(118,786)	(102,287)
Total liabilities and stockholders' deficit	$ 34,703	$ 53,525

See accompanying notes to unaudited condensed consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues	$ —	$ 80	$ 4	$ 291
Operating expenses:				
Research and development	10,547	5,820	23,720	18,282
Selling, general and administrative	12,774	8,147	30,083	30,014
Total operating expenses	23,321	13,967	53,803	48,296
Loss from operations	(23,321)	(13,887)	(53,799)	(48,005)
Interest expense, net	(2,592)	(2,773)	(7,975)	(8,305)
Gain on warrant liabilities	4,568	2,044	5,271	15,446
Other (expense) income, net	(52,108)	(100)	(52,194)	4,824
Loss before income taxes	(73,453)	(14,716)	(108,697)	(36,040)
Income tax expense (benefit)	1	158	5	(679)
Loss from continuing operations	(73,454)	(14,874)	(108,702)	(35,361)
Gain from discontinued operations	—	9,760	—	10,926
Net loss	(73,454)	(5,114)	(108,702)	(24,435)
Net loss per share from continuing operations, basic and diluted	$ (4.89)	$ (1.99)	$ (8.54)	$ (4.78)
Net gain per share from discontinued operations, basic and diluted	$ —	$ 1.31	$ —	$ 1.48
Net loss per share, basic and diluted	$ (4.89)	$ (0.68)	$ (8.54)	$ (3.30)
Weighted average shares outstanding, basic and diluted	15,024,726	7,478,150	12,727,650	7,394,243

See accompanying notes to unaudited condensed consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	Treasury Stock		Total Stockholders'
	Shares	Amount	Capital	Deficit	Shares	Amount	Deficit
Balance at December 31, 2022	**9,098,844**	**$ 8**	**$ 743,626**	**$ (826,843)**	**(170,346)**	**$ (19,078)**	**$ (102,287)**
Issuance of common stock, net	2,853,109	3	12,521	—	—	—	12,524
Issuance of common stock upon vesting of restricted stock units	146,321	—	(178)	—	(68,938)	—	(178)
Stock-based compensation expense	—	—	2,384	—	—	—	2,384
Net loss	—	—	—	(17,441)	—	—	(17,441)
Balance at March 31, 2023	**12,098,274**	**$ 11**	**$ 758,353**	**$ (844,284)**	**(239,284)**	**$ (19,078)**	**$ (104,998)**
Issuance of common stock, net	1,509,434	—	—	—	—	—	—
Issuance of common stock upon vesting of restricted stock units	79,256	—	(90)	—	(26,821)	—	(90)
Stock-based compensation expense	—	—	2,014	—	—	—	2,014
Net loss	—	—	—	(17,807)	—	—	(17,807)
Balance at June 30, 2023	**13,686,964**	**$ 11**	**$ 760,277**	**$ (862,091)**	**(266,105)**	**$ (19,078)**	**$ (120,881)**
Issuance of common stock, net	82,916	—	10	—	—	—	10
Issuance of common stock upon vesting of restricted stock units	1,142,484	1	(1,691)	—	(470,527)	(1)	(1,691)
Issuance of common stock upon conversion of debt, net	9,235,281	9	66,690	—	—	—	66,699
Stock-based compensation expense	—	—	10,531	—	—	—	10,531
Net loss	—	—	—	(73,454)	—	—	(73,454)
Balance at September 30, 2023	**24,147,645**	**$ 21**	**$ 835,817**	**$ (935,545)**	**(736,632)**	**$ (19,079)**	**$ (118,786)**

	Common Stock		Additional Paid-In	Accumulated	Treasury Stock		Total Stockholders'
	Shares	Amount	Capital	Deficit	Shares	Amount	Deficit
Balance at December 31, 2021	**7,429,458**	**$ 6**	**$ 722,782**	**$ (788,686)**	**(154,569)**	**$ (19,078)**	**$ (84,976)**
Issuance of common stock, net	85,213	—	3,626	—	—	—	3,626
Issuance of common stock upon vesting of restricted stock units	11,520	—	(80)	—	(3,723)	—	(80)
Stock-based compensation expense	—	—	2,053	—	—	—	2,053
Net loss	—	—	—	(13,808)	—	—	(13,808)
Balance at March 31, 2022	**7,526,191**	**$ 6**	**$ 728,381**	**$ (802,494)**	**(158,292)**	**$ (19,078)**	**$ (93,185)**
Issuance of common stock, net	69,028	—	1,168	—	—	—	1,168
Issuance of common stock under employee stock purchase plan	5,002	—	89	—	—	—	89
Issuance of common stock upon vesting of restricted stock units	12,667	—	(111)	—	(3,017)	—	(111)
Stock-based compensation expense	—	—	1,446	—	—	—	1,446
Net loss	—	—	—	(5,513)	—	—	(5,513)
Balance at June 30, 2022	**7,612,888**	**$ 6**	**$ 730,973**	**$ (808,007)**	**(161,309)**	**$ (19,078)**	**$ (96,106)**
Issuance of common stock, net	110,293	—	1,659	—	—	—	1,659
Issuance of common stock upon vesting of restricted stock units	2,817	—	(21)	—	(817)	—	(21)
Stock-based compensation expense	—	—	2,139	—	—	—	2,139
Net loss	—	—	—	(5,114)	—	—	(5,114)
Balance at September 30, 2022	**7,725,998**	**$ 6**	**$ 734,750**	**$ (813,121)**	**(162,126)**	**$ (19,078)**	**$ (97,443)**

See accompanying notes to unaudited condensed consolidated financial statements.

BIORA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Operating Activities:		
Net loss	$ (108,702)	$ (24,435)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from discontinued operations	—	(10,926)
Depreciation and amortization	438	749
Stock-based compensation expense	14,929	5,638
Inducement loss on convertible notes	53,198	—
Amortization of debt discount and non-cash interest	1,126	1,052
Loss on disposal of property and equipment	12	520
Impairment of property and equipment	100	545
Gain on investment in Enumera Molecular, Inc.	—	(5,731)
Change in fair value of warrant liabilities	(5,271)	(15,446)
Changes in operating assets and liabilities:		
Income tax receivable	10	(828)
Prepaid expenses and other current assets	734	1,441
Accounts payable	287	(6,352)
Accrued expenses and other liabilities	9,963	(56)
Other long-term liabilities	(1,578)	(1,482)
Net cash used in operating activities - continuing operations	(34,754)	(55,311)
Net cash provided by operating activities - discontinued operations	—	1,912
Net cash used in operating activities	(34,754)	(53,399)
Investing Activities:		
Purchases of property and equipment	(37)	(720)
Proceeds from sale of property and equipment	11	—
Net cash used in investing activities	(26)	(720)
Financing Activities:		
Proceeds from issuance of common stock	13,064	6,453
Proceeds from issuance of common stock warrants	8,000	—
Proceeds from issuance of common stock under employee stock purchase plan	—	89
Payments of offering costs	(471)	—
Payments for financing of insurance premiums	(1,771)	(3,748)
Tax payments to settle restricted stock units	(1,959)	—
Principal payments on capital lease obligations	—	(12)
Net cash provided by financing activities	16,863	2,782
Net decrease in cash, cash equivalents and restricted cash	(17,917)	(51,337)
Cash, cash equivalents and restricted cash at beginning of period	30,486	88,397
Cash, cash equivalents and restricted cash at end of period	$ 12,569	$ 37,060
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,196	$ 4,811
Cash paid for income taxes	$ 14	$ 18
Supplemental schedule of non-cash investing and financing activities:		
Lease assets obtained in exchange for operating lease liabilities	$ 1,344	$ 2,922
Investment in Enumera Molecular Inc. in exchange for assets	$ —	$ 6,000
Conversion of convertible note	$ 50,000	$ —
Issuance of common stock in settlement of accrued expenses	$ —	$ 89
Deferred offering costs in accrued expenses	$ 59	$ —
Purchases of property and equipment in accounts payable	$ 11	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

1. Organization and Description of Business

Biora Therapeutics, Inc. (the “Company” or “Biora” or "Biora Therapeutics") is a biotechnology company developing oral biotherapeutics that could enable new treatment approaches in the delivery of therapeutics. The Company's therapeutics pipeline includes two therapeutic delivery platforms:

- NAVICAP™ Targeted Oral Delivery Platform: Targeted oral delivery of therapeutics to the site of disease in the gastrointestinal tract designed to improve outcomes for patients with Inflammatory Bowel Disease; and
- BIOJET™ Systemic Oral Delivery Platform: Systemic oral delivery of biotherapeutics designed to replace injections with needle-free, oral delivery of large molecules for better management of chronic diseases.

Biora Therapeutics, a Delaware corporation, was formerly known as Progenity, Inc. (“Progenity”), and commenced operations in 2010 with its corporate office located in San Diego, California. The Company's historical operations included a licensed Clinical Laboratory Improvement Amendments and College of American Pathologists certified laboratory located in Michigan specializing in molecular testing markets serving women’s health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas in the United States. Previously, the Company's core business was focused on the carrier screening and noninvasive prenatal test market, targeting preconception planning and routine pregnancy management for genetic disease risk assessment. Through its former affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics (“Avero”), the Company’s operations also included anatomic and molecular pathology testing products.

In order to refocus efforts and resources on its research and development pipeline, in June 2021, the Company announced a strategic transformation ("Strategic Transformation") that included the closure of the Progenity genetics laboratory and in December 2021, the Company sold Avero, together referred to as the Laboratory Operations. The Company has reported all revenues and expenses associated with its Laboratory Operations as discontinued operations, see Note 3 for additional information. In April 2022, the Company announced that it would rebrand to better reflect the current focus on its therapeutics pipeline, and changed its name to Biora Therapeutics, Inc.

On December 29, 2022, the Company filed a certificate of amendment (the "Certificate of Amendment") to its eighth amended and restated certificate of incorporation to effect, as of January 3, 2023, a 1-for-25 reverse split of the Company's common stock (the "Reverse Stock Split"). On January 3, 2023, the Company effected the Reverse Stock Split. See Note 2 for additional information.

Liquidity

As of September 30, 2023, the Company had cash and cash equivalents of $7.8 million, restricted cash of $4.8 million and an accumulated deficit of $935.5 million. For the nine months ended September 30, 2023, the Company reported a net loss of $108.7 million and cash used in operating activities of $34.8 million. The Company’s primary sources of capital have historically been the sale of common stock and warrants, private placements of preferred stock and the incurrence of debt. As of September 30, 2023, the Company had $80.4 million of convertible senior notes, net ("Convertible Notes") outstanding (see Note 7). While the Company has greatly reduced its cash burn following the Strategic Transformation, management does not expect that the Company's current cash and cash equivalents will be sufficient to fund its operations for at least 12 months from the issuance date of the condensed consolidated financial statements for the three and nine months ended September 30, 2023, and will require additional capital to fund the Company's operations. As a result, substantial doubt exists about the Company’s ability to continue as a going concern for 12 months following the issuance date of the condensed consolidated financial statements for the three and nine months ended September 30, 2023.

The Company’s ability to continue as a going concern is dependent upon its ability to raise additional funding. Management believes that the Company’s liquidity position as of the date of this filing provides sufficient runway to achieve important research and development pipeline milestones. Management intends to raise additional capital through equity offerings and/or debt financings, or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of the Company’s research programs or patent portfolios or divestitures of the Company's assets. Adequate funding, if needed, may not be available to the Company on acceptable terms, or at all. The Company’s ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its research and development programs or other operations. If any of these events occur, the Company’s ability to achieve its operational goals would be adversely affected.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. These financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission, from which management derived the Company's condensed consolidated balance sheet as of December 31, 2022.

The condensed consolidated financial statements and notes thereto give retrospective effect to the Reverse Stock Split for all periods presented. All common stock, options exercisable for common stock, restricted stock units, warrants and per share amounts contained in the condensed consolidated financial statements have been retrospectively adjusted to reflect the Reverse Stock Split for all periods presented. Concurrent with the Reverse Stock Split, the Company effected a reduction in the number of authorized shares of common stock from 350,000,000 shares to 164,000,000 shares.

Unaudited Interim Financial Information

The accompanying condensed consolidated financial statements are unaudited, have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, that are necessary to present fairly the results for the interim periods presented. Results are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. The balance sheet as of December 31, 2022 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the interim financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include the valuation of stock options, the valuation of goodwill, accrual for reimbursement claims and settlements, the valuation of warrant liabilities, the valuation of assets held for sale, assessing future tax exposure and the realization of deferred tax assets, and the useful lives and the recoverability of property and equipment. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Restricted Cash

Restricted cash consists of amounts owed for interest held in an escrow account with a balance of $4.8 million and $0 as of September 30, 2023 and December 31, 2022, respectively.

Recent Accounting Pronouncements Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments–Credit Losses*, which included an amendment of the effective date. The Company adopted this standard on January 1, 2023, and it did not have a material impact on the condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments, amends the guidance on derivative scope

exceptions for contracts in an entity's own equity, and modifies the guidance on diluted earnings per share calculations as a result of these changes. The standard is effective for the Company for annual reporting periods beginning after December 15, 2023. The Company is currently evaluating the impact the adoption of this standard may have on its consolidated financial statements.

3. Strategic Transformation

Assets Held for Sale and Discontinued Operations

In June 2021, the Company announced its Strategic Transformation to reallocate resources to research and development to better position the business for future growth. The plan included the closure of the Company's genetics laboratory in Ann Arbor, Michigan and the divestiture of Avero. This plan represented a strategic business shift having a major effect on the Company's operations and financial results. The Company classified the results of its Laboratory Operations as discontinued operations in its condensed consolidated statements of operations and consolidated statements of cash flows. Additionally, the remaining assets have been reported as assets held for sale in the Company’s condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022.

The following table presents the combined results of discontinued operations of the Laboratory Operations (in thousands) for the three and nine months ended September 30, 2022. There was no gain or loss from discontinued operations for the three and nine months ended September 30, 2023:

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Revenues (1)	$ 9,923	$ 11,950
Operating expenses:		
Selling, general and administrative	163	1,024
Total operating expenses	163	1,024
Net gain from discontinued operations	$ 9,760	$ 10,926

(1) Refer to Note 9 for further discussion regarding the partial reversal of a previously-established accrual related to a third-party claim of recoupment during the three months ended September 30, 2022.

The following table presents the carrying amounts of the remaining assets held for sale related to the Laboratory Operations as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023	December 31, 2022
Current assets of disposal group held for sale		
Property and equipment, net	2,509	2,603
Total current assets of disposal group held for sale (2)	$ 2,509	$ 2,603

(2) The Company is actively looking to sell the remaining assets of the Laboratory Operations and has classified them as held for sale and current in the consolidated balance sheets at September 30, 2023 and December 31, 2022, because they are expected to be sold within one year.

On October 6, 2023, the Company entered into a Purchase and Sale Agreement to sell the building located in Ann Arbor, Michigan included in current assets held for sale. The transaction closed in October 2023 and the Company received gross proceeds of $2.8 million, incurred closing expenses of $0.2 million and recorded a gain of $0.3 million upon closing.

Investment in Enumera Molecular, Inc.

In May 2022, the Company completed the divesture of its single-molecule detection platform. Under the terms of the agreements, the Company contributed intellectual property and fixed assets related to the single-molecule detection platform to a newly-formed entity, Enumera Molecular, Inc. ("Enumera"), which intends to develop and commercialize the platform. As of the transaction date, the Company received 25% minority ownership, on a fully-diluted basis, of 6,000,000 Series A-1 preferred shares with an estimated value of $6.0 million in exchange for the assets. The Company concluded, based on a technical evaluation of the facts, that Enumera is not a variable interest entity. The Company also evaluated the characteristics of the investment and determined that the preferred stock is not in-substance common stock that would require equity method accounting. The Company concluded the appropriate accounting treatment for the investment in Enumera to be that of an equity security with no readily determinable fair value and has recorded the investment at cost, less impairment, adjusted for subsequent observable price changes. The investment is included in other assets in the Company’s condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022. No impairment was recorded as of September 30, 2023 or December 31, 2022.

Licensing Agreements

In November 2022, the Company entered into a license agreement with Northwest Pathology, doing business as Avero Diagnostics ("Northwest"), pursuant to which the Company licensed its Preecludia rule-out test for preeclampsia to Northwest for commercial development (the "Northwest License Agreement"). Under the terms of the Northwest License Agreement, Northwest received the rights to assets and intellectual property related to the Preecludia test and the Company will receive commercial milestone payments and royalties on net sales.

In June 2023, the Company entered into a purchase and license agreement with a diagnostics company pursuant to which the Company sold certain assets and licensed intellectual property related to preeclampsia for research and development (the "Preeclampsia Agreement"). Under the terms of the Preeclampsia Agreement, the Company received a one-time payment for the sale of assets, including rights to certain antibody sequences during the three months ended September 30, 2023 and recorded $1.5 million of other income.

In May 2023, the Company entered into a professional services agreement with an affiliate of Enumera, a related party. Pursuant to the agreement, the affiliate will assist in selling legacy assets. The Company incurred $0.4 million in other expenses in connection with the agreement.

4. Revenues

The Company's current revenue is related to license and collaboration agreements. Revenues historically were derived from contracts with healthcare insurers, government payors, laboratory partners and patients related to tests provided to patients. The Company evaluated its contracts and identified a single performance obligation, the delivery of a test result. The Company satisfied its performance obligation at a point in time upon the delivery of the test result, at which point the Company billed for its products. The amount of revenue recognized reflected the transaction price and considered the effects of variable consideration. All of the historical test revenue is part of the Company's Laboratory Operations and has been included in discontinued operations in the condensed consolidated statements of operations.

The Company had established an accrual for refunds of payments previously made by healthcare insurers based on historical experience and executed settlement agreements with healthcare insurers. Any refunds were accounted for as reductions in revenues in the statement of operations as an element of variable consideration.

The Company periodically updated its estimate of the variable consideration recognized for previously delivered performance obligations. These updates resulted in an additional $0.1 million and $2.0 million of revenue for the three and nine months ended September 30, 2022, respectively. These amounts included (i) adjustments for actual collections versus estimated variable consideration as of the beginning of the reporting period and (ii) cash collections and the related recognition of revenue in the current period for tests delivered in prior periods due to the release of the constraint on variable consideration, offset by (iii) reductions in revenue for the accrual for reimbursement claims and settlements described in Note 9.

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	September 30, 2023	December 31, 2022
Prepaid expenses	$ 3,179	$ 3,634
Other current assets	172	565
Total	$ 3,351	$ 4,199

Property and Equipment, Net

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

	September 30, 2023	December 31, 2022
Computers and software	$ 1,396	$ 2,715
Building and leasehold improvements	803	750
Laboratory equipment	565	958
Furniture, fixtures, and office equipment	871	1,138
Construction in progress	5	92
Total property and equipment	3,640	5,653
Less accumulated depreciation and amortization	(2,404)	(3,999)
Property and equipment, net	$ 1,236	$ 1,654

Depreciation expense was $0.1 million and $0.4 million for the three and nine months ended September 30, 2023, respectively, and $0.2 million and $0.7 million for the three and nine months ended September 30, 2022, respectively.

Other Assets

Other assets consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Investment in Enumera	$ 6,000	$ 6,000
Other	314	201
Total	$ 6,314	$ 6,201

Accrued Expenses and Other Current Liabilities

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

	September 30, 2023	December 31, 2022
Accrual for reimbursement claims and settlements, current (1)	$ 8,287	$ 8,372
Commissions and bonuses	2,037	1,433
Vacation and payroll benefits	1,326	1,724
Accrued professional services	711	307
Accrued interest	6,842	890
Lease liabilities, current	962	893
Insurance financing	959	445
Contract liabilities	42	47
Other (2)	3,148	2,050
Total	$ 24,314	$ 16,161

(1) Revenues related to Laboratory Operations have all been discontinued; amounts related to the revenue reserve generated from the Laboratory Operations remain on the balance sheet.
(2) Included in this amount are contracts that the Company is responsible for that were expensed in discontinued operations in 2021.

Other Long-term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Lease liabilities, net of current portion	1,051	601
Other (1)	2,516	4,095
Total	$ 3,567	$ 4,696

(1) Included in this amount are contracts that the Company is responsible for that were expensed in discontinued operations in 2021.

6. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The authoritative guidance establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. The three-level hierarchy for the inputs to valuation techniques is summarized as follows:

Level 1 - Quoted prices in active markets for identical assets and liabilities that the Company has the ability to access.

Level 2 - Observable market-based inputs or unobservable inputs that are corroborated by market data, such as quoted prices, interest rates, and yield curves.

Level 3 - Inputs that are unobservable data points that are not corroborated by market data.

There were no significant transfers between these fair value measurement classifications during the nine months ended September 30, 2023 and 2022.

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Level 1	Level 2	Level 3
September 30, 2023			
Warrant liabilities	$ —	$ —	$ 41,325
December 31, 2022			
Money market funds (1)	$ 5	$ —	$ —
Warrant liabilities	$ —	$ —	$ 3,538

(1) Included in cash, cash equivalents and restricted cash in the accompanying condensed consolidated balance sheets.

The Company's Level 3 liabilities consist of the warrant liabilities resulting from equity financings (see Note 10) and the Convertible Note exchange (see Note 7). The Company uses the Black-Scholes Model to value the warrant liabilities at inception and on subsequent valuation dates. This model incorporates transaction details such as the Company's stock price, contractual terms, maturity, risk free rates, and volatility. The significant unobservable input for the Level 3 warrant liabilities includes volatility. Given the limited period of time the Company's stock has been traded in an active market, the expected volatility is estimated by taking the average historical price volatility for industry peers, consisting of several public companies in the Company's industry that are similar in size, stage, or financial leverage, over a period of time commensurate to the expected term of the warrants. At September 30, 2023 and December 31, 2022, the fair value of the warrant liabilities were estimated using the Black-Scholes Model with the following inputs and assumptions:

	September 30, 2023	December 31, 2022
Risk-free interest rate	4.6% - 4.8%	4.0%
Expected volatility	96.5% - 99.4%	106.2% - 107.1%
Stock price	$ 2.17	$ 3.30
Expected life (years)	2.7 - 4.6	3.6 - 5.4

A summary of the changes in the warrant liabilities is presented below (in thousands):

Balance at December 31, 2022	$ 3,538
Recognition of new warrant liabilities	44,439
Change in fair value of warrant liabilities	(6,652)
Balance at September 30, 2023	$ 41,325

The carrying value of the Company's Convertible Notes does not approximate its fair value because the carrying value of the Convertible Notes reflects the balance of unamortized discount related to the derivative liability associated with the value of the conversion feature assessed at inception. The carrying value of the Company's Convertible Notes, net of discount, was $80.4 million and $127.8 million at September 30, 2023 and December 31, 2022, respectively. Based on unadjusted quoted prices in active market

obtained from third-party pricing services, the Company determined the fair value of the Convertible Notes was $45.7 million and $71.8 million as of September 30, 2023 and December 31, 2022, respectively.

7. Convertible Notes

In December 2020, the Company issued a total of $168.5 million principal amount of Convertible Notes in a private offering of the Convertible Notes pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The Convertible Notes were issued pursuant to, and are governed by, an indenture, dated as of December 7, 2020, by and between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (“Indenture”). The Convertible Notes are due on December 1, 2025, unless earlier repurchased, redeemed or converted, and accrue interest at a rate per annum equal to 7.25% payable semi-annually in arrears on June 1 and December 1 of each year, with the initial payment on June 1, 2021. The outstanding principal amount of Convertible Notes was $82.7 million and $132.7 as of September 30, 2023 and December 31, 2022, respectively. The Company recognized interest expense on the Convertible Notes of $2.3 million and $7.1 million for the three and nine months ended September 30, 2023, respectively, and $2.4 million and $7.2 million for the three and nine months ended September 30, 2022, respectively.

The Convertible Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's existing and future senior, unsecured indebtedness; (ii) senior in right of payment to the Company's existing and future indebtedness that is expressly subordinated to the Convertible Notes; (iii) effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company's subsidiaries.

At any time, noteholders may convert their Convertible Notes at their option into shares of the Company’s common stock, together, if applicable, with cash in lieu of any fractional share, at the then-applicable conversion rate. The initial conversion rate is 11.1204 shares of common stock per $1,000 principal amount of Convertible Notes, which represents an initial conversion price of approximately $89.92 per share of common stock. Noteholders that converted their Convertible Notes before December 1, 2022 were, in certain circumstances, entitled to an additional cash payment representing the present value of any remaining interest payments on the Convertible Notes through December 1, 2022. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain dilutive events. In addition, if certain corporate events that constitute a “Make-Whole Fundamental Change” (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for a specified period of time.

The Convertible Notes are redeemable, in whole and not in part, at the Company’s option at any time on or after December 1, 2023, at a cash redemption price equal to the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, but only if the last reported sale price per share of the Company’s common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (ii) the trading day immediately before the date the Company sends such notice. In addition, calling the Convertible Notes will constitute a Make-Whole Fundamental Change, which will result in an increase to the conversion rate in certain circumstances for a specified period of time.

The Convertible Notes have customary provisions relating to the occurrence of “Events of Default” (as defined in the Indenture), which include the following: (i) certain payment defaults on the Convertible Notes (which, in the case of a default in the payment of interest on the Convertible Notes, will be subject to a 30-day cure period); (ii) the Company’s failure to send certain notices under the Indenture within specified periods of time; (iii) the Company’s failure to comply with certain covenants in the Indenture relating to the Company’s ability to consolidate with or merge with or into, or sell, lease or otherwise transfer, in one transaction or a series of transactions, all or substantially all of the assets of the Company and its subsidiaries, taken as a whole, to another person; (iv) a default by the Company in its other obligations or agreements under the Indenture or the Convertible Notes if such default is not cured or waived within 60 days after notice is given in accordance with the Indenture; (v) certain defaults by the Company or any of its subsidiaries with respect to indebtedness for borrowed money of at least $7.5 million; (vi) the rendering of certain judgments against the Company or any of its subsidiaries for the payment of at least $7.5 million, where such judgments are not discharged or stayed within 60 days after the date on which the right to appeal has expired or on which all rights to appeal have been extinguished; and (vii) certain events of bankruptcy, insolvency and reorganization involving the Company or any of the Company’s significant subsidiaries. As of both September 30, 2023 and December 31, 2022, the Company was in compliance with all such covenants.

The Convertible Notes had a conversion option which was required to be bifurcated upon issuance and periodically remeasured to fair value separately as an embedded derivative. The conversion option included additional interest payments payable to the

noteholders if converted prior to December 1, 2022. The conversion feature was bifurcated and recorded separately as an embedded derivative as (1) the conversion feature was not clearly and closely related to the debt instrument and was not considered to be indexed to the Company's equity, (2) the conversion feature standing alone meets the definition of a derivative, and (3) the Convertible Notes are not remeasured at fair value each reporting period with changes in fair value recorded in the consolidated statement of operations. As of December 31, 2022, the conversion option has expired and there is no longer an embedded derivative.

In September 2023, certain related party holders of Convertible Notes exchanged an aggregate of $50.0 million principal amount for a combination of 9,235,281 shares of the Company's common stock, 7,399,226 pre-funded warrants at an exercise price of $0.001 per share and warrants to purchase up to 16,634,507 shares of common stock at an exercise price of $3.01 per share. The warrants are exercisable on or after September 18, 2023 until September 18, 2026 and the pre-funded warrants have no expiration date. The pre-funded warrants and the warrants (together, the "September Warrants") are subject to certain exercise limitations, including a limitation on the ability to exercise if the holder's beneficial ownership would exceed 49.9%. As the Convertible Notes were exchanged for an amount over the fair value of shares issuable under the original conversion terms, the Company recorded an inducement loss of $53.2 million, included in other (expense) income, net in the condensed consolidated statements of operations. Pursuant to ASC 815, the Company deemed the September Warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings. The September Warrants were recorded at a fair value of $35.1 million determined using the Black-Scholes Model. The warrant liability was remeasured at $36.8 million as of September 30, 2023 and the Company recognized a loss on warrant liability in the amount of $1.7 million in the condensed consolidated statements of operations during the three months ended September 30, 2023.

As of September 30, 2023 and December 31, 2022, the unamortized debt discount was $2.3 million and $4.9 million, respectively. The Company amortizes the debt discount using the effective interest method over the term of the Convertible Notes, resulting in an effective interest rate of approximately 8.7%. The amortization of the Convertible Notes debt discount was $0.4 million and $1.1 million for the three and nine months ended September 30, 2023, respectively, and $0.3 million and $1.0 million for the three and nine months ended September 30, 2022, respectively, and was included in interest expense, net in the condensed consolidated statements of operations.

8. Related Party Transactions

As of September 30, 2023 affiliates of Athyrium Capital Management, LP ("Athyrium") held 10,929,765 shares, or 46.7%, of the Company's common stock outstanding, 7,399,226 pre-funded warrants and warrants to purchase up to 16,634,507 and 824,136 shares of common stock at exercise prices of $3.01 and $8.22, respectively. As of December 31, 2022, Athyrium held 1,694,484 shares, or 19.0%, respectively, of the Company's common stock outstanding and warrants to purchase up to 824,136 shares of common stock at an exercise price of $8.22.

Athyrium also held $53.5 million and $103.5 million aggregate principal amount of Convertible Notes as of September 30, 2023 and December 31, 2022, respectively. In September 2023, Athyrium exchanged an aggregate of $50.0 million principal amount for a combination of 9,235,281 shares of the Company's common stock, 7,399,226 pre-funded warrants and warrants to purchase up to 16,634,507 shares of common stock at an exercise price of $3.01 (see Note 7). As of September 30, 2023 and December 31, 2022, the accrued interest expense related to the Convertible Notes held by Athyrium was $6.1 million and $0.6 million, respectively. As of September 30, 2023, $4.8 million of the interest owed is being held in an escrow account and is considered restricted cash.

In November 2022, the Company entered into a securities purchase agreement with affiliates of Athyrium relating to the offering and sale of an aggregate of 500,250 shares of common stock and accompanying warrants to purchase 500,250 shares of common stock, at a combined purchase price of $7.50 per share and accompanying warrant in a registered direct offering. The warrants have an exercise price of $8.22 per share and will become exercisable commencing six months following the date of issuance and will expire five years following the initial exercise date. The Company received approximately $3.8 million in gross proceeds from the offering as an in-kind payment. The in-kind payment was in the form of a waiver of the Company's cash interest payment obligation of approximately $3.8 million due on certain of the Company's 7.25% Convertible Senior Notes due 2025 held by affiliates of Athyrium for the payment date occurring on December 1, 2022. Additionally, the Company agreed with Athyrium to amend outstanding warrants previously issued in 2021 to purchase up to 323,886 shares of common stock with an exercise price of $71.00 per share. The warrants have an amended exercise price of $8.22 per share, will become exercisable on May 9, 2023 and will expire five years following the initial exercise date.

In November 2022, the Company entered into a securities purchase agreement with an institutional investor relating to the offering and sale of an aggregate of 800,000 shares of common stock and accompanying warrants to purchase 800,000 shares of common stock, at a combined purchase price of $7.50 per share and accompanying warrant in a registered direct offering (see Note 10). Following this transaction, the institutional investor became a related party due to greater than 5% ownership. On January 12,

2023, the Company issued warrants to purchase 90,000 shares of common stock to the institutional investor in exchange for the investor's agreement to waive the lockup provisions contained in the November 2022 securities purchase agreement. As of March 31, 2023 this institutional investor held less than 5% of the Company's outstanding common stock and is no longer considered a related party.

In June 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 1,509,434 shares of common stock in a registered direct offering at an offering price of $5.30 per share. In addition, in a concurrent private placement, the Company issued unregistered warrants to purchase 3,018,868 shares of common stock (see Note 10) to the same investors. Following this transaction, the institutional and accredited investors became related parties due to greater than 5% ownership. As of September 30, 2023 the institutional and accredited investors held less than 5% of the Company's outstanding common stock and are no longer considered related parties.

9. Commitments and Contingencies

Operating Leases

The Company has entered into various noncancelable operating lease agreements, primarily for office space, laboratory space, and equipment. In March 2023, the Company signed an amended lease agreement for certain office space in San Diego, California to decrease the office space and extend the term to June 2025. In August 2023, the Company signed a 36-month lease agreement for office space in Dallas, Texas. Cash paid for operating leases was $0.9 million and $1.2 million for the nine months ended September 30, 2023 and 2022, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease costs	$ 311	$ 399	$ 1,104	$ 1,135

Supplemental weighted-average information related to operating leases is as follows:

	September 30,	
	2023	2022
Weighted-average remaining lease term (years)	2.3	2.2
Weighted-average discount rate	9.7%	7.8%

As of September 30, 2023, future lease payments under the non-cancelable operating leases were as follows (in thousands):

Year ending December 31,	Minimum Operating Lease Payments
2023 (remaining)	$ 347
2024	1,019
2025	590
2026	264
2027 and thereafter	18
Total minimum lease payments	2,238
Less: interest	(225)
Present value of lease liabilities	$ 2,013

Contingencies

The Company, in the ordinary course of its business, can be involved in lawsuits, threats of litigation, and audit and investigative demands from third parties. While management is unable to predict the exact outcome of such matters, it is management's current belief that any potential liabilities of Biora resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

The regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and may be subject to interpretation. As a former provider of services to patients covered under government and commercial payor programs, post payment review audits, and other forms of reviews and investigations are routine. The Company believes it complied in all material respects with the statutes, regulations, and other requirements applicable to its former laboratory operations.

Federal Investigations

In April 2018, the Company received a civil investigative demand from an Assistant U.S. Attorney (“AUSA”) for the Southern District of New York and a Health Insurance Portability and Accountability Act subpoena issued by an AUSA for the Southern District of California (“SDCA”) around legacy commercial practices. In May 2018, the Company received a subpoena from the State of New York Medicaid Fraud Control Unit.

On July 21, 2020, July 23, 2020 and October 1, 2020, the Company entered into agreements (the "Agreements") with certain governmental agencies and the 45 states participating in the settlement (“State AGs”) to resolve, with respect to such agencies and State AGs, all of such agencies’ and State AGs’ outstanding civil, and, where applicable, federal criminal investigations described above. The Company did not make any payments during the nine months ended September 30, 2022. In November 2022, the Company entered into an agreement to extend the deadline for the Company’s payment due on December 31, 2022 to July 15, 2023. In July 2023 the Company made payments of $1.7 million and entered into agreements to extend the deadline for the remaining payments to the following:

- approximately $2.8 million on or before January 1, 2024; and
- approximately $2.6 million on or before July 1, 2024.

The remaining amounts payable to the government will be subject to interest at a rate of 1.25% per annum, and any or all amounts may be paid earlier at the option of the Company. As of December 31, 2022, the Company’s accrual consisted of $7.1 million in accrued expenses. As of September 30, 2023, the Company’s accrual consisted of $5.3 million in accrued expenses.

Furthermore, the Company has agreed that, if during calendar years 2020 through 2023, and so long as amounts payable to the government remain unpaid, the Company receives any civil settlement, damages awards, or tax refunds, to the extent that the amounts exceed $5.0 million in a calendar year, it will pay 26% of the amount received in such civil settlement, damages award, or tax refunds as an accelerated payment of the scheduled amounts set forth above, up to a maximum total acceleration of $4.1 million. The Company did not receive any tax refunds during the nine months ended September 30, 2023 and 2022.

Corporate Integrity Agreement

In connection with the resolution of the investigated matters, and in exchange for the Office of Inspector General of the Department of Health and Human Services ("OIG") agreement not to exercise its authority to permissively exclude the Company from participating in federal healthcare programs, effective July 21, 2020, the Company entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires, among other matters, that the Company maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; provide management certifications and compliance training and education; engage an independent review organization to conduct claims and arrangements reviews; and implement a risk assessment and internal review process. In view of the Company's Strategic Transformation, including cessation of its Laboratory Operations and related billing for services, effective March 7, 2023 the OIG agreed to suspend the Company’s obligations under the Corporate Integrity Agreement.

California Subpoena

On July 19, 2021, the Company received a subpoena from the California Attorney General’s Office, Division of Public Rights (the "OAG"), requesting documents and information related to the Company's former genetic testing practices, the Company's former non-invasive prenatal tests ("NIPT"), particularly those with a nexus to California patients. The OAG alleged that the Company violated California Business and Professions Code sections 17200 et seq. and 17500 et seq., in a complaint filed September 12, 2023 in the Superior Court of the State of California (case no. 23CV008397) for injunctive and other relief. The Company and OAG settled the matter via a stipulated entry of Final Judgment and Permanent Injunction that was entered and ordered by the Court on September 25, 2023. Pursuant to the order, the Company paid civil penalties in the total amount of $0.2 million.

Payor Dispute

On November 16, 2020, the Company received a letter from Anthem, Inc. (“Anthem”) informing the Company that Anthem is seeking recoupment for historical payments made by Anthem in an aggregate amount of approximately $27.4 million. The historical

payments for which Anthem is seeking recoupment are claimed to relate primarily to discontinued legacy billing practices for the Company's former NIPT and microdeletion tests and secondarily to discontinued legacy billing practices involving the implementation of a new Current Procedure Terminology code for reimbursement for the Company's former Preparent expanded carrier screening tests. Management disputes this claim of recoupment with Anthem in full, with offsets for amounts owed by Anthem to the Company. Management had previously established an accrual for the estimated probable loss for this matter. During the year ended December 31, 2022, the Company reversed this accrual for a substantial majority portion of the matter in view of applicable statute of limitations and reflected this change in revenue within discontinued operations.

The Company has historically negotiated and settled similar claims with third-party payors. Although the Company's practice in resolving disputes with other similar large commercial payors has generally led to agreed settlement amounts substantially less than the originally claimed amount, there can be no assurance that the Company will be successful in a similar settlement amount in any ongoing or future dispute. Historical settlement amounts and payment time periods may not be indicative of the final settlement terms with Anthem, if any.

Payor Recoveries

As noted above, the regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and may be subject to interpretation. As a former provider of services to patients covered under government reimbursement and commercial payor programs, the Company is routinely subject to post-payment review audits and other forms of reviews and investigations. For example, the Company currently disputes several managed Medicaid payor recoupment requests aggregating to $1.1 million. If a third-party payor successfully challenges that a payment to the Company for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup such payment. The Company may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. In the ordinary course of business, the Company addresses and evaluates a number of such claims from payors. In the past, the Company has negotiated and settled these types of claims with third-party payors. The Company may be required to resolve further disputes in the future. While management is unable to predict the exact outcome of any such claims, it is management's current belief that any potential liabilities resulting from these contingencies, individually or in the aggregate, could have a material impact on the Company's financial position and results of operations.

Ravgen Lawsuit

On December 22, 2020, Ravgen, Inc. ("Ravgen") filed suit in the District of Delaware (D. Del. Civil Action No. 1:20-cv-1734) asserting the Company's infringement of two Ravgen patents based on the Company's former NIPT testing business. The complaint seeks monetary damages and injunctive relief. The Company responded to the complaint on March 23, 2021. Management believes the claims in Ravgen's complaint are without merit, and the Company is vigorously defending against them. On March 1, 2022 the court ordered a stay of the litigation pending resolution of patent validity challenges made against the two patents in inter partes review proceedings currently pending before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. On February 13, 2023 the court ordered the stay lifted. Given the uncertainty of litigation and the legal standards that must be met for, among other things, success on the merits, the Company is unable to predict the ultimate outcome of this matter, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from this action.

IPO Litigation

On June 23, 2020, the Company closed its IPO. Lawsuits were filed on August 28, 2020 and September 11, 2020 against the Company, certain of its executive officers and directors, and the underwriters of the IPO. On December 3, 2020, the U.S. District Court for the Southern District of California consolidated the two actions, appointed Lin Shen, Lingjun Lin and Fusheng Lin to serve as Lead Plaintiffs, and approved Glancy Prongay & Murray LLP to be Lead Plaintiffs' Counsel. Lead Plaintiffs filed their first amended complaint on February 4, 2021. Together with the underwriters of the IPO, the Company moved to dismiss the first amended complaint. On September 1, 2021, the court granted the Company's motion to dismiss, dismissing Lead Plaintiffs' claims without prejudice. On September 22, 2021, Lead Plaintiffs filed their second amended complaint. Together with the underwriters of the IPO, the Company moved to dismiss the second amended complaint on November 15, 2021. On January 13, 2023, the court again granted our motion to dismiss, dismissing Lead Plaintiffs' claims for failure to state a claim without prejudice. On February 3, 2023, Lead Plaintiffs filed their third amended complaint, adding information allegedly produced to Plaintiffs in response to freedom of information requests. The third amended complaint alleges that the Company's registration statement and related prospectus for the IPO contained false and misleading statements and omissions in violation of the Securities Act by failing to disclose that (i) the Company had overbilled government payors for Preparent tests beginning in 2019 and ending in or before early 2020; (ii) there was a high probability that the Company had received, and would have to refund, a material amount of overpayments from government payors for Preparent tests; (iii) in February 2020 the Company ended a supposedly improper marketing practice on which the competitiveness of the Company's business depended; and (iv) the Company was suffering from material negative trends with respect to testing volumes, average selling prices for its tests, and revenues. Lead Plaintiffs seek certification as a class, unspecified

compensatory damages, interest, costs and expenses including attorneys' fees, and unspecified extraordinary, equitable, and/or injunctive relief. The Company filed a motion to dismiss the third amended complaint with prejudice on March 20, 2023, which the court granted on July 12, 2023. Lead Plaintiffs filed a notice of appeal on August 11, 2023. The Company will continue to vigorously defend against these claims. Subject to a reservation of rights, the Company is advancing expenses subject to indemnification to the underwriters of the IPO.

On June 4, 2021, a purported shareholder filed a lawsuit in the U.S. District Court for the SDCA, claiming to sue derivatively on behalf of the Company. The complaint names certain of the Company's officers and directors as defendants, and names the Company as a nominal defendant. Premised largely on the same allegations as the above-described securities lawsuit, it alleges that the individual defendants breached their fiduciary duties to the Company, wasted corporate assets, and caused the Company to issue a misleading proxy statement in violation of the Securities Exchange Act of 1934, as amended. The complaint seeks the award of unspecified damages to the Company, equitable and injunctive remedies, and an order directing the Company to reform and improve its internal controls and board oversight. It also seeks the costs and disbursements associated with bringing suit, including attorneys', consultants', and experts' fees. The case is stayed pending the resolution of the appeal in the above-described securities lawsuit. The Company intends to vigorously defend against these claims.

On August 17, 2021, the Company received a letter purportedly on behalf of a stockholder of the Company demanding that the Company's board of directors investigate and take action against certain of the Company's current and former officers and directors to recover damages for alleged breaches of fiduciary duties and related claims arising out of the IPO litigation discussed above. This matter is pending the outcome of the companion securities litigation.

Given the uncertainty of litigation, the preliminary stages of the litigation and other matters described above, and the legal standards that must be met for, among other things, success on the merits, the Company is unable to predict the ultimate outcome of these actions, and therefore cannot estimate the reasonably possible loss or range of loss, if any, that may result from these actions.

10. Stockholders' Equity

Common Stock

On January 3, 2023, the Company effected a 1-for-25 reverse stock split of the Company's common stock. The Reverse Stock Split, which has been retroactively reflected throughout the condensed consolidated financial statements, reduced the authorized shares of the Company to 164,000,000 and did not change the par value of the Company's common stock.

PIPE Financings

In February 2021, the Company entered into a securities purchase agreement for a private placement with certain institutional and accredited investors for an aggregate of 174,825 units, representing (i) 174,825 shares of the Company's common stock and (ii) warrants to purchase up to 174,825 shares of common stock. The warrants are exercisable for cash at an exercise price of $171.50 per share, subject to adjustments as provided under the terms of the warrants. The warrants were immediately exercisable and expire on the fifth anniversary of the date of issuance.

In June 2021, the Company entered into a securities purchase agreement for a private placement with certain institutional and accredited investors for an aggregate of 647,773 units, representing (i) 627,773 shares of the Company's common stock (ii) warrants to purchase up to 647,773 shares of common stock and (iii) pre-funded warrants to purchase up to 20,000 shares of common stock. The warrants are exercisable for cash at an exercise price of $71.00 per share, subject to adjustments as provided under the terms of the warrants. The warrants were immediately exercisable and expire on the fifth anniversary of the date of issuance.

Registered Offerings

In August 2021, the Company issued and sold an aggregate of (i) 1,600,000 shares of common stock and (ii) warrants to purchase 1,600,000 shares of common stock in an underwritten public offering. Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $25.00 per share of the common stock and the accompanying warrant. The warrants have an exercise price of $25.00 per share, are exercisable at any time, and will expire five years following the date of issuance. In addition, the Company granted the underwriter a 30-day option to purchase up to 240,000 shares of common stock ("Overallotment Stock Option") and/or warrants to purchase 240,000 shares of common stock ("Overallotment Warrant Option") at a price of $24.75 per share of common stock and/or $0.25 per warrant.

Pursuant to ASC 815, the Company deemed the Overallotment Stock Option to meet the scope exception for equity classification, and the warrants and Overallotment Warrant Option to be classified as a liability (collectively, the "Warrant Liability") at fair value initially with subsequent changes in fair value recorded in earnings. The Overallotment Warrant Option was partially

exercised in August 2021 for warrants to purchase an aggregate of 77,280 shares of common stock and the remaining Overallotment Warrant Option expired in September 2021. The Warrant Liability was remeasured at September 30, 2022 and the Company recognized a gain on warrant liability in the amount of $15.4 million in the condensed consolidated statements of operations during the nine months ended September 30, 2022. The Warrant Liability was remeasured at $0.5 million as of December 31, 2022. The Warrant Liability was remeasured at $0.2 million at September 30, 2023 and the Company recognized a gain on warrant liability in the amount of $0.4 million in the condensed consolidated statements of operations during the nine months ended September 30, 2023.

In November 2022, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of an aggregate of (i) 1,300,250 shares of common stock and (ii) warrants to purchase 1,300,250 shares of common stock in registered direct offering (the “November 2022 Offering”). Each share was sold together with one warrant to purchase one share of common stock at a combined public offering price of $7.50 per share of the common stock and the accompanying warrant. The Company received approximately $9.0 million in net proceeds, after deducting placement agent fees and offering expenses. Approximately $3.8 million of the gross proceeds were received in the form of a waiver of the Company's December 1, 2022 interest payment on the Convertible Notes. The warrants have an exercise price of $8.22 per share, are exercisable six months following the date of issuance, and will expire five years following the initial exercise date.

Additionally, the Company agreed with certain institutional investors to amend outstanding warrants previously issued (i) in the February Units to purchase up to 104,895 shares of common stock with an exercise price of $171.50 per share and (ii) in the June Units to purchase up to 403,887 shares of common stock with an exercise price of $71.00 per share. Accordingly, the Company agreed to (i) lower the exercise price of such existing warrants to $8.22 per share, (ii) provide that such existing warrants, as amended, will not be exercisable until May 9, 2023 and (iii) extend the original expiration date of such existing warrants to May 9, 2028.

Pursuant to ASC 815, the Company deemed the warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings. The warrants were recorded at a fair value of $6.0 million determined using the Black-Scholes Model. As the total fair value of the warrant liability and common stock exceeds the in-kind payment proceeds of $3.8 million, the Company recorded an extinguishment loss of the $1.6 million excess to other income, net in the consolidated statements of operations. The Company incurred a total of $0.8 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis. The modified warrants are equity classified both before and after the modification and were fair valued as of the date of the amendment, this resulted in an increase in the value of the warrants and an additional $0.9 million was recorded to additional paid in capital on the condensed consolidated balance sheet. The warrant liability was remeasured at $3.0 million as of December 31, 2022. The warrant liability was remeasured at $1.4 million as of September 30, 2023 and the Company recognized a loss on warrant liability in the amount of $1.5 million in the condensed consolidated statements of operations during the nine months ended September 30, 2023.

In January 2023, the Company issued warrants to purchase 90,000 shares of common stock to an institutional investor in exchange for the investor’s agreement to waive the lockup provisions contained in the November 2022 Offering securities purchase agreement. The warrant has an exercise price of $8.22, is exercisable beginning on May 9, 2023 and expires on May 9, 2028. Pursuant to ASC 815, the Company deemed the warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings. The warrants were recorded at a fair value of $0.4 million determined using the Black-Scholes Model. The warrant liability was remeasured at $0.1 million as of September 30, 2023 and the Company recognized a gain on warrant liability in the amount of $0.3 million in the condensed consolidated statements of operations during the nine months ended September 30, 2023.

In June 2023, the Company entered into a securities purchase agreement with certain institutional and accredited investors relating to the offering and sale of 1,509,434 shares of common stock in a registered direct offering at an offering price of $5.30 per share (the "June 2023 Offering"). In addition, in a concurrent private placement with the same investors, the Company issued unregistered warrants to purchase 3,018,868 shares of common stock. The warrants have an exercise price of $5.05 per share, are exercisable at any time, and will expire three years following the date of issuance. The Company received approximately $7.3 million in net proceeds, after deducting placement agent fees and offering expenses.

Pursuant to ASC 815, the Company deemed the warrants to be classified as a liability at fair value initially with subsequent changes in fair value recorded in earnings. The warrants were recorded at a fair value of $9.0 million determined using the Black-Scholes Model. As the total fair value of the warrant liability exceeds the gross proceeds of $8.0 million, the Company recorded a loss of the $1.0 million excess to gain (loss) on warrant liabilities in the consolidated statements of operations. Accordingly, there were no proceeds allocated to the common stock issued as part of this transaction. The Company incurred a total of $0.7 million in issuance costs, which were allocated between the warrants and common stock on a relative fair value basis. The warrant liability was remeasured at $2.8 million as of September 30, 2023 and the Company recognized a gain on warrant liability in the amount of $4.0 million in the condensed consolidated statements of operations during the three months ended September 30, 2023.

At-The-Market Sales Agreement and Offering

In November 2021, the Company entered into an At Market Issuance Sales Agreement ("ATM Sale Agreement") with B. Riley Securities, Inc., BTIG, LLC, and H.C. Wainwright & Co. LLC ("Agents"), pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to $90.0 million from time to time, in “at the market” offerings through the Agents. In connection with the November 2022 Offering, the aggregate price was reduced to $70.0 million. The Company further reduced the aggregate offering price to $12.0 million in connection with the June 2023 Offering. As of October 9, 2023, the aggregate offering price was increased to $37.6 million. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agents. The Agents will receive a commission from the Company of up to 3.0% of the gross proceeds of any shares of common stock sold under the ATM Sale Agreement. The following table provides information on the shares sold under the ATM Sale Agreement for the three and nine months ended September 30, 2023 and 2022.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net proceeds (in millions)	$ 0.2	$ 1.8	$ 12.7	$ 6.6
Number of shares	82,916	110,293	2,936,025	264,535
Weighted average purchase price	$ 2.19	$ 17.09	$ 4.54	$ 31.90

Preferred Stock

Pursuant to the Company’s eighth amended and restated certificate of incorporation, which went into effect immediately prior to the completion of the IPO, the Company was authorized to issue 10,000,000 shares of undesignated preferred stock. This amount and the par value of preferred stock remained unchanged after the Reverse Stock Split.

On November 10, 2022, the Board declared a dividend of one one-thousandth of a share of Series X Preferred Stock, par value $0.001 per share (“Series X Preferred Stock”), for each outstanding share of common stock to stockholders of record as of November 21, 2022. This Series X Preferred Stock entitled its holders to 3,000 votes per share exclusively on the vote for the proposal to approve the Reverse Stock Split. All shares of Series X Preferred Stock that were not present to vote on the Reverse Stock Split were redeemed by the Company (the “Initial Redemption”). Any outstanding shares of Series X Preferred Stock that were not redeemed pursuant to an Initial Redemption would be redeemed in whole, but not in part, (i) if such redemption is ordered by the Board in its sole discretion, automatically and effective on such time and date specified by the Board in its sole discretion or (ii) automatically upon the effectiveness of the Certificate of Amendment implementing the Reverse Stock Split. At the December 19, 2022 special meeting of the Company's stockholders, the holders of 136,961 shares of Series X Preferred Stock were represented in person or by proxy. Immediately prior to the special meeting, all 86,210 shares of Series X Preferred Stock that were not voted were redeemed. The remaining 136,961 outstanding shares of Series X Preferred Stock were redeemed automatically upon the effectiveness of the Certificate of Amendment on January 3, 2023.

On January 9, 2023, the Company filed a Certificate of Elimination of Series X Preferred Stock with the Secretary of State of the State of Delaware, which, effective immediately upon filing, eliminated all matters set forth in the Certificate of Designation of Series X Preferred Stock filed with the Secretary of State of the State of Delaware on November 21, 2022.

11. Stock-Based Compensation

In February 2018, the Company adopted the 2018 Equity Incentive Plan (“2018 Plan”). The 2018 Plan is the successor to and continuation of the Second Amended and Restated 2012 Stock Plan (“2012 Plan”) and is administered with either stock options or restricted stock units. The Board of Directors administers the plans. Upon adoption of the 2018 Plan, no new stock options or awards are issuable under the 2012 Plan, as amended. The 2018 Plan also provides for other types of equity to issue awards, which at this time the Company does not plan to utilize.

On June 14, 2023, the Company’s stockholders approved the Fifth Amended and Restated 2018 Equity Incentive Plan ("2018 Fifth Amended Plan"), which includes an increase of 5,500,000 shares of common stock reserved for issuance. As of September 30, 2023, 3,307,228 shares were available for issuance under the 2018 Fifth Amended Plan.

On November 3, 2021, the Board of Directors approved and adopted the Company’s 2021 Inducement Plan ("2021 Inducement Plan") to provide for the reservation of 260,000 shares of the Company’s common stock to be used exclusively for the grant of awards to individuals not previously an employee or non-employee director of the Company. As of September 30, 2023, 63,964 shares were available for grant under the 2021 Inducement Plan.

Stock Options

The following table summarizes stock option activity, which includes Performance Awards, under the 2012 Plan, the 2018 Fourth Amended Plan and the 2021 Inducement Plan during the nine months ended September 30, 2023:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2022	582,557	$ 59.89		
Options granted	229,800	$ 3.88		
Options exercised	—	$ —		
Options forfeited/cancelled	(26,446)	$ 40.86		
Options expired	(53,414)	$ 126.54		
Balance at September 30, 2023	732,497	$ 38.14	8.3	$ —
Vested and expected to vest at September 30, 2023	732,497	$ 38.14	8.3	$ —
Vested and exercisable at September 30, 2023	245,870	$ 69.44	7.4	$ —

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options granted during the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
Risk-free interest rate	3.5% - 4.4%	2.0% - 3.6%
Expected volatility	98.5% - 102.7%	90.7% - 101.3%
Expected dividend yield	—%	—%
Expected life (years)	5.5 - 6.3 years	5.5 - 6.3 years

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2023 and 2022 was $2.88 per option and $19.18 per option, respectively.

Restricted Stock Units

The following table summarizes restricted stock unit ("RSU") activity for the nine months ended September 30, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	278,112	$ 38.95
Granted	3,703,321	$ 3.09
Vested	(1,368,060)	$ 9.63
Forfeited/cancelled	(48,857)	$ 10.40
Balance at September 30, 2023	2,564,516	$ 3.35

In August 2023, the Board of Directors approved the acceleration of vesting of all unvested, outstanding RSUs. As a result of this modification, an additional $7.9 million of stock-based compensation expense was recognized during the three months ended September 30, 2023.

2020 Employee Stock Purchase Plan

In June 2020, the Company’s board of directors adopted the ESPP with 20,400 shares of common stock reserved for future issuance under the ESPP. The ESPP also provides for automatic annual increases in the number of shares of common stock reserved for issuance. As of September 30, 2023, there were 71,450 total shares of common stock reserved for future issuance. The ESPP was suspended on November 6, 2022. All employee payroll withholdings related to the ESPP were either reimbursed or shares were purchased subsequent to the suspension of the program.

Stock-Based Compensation Expense

The following table presents total stock-based compensation expense included in each functional line item in the accompanying condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	4,680	826	6,308	1,882
Selling, general and administrative	5,851	1,313	8,621	3,756
Total stock-based compensation expense	$ 10,531	$ 2,139	$ 14,929	$ 5,638

At September 30, 2023 there was $7.5 million of compensation cost related to unvested stock options expected to be recognized over a remaining weighted average vesting period of 2.6 years and $8.1 million of compensation cost related to unvested RSUs expected to be recognized over a remaining weighted average vesting period of 3.8 years.

12. Income Taxes

The Company calculates its interim income tax provision in accordance with ASC Topic 270, *Interim Reporting*, and ASC Topic 740, *Accounting for Income Taxes*. At the end of each interim period, management estimates the annual effective tax rate and applies such rate to the Company's ordinary quarterly earnings to calculate income tax expense related to ordinary income. The Company's effective tax rate was 0.0% for both the three and nine months ended September 30, 2023. The Company's effective tax rate was 1.0% and effective tax benefit was 1.9% for the three and nine months ended September 30, 2022, respectively. The change in the effective tax rate from September 30, 2022 to September 30, 2023 relates to prior year federal and state income tax refunds. The Company's effective tax rate differs from the federal statutory rate of 21% in each period primarily due to the Company's net loss position and valuation allowance. The tax effects of items significant, unusual and infrequent in nature are discretely calculated and recognized in the period during which they occur.

The Company's net operating loss carryforwards and research and development expenditure credit carryforwards may be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions if the Company experiences an ownership change within the meaning of such Code sections. In general, an ownership change, as defined by Sections 382 and 383 of the Code, occurs when there is a 50 percentage points or more shift in ownership, consisting of shareholders owning more than 5% in the Company, occurring within a three-year testing period. The Company performed a formal study through the date of the IPO and determined future utilization of tax attribute carryforwards were not limited per Section 382 of the Internal Revenue Code. The Company has not updated its Section 382 study since the IPO offering in 2020. However, because the Company has raised and expects to continue to raise significant amounts of equity, the Company expects that Section 382 will limit future utilization of tax attribute carryforwards. Due to the existence of the valuation allowance, limitations created by ownership changes do not impact the Company's effective tax rate.

13. Net Loss Per Share

The table below provides potentially dilutive securities in equivalent shares of common stock not included in the Company's calculation of diluted loss per share because to do so would be antidilutive:

	September 30, 2023	September 30, 2022
Stock options to purchase common stock	732,497	587,052
Restricted stock units	2,564,516	298,190
Common stock warrants and pre-funded warrants	29,474,198	1,047,353
Common stock issuable upon conversion of Convertible Notes	1,011,926	1,623,546
Total	33,783,137	3,556,141

14. Subsequent Events

On October 10, 2023, the Company issued a warrant to purchase up to 1,000,000 shares of the Company's common stock, with an exercise price of $1.93 per share, to an accredited investor in a private placement transaction. The warrant is exercisable six months following the date of issuance. The investor may from time to time agree to acquire, and the Company may agree to sell, up to an aggregate of $1.9 million of common stock any time prior to January 31, 2024. The warrant will vest in proportion to issuances

described in the preceding sentence. Neither the investor nor the Company has any obligation to agree to or consummate any such issuances.

On October 12, 2023, the Company issued a warrant to purchase up to 4,278,074 shares of the Company's common stock, with an exercise price of $1.87 per share, to an accredited investor in a private placement transaction. The warrant is exercisable six months following the date of issuance. The investor may from time to time agree to acquire, and the Company may agree to sell, up to an aggregate of $8.0 million of common stock any time prior to January 31, 2024. The warrant will vest in proportion to issuances described in the preceding sentence. Neither the investor nor the Company has any obligation to agree to or consummate any such issuances.

From October 1, 2023 through November 7, 2023, the Company received net proceeds of $1.2 million, after deducting commissions and other offering expenses, from the sale of 750,350 shares under the ATM Sale Agreement. The Company sold such shares at a weighted average purchase price of $1.69 per share.

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

General

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and notes thereto and other financial information included elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2022 included in our Annual Report on Form 10-K ("Annual Report"). Unless the context requires otherwise, references in this Quarterly Report to "we," "us," and "our" refer to Biora Therapeutics, Inc.

This Quarterly Report includes forward-looking statements that involve a number of risks, uncertainties and assumptions. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "estimate," "predict," "potential," "continue," "likely," "target," "forecast," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the Securities and Exchange Commission (the "SEC"). These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified below and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.

Overview

We are a biotechnology company developing oral biotherapeutics that could enable new treatment approaches in the delivery of therapeutics. Our therapeutics pipeline includes two therapeutic delivery platforms:

- NAVICAP™ Targeted Oral Delivery Platform: Targeted oral delivery of therapeutics to the site of disease in the gastrointestinal tract designed to improve outcomes for patients with Inflammatory Bowel Disease; and
- BIOJET™ Systemic Oral Delivery Platform: Systemic oral delivery of biotherapeutics designed to replace injections with needle-free, oral delivery of large molecules for better management of chronic diseases.

Our historical operations included a licensed Clinical Laboratory Improvement Amendments and College of American Pathologists certified laboratory specializing in the molecular testing markets serving women's health providers in the obstetric, gynecological, fertility, and maternal fetal medicine specialty areas. Previously, our core business was focused on carrier screening and noninvasive prenatal test market, targeting preconception planning and routine pregnancy management for genetic disease risk assessment. Through our former affiliation with Mattison Pathology, LLP, a Texas limited liability partnership doing business as Avero Diagnostics ("Avero"), our historical operations also included anatomic and molecular pathology testing products in the United States.

Common Stock Reverse Split

On December 29, 2022, we filed a certificate of amendment to our eighth amended and restated certificate of incorporation (the "Certificate of Amendment") to effect, as of January 3, 2023, a 1-for-25 reverse split of our common stock. The Certificate of Amendment also decreased the number of authorized shares of our common stock from 350,000,000 to 164,000,000. All shares, options, restricted stock units, warrants and per share amounts included in this Quarterly Report have been retroactively adjusted to reflect the stock split.

Factors Affecting Our Performance

In June 2021, we announced a strategic transformation ("Strategic Transformation") pursuant to which we have refocused our efforts on our robust research and development pipeline to better position the business for future growth. The Strategic Transformation

included the closure of our genetics laboratory in Ann Arbor, Michigan, the sale of our Avero laboratory business, a reduction in force and other cost-cutting measures and operational improvements, together referred to as the Laboratory Operations.

We are engaged in research and development activities with respect to therapeutics product candidates. Following the Strategic Transformation, we are devoting substantially all of our resources to developing and perfecting our intellectual property rights, conducting research and development activities (including undertaking preclinical and clinical studies of our therapeutics product candidates), conducting clinical trials of our most advanced therapeutics product candidates, organizing and staffing our company, business planning and raising capital. We do not have any therapeutics products approved for sale, and we have not generated any revenue from therapeutics product sales.

Our business involves significant investment in research and development activities for the development of new products. We intend to continue investing in our pipeline of new products and technologies. We expect our investment in research and development to increase as we pursue regulatory approval of our targeted therapeutics and systemic therapeutics product candidates. The achievement of key development milestones is a key factor in evaluating our performance.

We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses may increase in connection with our ongoing activities as we:

- continue to advance the preclinical and clinical development of our lead targeted therapeutics and systemic therapeutics product candidates;
- initiate preclinical studies and clinical trials for additional targeted therapeutics and systemic therapeutics product candidates that we may identify in the future;
- increase personnel and infrastructure to support our clinical development, research and manufacturing efforts;
- build out and expand our in-house process development and engineering and manufacturing capabilities for R&D and clinical purposes;
- continue to develop, perfect and defend our intellectual property portfolio; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

We do not expect to generate significant product revenue unless and until we successfully complete development and obtain regulatory and marketing approval of, and begin to sell, one or more of our targeted therapeutics and systemic therapeutics product candidates, which we expect will take several years. We expect to spend a significant amount in development costs prior to such time. We may never succeed in achieving regulatory and marketing approval for our therapeutics product candidates. We may obtain unexpected results from our preclinical and clinical trials. We may elect to discontinue, delay or modify preclinical and clinical trials of our therapeutics product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. Accordingly, until such time as we can generate significant product revenue, if ever, we expect to continue to seek private or public equity and debt financing to meet our capital requirements. There can be no assurance that such funding may be available to us on acceptable terms, or at all, or that we will be able to commercialize our therapeutics product candidates. In addition, we may not be profitable even if we commercialize any of our therapeutics product candidates.

Key Components of Our Results of Operations

We are providing the following summary of our revenues, research and development expenses and selling, general and administrative expenses to supplement the more detailed discussion below. This summary excludes our revenues, research and development expenses, selling and marketing, general and administrative and other expenses associated with our Laboratory Operations, which are reported within loss from discontinued operations.

Revenue

Historically, all of our revenue has been derived from molecular laboratory tests, principally from the sale of non-invasive prenatal tests, genetic carrier screening, and pathology molecular testing. If our development efforts for our targeted therapeutics and systemic therapeutics product candidates are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for any of our therapeutic product candidates, other pipeline products or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our

therapeutics product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for any of our therapeutics product candidates.

Research and Development

Research and development expenses consist primarily of costs associated with developing our therapeutics product candidates. Research and development expenses also consist of personnel expenses, including salaries, bonuses, stock-based compensation expense, benefits, consulting costs, and allocated overhead costs. Research and development costs are expensed as incurred.

We plan to continue investing in research and development activities for the foreseeable future as we focus on our targeted therapeutics and systemic therapeutics programs through preclinical studies and clinical trials. We expect our investment in research and development to remain relatively flat as we pursue regulatory approval of our product candidates.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. While we plan to partner with large pharmaceutical companies, especially for the later stage clinical work, we still expect our research and development expenses to increase over the next several years as we conduct additional preclinical studies and clinical trials, including later-stage clinical trials, for our current and future product candidates and pursue regulatory approval of our product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including:

- the safety and efficacy of our product candidates;
- early clinical data for our product candidates;
- investment in our clinical programs;
- the ability of collaborators to successfully develop our licensed product candidates;
- competition;
- manufacturing capability; and
- commercial viability.

We may never succeed in achieving regulatory approval for any of our product candidates due to the uncertainties discussed above. We are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if ever.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel costs, including salaries, bonuses, stock-based compensation expense, and benefits, for our finance and accounting, legal, human resources, and other administrative teams. Additionally, these expenses include costs for communications, conferences, and professional fees of audit, legal, and recruiting services. Additionally, expenses related to maintaining compliance with the stipulations of the government settlement and the legal costs associated with the legal matters described in Note 9, "Commitments and Contingencies."

Interest Expense, Net

Interest expense, net is primarily attributable to borrowings under our credit and security agreement, lease agreements and interest income earned from our cash and cash equivalents.

Gain on Warrant Liabilities

Gain on warrant liabilities consists of changes in the fair value of our liability-classified warrants to purchase common stock.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of inducement loss on our Convertible Notes, impairment of property and equipment, and loss on disposals of property and equipment.

Income Tax Provision

We account for income taxes under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We recognize the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is more than 50% likely of being realized. Changes in recognition or measurement are recognized in the period in which the change in judgment occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. Due to losses generated in the past and projected future taxable losses anticipated in the future, we established a 100% valuation allowance on net deferred tax assets.

Results of Operations.

Comparison of the Three and Nine Months Ended September 30, 2023 and 2022

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	Change	2023	2022	Change
	(in thousands)			(in thousands)		
Statement of Operations Data:	(unaudited)			(unaudited)		
Revenues	$ —	$ 80	$ (80)	$ 4	$ 291	$ (287)
Operating expenses:						
Research and development	10,547	5,820	4,727	23,720	18,282	5,438
Selling, general and administrative	12,774	8,147	4,627	30,083	30,014	69
Total operating expenses	23,321	13,967	9,354	53,803	48,296	5,507
Loss from operations	(23,321)	(13,887)	(9,434)	(53,799)	(48,005)	(5,794)
Interest expense, net	(2,592)	(2,773)	181	(7,975)	(8,305)	330
Gain on warrant liabilities	4,568	2,044	2,524	5,271	15,446	(10,175)
Other (expense) income, net	(52,108)	(100)	(52,008)	(52,194)	4,824	(57,018)
Loss before income taxes	(73,453)	(14,716)	(58,737)	(108,697)	(36,040)	(72,657)
Income tax expense (benefit)	1	158	(157)	5	(679)	684
Loss from continuing operations	(73,454)	(14,874)	(58,580)	(108,702)	(35,361)	(73,341)
Gain from discontinued operations	—	9,760	(9,760)	—	10,926	(10,926)
Net loss	$ (73,454)	$ (5,114)	$ (68,340)	$ (108,702)	$ (24,435)	$ (84,267)

Research and Development Expenses

Research and development expenses increased by $4.7 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, primarily due to an increase in salaries and benefits attributable to the accelerated vesting of unvested RSU awards and an increase in consulting and professional fees. For the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, research and development expenses increased by $5.4 million, primarily due to an increase in salaries and benefits attributable to the accelerated vesting of unvested restricted stock unit ("RSU") awards, an increase in consulting and professional fees and the cost of supplies, offset by a decrease in facilities costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $4.6 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, primarily due to an increase in salaries and benefits attributable to the accelerated vesting of unvested RSU awards, an increase in consulting and professional fees, offset by a decrease in business insurance, facilities and software costs. For the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, selling, general and administrative expenses remained consistent.

Gain on Warrant Liabilities

Gain on warrant liabilities increased by $2.5 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 due to the change in fair value of the warrant liabilities for outstanding warrants. For the nine

months ended September 30, 2023 compared to the nine months ended September 30, 2022, gain on warrant liabilities decreased by $10.2 million, due to the change in fair value of the warrant liabilities for outstanding warrants.

Other (Expense) Income, Net

Other (expense) income, net increased by $52.0 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, primarily due to an inducement loss on our Convertible Notes (defined below), offset by an increase in income related to the sale of preeclampsia assets and intellectual property. The change in other (expense) income, net of $57.0 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 is primarily due to an inducement loss on our Convertible Notes and a gain on investment in Enumera Molecular, Inc. ("Enumera") for the nine months ended September 30, 2022 that did not reoccur in 2023, offset by an increase in income related to the sale of preeclampsia assets and intellectual property and a decrease in loss on asset disposal and impairment of property and equipment.

Income Tax Expense (Benefit)

Income tax expense (benefit) decreased by $0.2 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 primarily due to prior year deferred tax expense that did not reoccur in 2023. For the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, income tax expense (benefit) increased by $0.7 million, primarily due to federal and state income tax refunds that did not reoccur in 2023, offset by prior year deferred tax expense that did not reoccur in 2023.

Discontinued Operations

The decrease in gain from discontinued operations for the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 was due to the closure of our Laboratory Operations during 2021. See Note 3 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information regarding discontinued operations.

Liquidity and Capital Resources.

Since our inception, our primary sources of liquidity have been generated by our operations, sales of common stock, preferred stock, warrants to purchase common stock and preferred stock, and cash from debt financings, including our convertible senior notes ("Convertible Notes").

As of September 30, 2023, we had $7.8 million of cash and cash equivalents, restricted cash of $4.8 million and $80.4 million of Convertible Notes, net outstanding. Our accumulated deficit as of September 30, 2023 was $935.5 million. For the nine months ended September 30, 2023, we had a net loss of $108.7 million and cash used in operations of $34.8 million. Our primary requirements for liquidity have been to fund our working capital needs, capital expenditures, research and development, and general corporate needs.

Based on our planned operations, we do not expect that our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months from the issuance date of the condensed consolidated financial statements for the three and nine months ended September 30, 2023, and we will require additional capital to fund our operations. As a result, substantial doubt exists about our ability to continue as a going concern for 12 months following the issuance date of the condensed consolidated financial statements for the three and nine months ended September 30, 2023. We therefore intend to raise additional capital through equity offerings, including in "at the market" offerings pursuant to our At Market Issuance Sales Agreement ("ATM Sale Agreement") and/or debt financings or from other potential sources of liquidity, which may include new collaborations, licensing or other commercial agreements for one or more of our research programs or patent portfolios. Adequate funding, if needed, may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. If any of these events occur, our ability to achieve our operational goals would be adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in “Risk Factors.” Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on terms favorable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from global political tensions and economic uncertainty.

Convertible Notes

See Note 7 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for information on our Convertible Notes.

Equity Financings

See Note 10 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for information on our equity financings.

Cash Flows

Our primary uses of cash are to fund our operations and research and development as we continue to grow our business. We expect to continue to incur operating losses in future periods as our operating expenses increase to support the growth of our business. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Cash used in operating activities	$ (34,754)	$ (53,399)
Cash used in investing activities	(26)	(720)
Cash provided by financing activities	16,863	2,782

Operating Activities

Net cash used in operating activities in the nine months ended September 30, 2023 was primarily attributable to a $108.7 million net loss, adjusted for non-cash charges of $64.5 million, primarily driven by a $53.2 million inducement loss, $14.9 million of stock-based compensation expense, $1.1 million of debt discount amortization and non-cash interest, $0.4 million of depreciation and amortization and $0.1 million of property and equipment impairment, partially offset by a $5.3 million change in fair value related to the warrant liability. The net cash inflow from changes in operating assets and liabilities was attributable to a $10.0 million increase in accrued expenses, a $0.7 million decrease in prepaid and other current assets and a $0.3 million increase in accounts payable, offset by a $1.6 million decrease in other long-term liabilities.

Net cash used in operating activities in the nine months ended September 30, 2022 was primarily attributable to a $24.4 million net loss, adjusted for a $10.9 million gain from discontinued operations and non-cash charges, primarily driven by a $15.4 million change in fair value related to the warrant liability and $5.7 million gain on investment in Enumera, partially offset by $5.6 million of stock-based compensation expense, $1.0 million of debt discount amortization, $0.7 million of depreciation and amortization, $0.5 million of fixed asset impairment and $0.5 million of loss on disposal of fixed assets. The net cash outflow from changes in operating assets and liabilities was attributable to a $6.4 million decrease in accounts payable, a $1.5 million decrease in other long-term liabilities, and a $56,000 decrease in accrued expenses and other current liabilities, offset by a $1.4 million increase in prepaid expenses and other current assets. Additionally, net cash provided by operating activities from discontinued operations contributed $11.6 million of inflows.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2023 was less than $0.1 million. Net cash used in investing activities for the nine months ended September 30, 2022 was attributable to $0.7 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2023 was primarily attributable to $13.1 million in proceeds from the issuance of common stock and $8.0 million in proceeds from the issuance of warrants, partially offset by $2.0 million in tax payments to settle RSUs, $1.8 million in payments for insurance financing and $0.5 million in payments of offering costs. Net cash provided by financing activities during the nine months ended September 30, 2022 was primarily attributable to $6.5 million in net proceeds from the issuance of common stock, partially offset by $3.7 million in payments for insurance financing.

Other Contractual Obligations and Commitments

See Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information. There have been no other material changes from the contractual obligations and commitments disclosed in our Annual Report.

Critical Accounting Policies and Significant Judgments and Estimates.

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with GAAP. The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions about future events that affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenue and expenses. These estimates and assumptions are based on management's best estimates and judgment. Management regularly evaluates its estimates and assumptions using historical experience and other factors; however, actual results could differ materially from these estimates and could have an adverse effect on our financial statements.

During the nine months ended September 30, 2023, there were no significant changes to the information discussed under "Critical Accounting Policies and Significant Judgments and Estimates" included in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report.

Recent Accounting Pronouncements.

Refer to Note 2, "Summary of Significant Accounting Policies" to the condensed consolidated financial statements included in this Quarterly Report for information on recently issued accounting pronouncements.

JOBS Act Accounting Election.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose 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, as appropriate, to allow timely decisions regarding required disclosure.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the quarter ended September 30, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

The information in Note 9, "Commitments and Contingencies" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q is incorporated herein by reference. There are no matters which constitute material pending legal proceedings to which we are a party other than those incorporated into this item by reference to Note 9 to the condensed consolidated financial statements for the quarter ended September 30, 2023 contained in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including "Management's Discussion & Analysis" and the financial statements and related notes, before deciding to make an investment decision with respect to shares of our common stock. If any of the following risks actually occurs, our business, financial condition, operating results, reputation, and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Quarterly Report on Form 10-Q may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks. In this "Risk Factors" section, unless the context requires otherwise, references to "we," "us," "our," "Biora," "Biora Therapeutics" or the "company" refer to Biora Therapeutics, Inc. and its subsidiaries.

Risk Factor Summary

- We have incurred losses in the past, expect to incur losses in the future, have limited capital resources as disclosed in this Quarterly Report, and we may not be able to continue operations or achieve or sustain profitability in the future.
- Operating our business will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control. An adverse judgment and/or significant damage award against us resulting from our pending litigation matters that we are currently defending would negatively impact our financial position and our ability to raise additional capital. We expect to need to raise additional capital, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.
- We rely on a limited number of suppliers or, in some cases, single suppliers, and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.
- The manufacturing of our therapeutics product candidates, and other products under development, is highly exacting and complex, and we depend on third parties to supply materials and manufacture certain products and components.
- We operate in a highly competitive business environment.
- Our success depends on our ability to develop new product candidates, which is complex and costly and the results are uncertain.
- We are still developing our therapeutics pipeline and are in the early stages of its development, have conducted some early preclinical studies, and limited early clinical studies, and to date have generated no therapeutics products or product revenue. There can be no assurance that we will develop any therapeutics products that deliver therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.
- Our outstanding debt, and any new debt, may impair our financial and operating flexibility.
- We may not be able to obtain and maintain the third-party relationships that are necessary to develop, fund, commercialize, and manufacture some or all of our product candidates.
- If third-party payors do not adequately reimburse for our products under development, they might not be purchased or used, which may adversely affect our revenue and profitability.
- If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.
- New third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products.

Risks Related to Our Business and Industry

We have incurred losses in the past, expect to incur losses in the future, have limited capital resources as disclosed in this Quarterly Report, and we may not be able to continue operations or achieve or sustain profitability in the future.

We expect to incur significant costs in connection with the development, approval, and commercialization of our products under development. Even if we succeed in creating such product candidates from these investments, those innovations still may fail to result in commercially successful products.

Other than potential revenues from partnerships similar to those we have entered into in the past, we do not expect to generate significant revenues in the immediate future. We do not expect to generate sufficient revenue to cover our costs for the foreseeable future, including research and development and clinical study expenses related to furthering our product pipeline, and expect to incur losses in the future. We may not generate significant revenue in the future until we are able to achieve commercialization of our product candidates or enter into licensing or collaboration agreements with respect to such product candidates.

Since we or any collaborators or licensees may not successfully develop product candidates, obtain required regulatory authorizations, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such product candidates with desired margins, our expenses may continue to exceed any revenues we may receive. Our operating expenses also will increase as and if, among other things:

- our earlier-stage product candidates move into later-stage clinical development, which is generally more expensive than early-stage development;
- additional technologies or products are selected for development;
- we pursue development of our product candidates for new uses;
- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products, or businesses.

Given our limited capital resources as disclosed elsewhere in the Quarterly Report, if we are not able to raise additional capital or generate revenue to fund our operations, we may not be able to continue operations or achieve or sustain profitability in the future.

Operating our business will require a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control. An adverse judgment and/or significant damage award against us resulting from our pending litigation matters that are currently defending would negatively impact our financial position and our ability to raise additional capital. We expect to need to raise additional capital, and if we cannot raise additional capital when needed, we may have to curtail or cease operations.

We expect to incur significant costs in connection with our operations, including, but not limited to, the research and development, marketing authorization, and/or commercialization of new medical devices, therapeutics, and other products. These development activities generally require a substantial investment before we can determine commercial viability, and the proceeds from our offerings to date will not be sufficient to fully fund these activities. In addition, as a result of the Strategic Transformation, our revenue has been substantially eliminated. We will need to raise additional funds through public or private equity or debt financings, collaborations, licensing arrangements or sales of assets to continue to fund or expand our operations. Following the Strategic Transformation, we no longer generate revenue from our historical testing business, and we would be dependent on such additional sources of capital, including public or private equity or debt financings, collaborations, licensing arrangements or sales of assets for all of our future capital requirements if we do not achieve commercialization of our product candidates.

Our actual liquidity and capital funding requirements will depend on numerous factors, including:

- the scope and duration of and expenditures associated with our discovery efforts and research and development programs for our therapeutics pipeline;
- the costs to fund our commercialization strategies for any product candidates for which we receive marketing authorization or otherwise launch and to prepare for potential product marketing authorizations, as required;
- the costs of any acquisitions of complementary businesses or technologies that we may pursue;
- potential licensing or partnering transactions, if any;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;

- the scope and extent of any future sales and marketing efforts;
- pending and potential litigation and any resulting adverse judgments, damages awards or liabilities, potential payor recoupments of reimbursement amounts as related to our historical testing business, and other contingencies;
- the commercial success of our future products;
- the termination costs associated with our Strategic Transformation; and
- any proceeds from strategic transactions.

The availability of additional capital, whether from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and market conditions in general change. There may be times when the private capital sources and the public capital markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, or at all, in which case we would not be able to access capital from these sources. In addition, a weakening of our financial condition, a further decline in our share price or a deterioration in our credit ratings could adversely affect our ability to obtain necessary funds. Even if available, additional financing could be costly or have adverse consequences.

Additional capital, if needed, may not be available on satisfactory terms or at all. Our ability to raise capital in the public capital markets, including through our ATM Facility, may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Furthermore, any additional capital raised through the sale of equity or equity-linked securities, including through our ATM Facility will dilute our stockholders' ownership interests and may have an adverse effect on the price of our common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

To minimize dilution to our equity holders, we are also exploring non-dilutive financing options, which could include licenses or collaborations and/or sales of certain assets or business lines. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us. To the extent that we raise additional funds through strategic transactions, including a sale of one of our lines of business, we may not ultimately realize the value of or synergies from such transactions and our long-term prospects could be diminished as a result of the divestiture of these assets. We may also be required to use some or all of these sale proceeds to pay down indebtedness, which would then not serve to increase our working capital.

If we are not able to obtain adequate funding when needed, we may be required to delay development programs or other initiatives. If we are unable to raise additional capital in sufficient amounts or on satisfactory terms, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development, and commercialization efforts and exploiting other corporate opportunities. In addition, it may be necessary to work with a partner on one or more of our product candidates, which could reduce the economic value of those products to us. If we engage in strategic transactions with respect to revenue-producing assets or business lines, our revenue may be adversely affected and such transactions could negatively affect the viability of our business. Each of the foregoing may harm our business, operating results, and financial condition, and may impact our ability to continue as a going concern.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

We rely on a limited number of suppliers or, in some cases, single suppliers, and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.

We source components of our technology from third parties and certain components are sole sourced. Obtaining substitute components may be difficult or require us to re-design our products under development, including those for which we are required to obtain marketing authorization from the U.S. Federal Drug Administration ("FDA") and would need to obtain a new marketing authorization from the FDA to use a new supplier. Any natural or other disasters, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at our third-party manufacturers' facilities that cause a loss of manufacturing capacity or a reduction in the quality or yield of the items manufactured would heighten the risks that we face. For example, our targeted therapeutics device under development includes complex components including circuit boards that have to be built to exacting standards, and the failure of a manufacturer to meet our requirements on time, as we have experienced in the past and continue to experience, could lead to delays in our plans for testing, pre-clinical and clinical studies and other development activities. Changes to, failure to renew or termination of our existing agreements or our inability to enter into new agreements with other suppliers could result in the loss of access to important components of our products under development and could impair, delay or suspend our commercialization efforts. Our failure to maintain a continued and cost-effective supply of high-quality components could materially and adversely harm our business, operating results, and financial condition.

The manufacturing of our therapeutics product candidates, and other products under development, is highly exacting and complex, and we depend on third parties to supply materials and manufacture certain products and components.

Manufacturing is highly exacting and complex due, in part, to strict regulatory requirements governing the manufacture of our future products and product candidates, including medical devices with complex components including, but not limited to, circuit boards and pharmaceutical products. We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborators and other third parties, including sole source suppliers, to provide raw materials meeting FDA quality standards and related regulatory requirements, manufacture devices, and drug substances, produce drug products and provide certain analytical services with respect to our products and product candidates. The FDA and other regulatory authorities require that many of our products be manufactured according to current good manufacturing practice ("cGMP") regulations and that proper procedures be implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborators, or our third-party manufacturers to comply with cGMP and/or scale-up manufacturing processes could lead to a delay in, or failure to obtain, marketing authorizations. In addition, such failure could be the basis for action by the FDA, including issuing a warning letter, initiating a product recall or seizure, fines, imposing operating restrictions, total or partial suspension of production or injunctions and/or withdrawing marketing authorizations for products previously granted to us. To the extent we rely on a third-party manufacturer, the risk of noncompliance with cGMP regulations may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

Moreover, we expect that certain of our therapeutics product candidates, including BT-600, BT-001, BT-200, and BT-002, are drug-device combination products that will be regulated under the drug and biological product regulations of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and Public Health Service Act (the "PHSA") based on their primary modes of action as drugs and biologics. Third-party manufacturers may not be able to comply with cGMP regulations, applicable to drug/device combination products, including applicable provisions of the FDA's drug and biologics cGMP regulations, device cGMP requirements embodied in the Quality System Regulation ("QSR"), or similar regulatory requirements outside the United States.

In addition, we or third parties may experience other problems with the manufacturing, quality control, yields, storage or distribution of our products, including equipment breakdown or malfunction, failure to follow specific protocols and procedures, problems with suppliers and the sourcing or delivery of raw materials and other necessary components, problems with software, labor difficulties, and natural disaster-related events or other environmental factors. These problems can lead to increased costs, delays to development and preclinical study timelines, lost collaboration opportunities, damage to collaborator relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. For example, our therapeutics devices under development includes complex components including circuit boards that have to be built to exacting standards, and the failure of a manufacturer to meet our requirements on time, as we have experienced in the past and continue to experience, could lead to delays in our plans for testing, pre-clinical and clinical studies and other development activities. If problems are not discovered before the product is released to the market, recalls, corrective actions, or product liability-related costs also may be incurred. Problems with respect to the manufacture, storage, or distribution of products could materially disrupt our business and have a material and adverse effect on our operating results and financial condition.

We may be unable to successfully divest certain assets or recover any of the costs of our investment in certain R&D programs.

In connection with our Strategic Transformation, we have divested certain assets that do not align with our current operational plans and strategies, including the sale of certain laboratory assets and the divesture of Avero. We have explored the potential divestiture and/or out-license of other assets and intellectual property as well. It is possible that we will be unable to successfully divest and/or license these assets, and we may never recover any of the costs of our historical R&D investments.

On May 4, 2022, we completed the divesture of our single-molecule detection platform and contributed all assets related to the single-molecule detection platform to newly-formed Enumera, which intends to develop and commercialize the platform. We received a minority ownership stake in Enumera in exchange for the assets. It is possible that the value of our equity stake in Enumera will decrease over time, and it is possible that we may never recover any of the costs of the historical R&D investments related to this platform.

Additionally, on November 29, 2022, we announced that we had signed an agreement to license our Preecludia™ rule-out test for preeclampsia to Avero Diagnostics (formerly known as Northwest Pathology) for commercial development in exchange for commercial milestone payments and royalties on net sales. There is no assurance that Avero will be able to successfully commercialize the test. As a result, there is no assurance that we will receive any payments from the transaction and we may never recover any of the costs of the historical R&D investments related to this program.

We operate in a highly competitive business environment.

The industries in which we operate are highly competitive and require an ongoing, extensive search for technological innovation. They also require, among other things, the ability to effectively develop, test, commercialize, market, and promote products, including communicating the effectiveness, safety, and value of products to actual and prospective healthcare providers. Other competitive factors in our industries include quality and price, product technology, reputation, customer service, and access to technical information.

We expect our future products, if approved, to face substantial competition from major pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and public and private research institutions. The larger competitors have substantially greater financial and human resources, as well as a much larger infrastructure than we do. For more information on our therapeutics competitors, see Part I, Item 1. “Business—Competition” in our Annual Report.

Additionally, we compete to acquire the intellectual property assets that we require to continue to develop and broaden our product pipeline. In addition to our in-house research and development efforts, we may seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing, and joint venture arrangements. Competitors with greater resources may acquire intellectual property that we seek, and even where we are successful, competition may increase the acquisition price of such intellectual property or prevent us from capitalizing on such acquisitions, licensing opportunities, or joint venture arrangements. If we fail to compete successfully, our growth may be limited.

It is possible that developments by our competitors could make our products or technologies under development less competitive or obsolete. Our future growth depends, in part, on our ability to provide products that are more effective than those of our competitors and to keep pace with rapid medical and scientific change. Sales of any future products may decline rapidly if a new product is introduced by a competitor, particularly if a new product represents a substantial improvement over our products. In addition, the high level of competition in our industry could force us to reduce the price at which we sell our products or require us to spend more to market our products.

Many of our competitors have greater resources than we have. This enables them, among other things, to spread their marketing and promotion costs over a broader revenue base. In addition, we may not be able to compete effectively against our competitors because their products and services are superior. Our current and future competitors could have greater experience, technological and financial resources, stronger business relationships, broader product lines and greater name recognition than us, and we may not be able to compete effectively against them. Increased competition is likely to result in pricing pressures, which could harm our revenues, operating income, or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenues or achieve or sustain profitability.

Our success depends on our ability to develop new product candidates, which is complex and costly and the results are uncertain.

Effective execution of research and development activities and the timely introduction of new products and product candidates to the market are important elements of our business strategy. However, the development of new products and product candidates is complex, costly, and uncertain and requires us to, among other factors, accurately anticipate patients’, clinicians’, and payors’ needs, and emerging technology trends. For more information on our current research and development efforts, see Part I, Item 1. “Business” in our Annual Report.

In the development of new products and product candidates, we can provide no assurance that:

- we will develop any products that meet our desired target product profile and address the relevant clinical need or commercial opportunity;
- any products that we develop will prove to be effective in clinical trials, platform validations, or otherwise;

- we will obtain necessary regulatory authorizations, in a timely manner or at all;
- any products that we develop will be successfully marketed to and ordered by healthcare providers;
- any products that we develop will be produced at an acceptable cost and with appropriate quality;
- our current or future competitors will not introduce products similar to ours that have superior performance, lower prices, or other characteristics that cause healthcare providers to recommend, and consumers to choose, such competitive products over ours; or
- third parties do not or will not hold patents in any key jurisdictions that would be infringed by our products.

These and other factors beyond our control could delay our launch of new products and product candidates.

The research and development process in our industries generally requires a significant amount of time from the research and design stage through commercialization. The launch of such new products requires the completion of certain clinical development and/or assay validations in a commercial laboratory. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals and will not be able to complete clinical development for any planned product in a timely manner. Such development and/or validation failures could prevent or significantly delay our ability to obtain FDA clearance or approval as may be necessary or desired or launch any of our planned products and product candidates. At times, it may be necessary for us to abandon a product in which we have invested substantial resources. Without the timely introduction of new product candidates, our future products may become obsolete over time and our competitors may develop products that are more competitive, in which case our business, operating results, and financial condition will be harmed.

We are still developing our therapeutics pipeline and are in the early stages of its development, have conducted some early preclinical studies, and limited early clinical studies, and to date have generated no therapeutics products or product revenue. There can be no assurance that we will develop any therapeutics products that deliver therapeutic solutions, or, if developed, that such product candidates will be authorized for marketing by regulatory authorities, or will be commercially successful. This uncertainty makes it difficult to assess our future prospects and financial results.

Our operations with respect to our therapeutics pipeline to date have been limited to developing our platform technology, undertaking preclinical studies and feasibility studies with human subjects, and conducting research to identify potential product candidates. To date, we have only conducted limited feasibility studies in humans to evaluate whether our platform localization technology enables identification of the location of our ingestible medical devices within the gastrointestinal tract as well as the function of our devices.

We seek to develop a suite of ingestible capsules for both therapeutic and diagnostic solutions. However, medical device and related therapeutic and diagnostic product development is a highly speculative undertaking and involves a substantial degree of uncertainty and we are in the early stages of our development programs. Our therapeutics pipeline has not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as ours. Consequently, the ability to accurately assess the future operating results or business prospects of our therapeutics pipeline is significantly more limited than if we had an operating history or approved commercial therapeutics products. Our success in developing commercial products that are based on our therapeutics pipeline will depend on a variety of factors, many of which are beyond our control, including, but not limited to:

- the outcomes from our product development efforts;
- competition from existing products or new products;
- the timing of regulatory review and our ability to obtain regulatory marketing authorizations of our product candidates;
- potential side effects of our product candidates that could delay or prevent receipt of marketing authorizations or cause an approved or cleared product to be taken off the market;
- our ability to attract and retain key personnel with the appropriate expertise and experience to potentially develop our product candidates; and
- the ability of third-party manufacturers to manufacture our product candidates in accordance with cGMP, for the conduct of clinical trials and, if approved or cleared, for successful commercialization.

Even if we are able to develop one or more commercial therapeutics products, we expect that the operating results of these products will fluctuate significantly from period to period due to the factors above and a variety of other factors, many of which are beyond our control, including, but not limited to:

- market acceptance of our product candidates, if approved or cleared;

- our ability to establish and maintain an effective sales and marketing infrastructure for our products;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability, as well as the ability of any third-party collaborators, to obtain, maintain and enforce intellectual property rights covering our products, product candidates and technologies, and our ability to develop, manufacture and commercialize our products, product candidates, and technologies without infringing on the intellectual property rights of others; and
- our ability to attract and retain key personnel with the appropriate expertise and experience to manage our business effectively.

Accordingly, the likelihood of the success of our therapeutics pipeline must be evaluated in light of these many potential challenges and variables.

The development of new product candidates will require us to undertake clinical trials, which are costly, time-consuming, and subject to a number of risks.

The development of new product candidates, including development of the data necessary for IND submissions and to obtain clearance or approval for such product candidates, is costly, time-consuming, and carries with it the risk of not yielding the desired results. Once filed, our IND submissions may not become effective if the FDA raises concerns with respect to those submissions. Further, the outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and even if we achieve positive results in earlier trials, we could face similar setbacks. The design of a clinical trial can determine whether its results will support a product candidate's marketing authorization, to the extent required, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing authorization for the product candidates. Furthermore, limited results from earlier-stage studies may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period of time.

Unfavorable results from ongoing preclinical studies and clinical trials could result in delays, modifications, or abandonment of ongoing or future analytical or clinical trials, or abandonment of a product development program, or may delay, limit, or prevent marketing authorizations, where required, or commercialization of our product candidates. Even if we, or our collaborators, believe that the results of clinical trials for our product candidates warrant marketing authorization, the FDA and other regulatory authorities may disagree and may not grant marketing authorizations for our product candidates.

Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as the Good Clinical Practice ("GCP"), requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety, and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, enforcement action, adverse publicity, and civil and criminal sanctions.

The initiation and completion of any clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in initiation or completion of our clinical trials for a number of reasons, which could adversely affect the costs, timing, or success of our clinical trials, including related to the following:

- we may be required to submit an investigational device exemption ("IDE"), application to the FDA with respect to our medical device product candidates, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards ("IRBs"), or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators may have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks or based on a requirement or recommendation from regulators, IRBs or other parties due to safety signals or noncompliance with regulatory requirements;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- marketing authorization policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for authorization; and
- our product candidates may have undesirable side effects or other unexpected characteristics.

Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our product candidates. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be also conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with the FDA's GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP requirements, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

The clinical trial process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our product candidates. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products or product candidates.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned, or future products and product candidates may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

Interim "top-line" and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could seriously harm our business.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our results of operations, liquidity and financial condition. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain marketing authorization for, and commercialize, product candidates may be harmed, which could seriously harm our business.

The results of our clinical trials may not support the use of our product candidates, or may not be replicated in later studies required for marketing authorizations.

As the healthcare reimbursement system in the United States evolves to place greater emphasis on comparative effectiveness and outcomes data, we cannot predict whether we will have sufficient data, or whether the data we have will be presented to the satisfaction of any payors seeking such data for determining coverage for our products under development, particularly in new areas such as in drug-device combination or therapeutic applications.

The administration of clinical and economic utility studies is expensive and demands significant attention from certain members of our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community or payors. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our products would suffer and our business would be harmed.

Peer-reviewed publications regarding our product candidates may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies, as well as delays in the review, acceptance, and publication process. If our products under development or the underlying technology do not receive sufficient favorable exposure in peer-reviewed publications, or are not published, the rate of healthcare provider adoption of our products under development and positive reimbursement coverage decisions for our products under development could be negatively affected. The publication of clinical data in peer-reviewed journals can be a crucial step in commercializing and obtaining reimbursement for products under development, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test or other product that is the subject of a study. The performance achieved in published studies might not be

repeated in later studies that may be required to obtain FDA clearance or marketing authorizations should we decide for business reasons, or be required to submit applications to the FDA or other health authorities seeking such authorizations.

Our outstanding debt, and any new debt, may impair our financial and operating flexibility.

As of September 30, 2023, we had approximately $80.4 million of Convertible Notes outstanding. Certain of our debt agreements contain various restrictive covenants.

The Indenture for our Convertible Notes does not prohibit us or our subsidiaries from incurring additional indebtedness in the future, with certain exceptions. Under the Convertible Notes, we will not, and we will not permit any subsidiary of ours to, create, incur, assume or permit to exist any lien on any property or asset now owned or later acquired by us or any subsidiary that secures any indebtedness for borrowed money, other than (i) secured indebtedness for borrowed money in existence on the date of the Indenture; (ii) permitted refinancing indebtedness incurred in exchange for, or the net proceeds of which are used to renew, refund, refinance, replace, defease or discharge any secured indebtedness for borrowed money permitted by clause (i) of this sentence; and (iii) additional secured indebtedness for borrowed money that, in an aggregate principal amount (or accredited value, as applicable), does not exceed $15.0 million at any time outstanding.

Accordingly, we may incur a significant amount of additional indebtedness in the future. Our current indebtedness and the incurrence of additional indebtedness could have significant negative consequences for our stockholders and our business, results of operations and financial condition by, among other things:

- making it more difficult for us to satisfy our obligations under our existing debt instruments;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our ability to obtain additional financing to fund our research, development, and commercialization activities, particularly when the availability of financing in the capital markets is limited;
- requiring a substantial portion of our cash flows from operations for the payment of principal and interest on our debt, reducing our ability to use our cash flows to fund working capital, research and development, and other general corporate requirements;
- limiting our flexibility to plan for, or react to, changes in our business and the industries in which we operate;
- further diluting our current stockholders as a result of issuing shares of our common stock upon conversion of our Convertible Notes; and
- placing us at a competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to make principal and interest payments will depend on our ability to generate cash in the future. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, and our cash needs may increase in the future. If we do not generate sufficient cash to meet our debt service requirements and other operating requirements, we may need to seek additional financing. In that case, it may be more difficult, or we may be unable, to obtain financing on terms that are acceptable to us or at all.

In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

Actual or perceived failures to comply with applicable data protection, privacy, consumer protection and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

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

enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, the manner in which we collect, use, access, disclose, transmit and store protected health information ("PHI"), is subject to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and the health data privacy, security and breach notification regulations issued pursuant to these statutes.

HIPAA establishes a set of national privacy and security standards for the protection of PHI, by health plans, healthcare clearinghouses, and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services that involve the use or disclosure of PHI. HIPAA requires healthcare providers like us to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical, and technical safeguards to protect such information.

HIPAA further requires covered entities to notify affected individuals “without unreasonable delay and in no case later than 60 calendar days after discovery of the breach” if their unsecured PHI is subject to unauthorized access, use or disclosure. If a breach affects 500 patients or more, covered entities must report it to the U.S. Department of Health and Human Services ("HHS"), and local media without unreasonable delay (and in no case later than 60 days after discovery of the breach), and HHS will post the name of the entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims.

Penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly depending on the failure and could include requiring corrective actions, and/or imposing civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, on June 28, 2018, California enacted the California Consumer Privacy Act, which went into effect on January 1, 2020 and was amended by the California Privacy Rights Act of 2020 ("CPRA"), which went into effect on January 1, 2023. The CPRA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CPRA provides for civil penalties for violations, as well as a private right of action for data breaches that could increase data breach litigation. The CPRA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and proposed or enacted in other states. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and reputation.

In the ordinary course of our business, including our now discontinued historical testing business, we collect and store sensitive data, including PHI (such as patient medical records, including test results), and personally identifiable information. We also store business and financial information, intellectual property, research and development information, trade secrets and other proprietary and business critical information, including that of our customers, payors, and collaboration partners. We manage and maintain our data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We are highly dependent on information technology networks and systems, including the internet, to securely process, transmit, and store critical information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider and other service providers, may be vulnerable to attacks by hackers, viruses, disruptions and breaches due to employee error or malfeasance.

A security breach or privacy violation that leads to unauthorized access, disclosure or modification of, or prevents access to, patient information, including PHI, could compel us to comply with state and federal breach notification laws, subject us to mandatory corrective action and require us to verify the correctness of database contents. Such a breach or violation also could result in legal claims or proceedings brought by a private party or a governmental authority, liability under laws and regulations that protect the privacy of personal information, such as HIPAA, HITECH, and laws and regulations of various U.S. states and foreign countries, as well as penalties imposed by the Payment Card Industry Security Standards Council for violations of the Payment Card Industry Data Security Standard. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, we may suffer loss of reputation, financial loss and civil or criminal fines or other penalties because of lost or misappropriated information. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Unauthorized access, loss or dissemination of information could disrupt our operations, including our ability to process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize products, collect, process and prepare company financial information, provide information about products, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, health-related, privacy, and data protection laws and regulations in the United States and elsewhere are subject to interpretation and enforcement by various governmental authorities and courts, resulting in complex compliance issues and the potential for varying or even conflicting interpretations, particularly as laws and regulations in this area are in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business and our reputation. Complying with these laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business, operating results, and financial condition.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. We could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

If we lose the services of members of our senior management team or other key employees, we may not be able to execute our business strategy.

Our success depends in large part upon the continued service of our senior management team and certain other key employees who are important to our vision, strategic direction, and culture. Our current long-term business strategy was developed in large part by our senior management team and depends in part on their skills and knowledge to implement. We may not be able to offset the impact on our business of the loss of the services of any member of our senior management or other key officers or employees or attract additional talent. The loss of any members of our senior management team or other key employees could have a material and adverse effect on our business, operating results, and financial condition.

An inability to attract and retain highly skilled employees could adversely affect our business.

To execute our business plan, we must attract and retain highly qualified personnel. Competition for qualified personnel is intense, especially for personnel in our industry and especially in the areas where our facilities are located. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees have breached their legal obligations to their former employees, resulting in a diversion of our time and resources. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may adversely affect our ability to attract and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business, operating results, and financial condition could be adversely affected.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop, fund, commercialize, and manufacture some or all of our product candidates.

We expect to depend on collaborators, partners, licensees, manufacturers, and other third parties to support our product candidate development efforts, including, to manufacture our product candidates and to market, sell, and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization, and manufacturing of our product candidates, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, manufacturers, and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, manufacture, obtain regulatory authorizations for, or commercialize any future product candidates, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our research and development programs and products under development, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of and protection of intellectual property with respect to such third parties.

We rely on third parties for matters related to the design of our product candidates and for our preclinical research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such preclinical research and trials.

We rely and expect to continue to rely on third parties, such as engineering firms, CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct and manage certain aspects of the design, preclinical testing, and clinical trials for our products under development. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with GCP requirements, the general investigational plan, and the protocols established for such trials.

These third parties may be slow to recruit patients and complete the studies. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed, or terminated or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing authorizations for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Even if our newly developed product candidates receive marketing authorizations, to the extent required, they may fail to achieve market acceptance.

If we can develop enhanced, improved, or new product candidates that receive marketing authorizations, they may nonetheless fail to gain sufficient market acceptance by healthcare providers, patients, third-party payors, and others in the medical community to be commercially successful. The degree of market acceptance of any of our new product candidates following receipt of marketing authorizations, if any, will depend on a number of factors, including:

- our ability to anticipate and meet customer and patient needs;
- the timing of regulatory approvals or clearances, to the extent such are required for marketing;
- the efficacy, safety and other potential advantages, such as convenience and ease of administration, of our product candidates as compared to alternative tests or treatments;
- the clinical indications for which our product candidates are approved or cleared;
- concordance with clinical guidelines established by relevant professional colleges;
- compliance with state guidelines and licensure, if applicable;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try our new products, and of physicians to prescribe these products;
- the strength of our marketing and distribution support;

- the availability and requirements of third-party payor insurance coverage and adequate reimbursement for our product candidates;
- the prevalence and severity of side effects and the overall safety profiles of our product candidates;
- any restrictions on the use of our product candidates together with other products and medications;
- our ability to manufacture quality products in an economic and timely manner;
- interactions of our product candidates with other medications patients are taking; and
- the ability of patients to take and tolerate our product candidates.

If our newly developed product candidates are unable to achieve market acceptance, our business, operating results, and financial condition will be harmed.

Additional time may be required to obtain marketing authorizations for certain of our therapeutics product candidates because they are combination products.

Some of our therapeutics product candidates are drug-device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

Our therapeutics product candidates under development include complex medical devices that, if authorized for marketing, will require training for qualified personnel and care for data analysis.

Our therapeutics product candidates under the early stages of development include complex medical devices that, if authorized for marketing, will require training for qualified personnel, including physicians, and care for data analysis. Although we will be required to ensure that our therapeutics product candidates are prescribed only by trained professionals, the potential for misuse of our therapeutics product candidates, if authorized for marketing, still exists due to their complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation, and otherwise have a material and adverse effect on our business, operating results, and financial condition.

The successful discovery, development, manufacturing, and sale of biologics is a long, expensive, and uncertain process and carries unique risks and uncertainties. Moreover, even if successful, our biologic products may be subject to competition from biosimilars.

We may develop product candidates regulated as biologics in the future in connection with our therapeutics pipeline. The successful development, manufacturing, and sale of biologics is a long, expensive, and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the testing, development, approval, manufacturing, distribution, and sale of biologics is subject to applicable provisions of the FD&C Act, PHSA, and regulations issued thereunder that are often more complex and extensive than the regulations applicable to other pharmaceutical products or to medical devices. Manufacturing biologics, especially in large quantities, is often complicated and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically.

Failure to successfully discover, develop, manufacture, and sell biologics could adversely impact our business, operating results, and financial condition.

Even if we are able to successfully develop biologics in the future, the Biologics Price Competition and Innovation Act ("BPCIA"), created a framework for the approval of biosimilars in the United States that could allow competitors to reference data from any future biologic products for which we receive marketing approvals and otherwise increase the risk that any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the original biologic was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full Biologics License Application ("BLA"), for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, the law’s ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when

such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological product candidates.

In addition, there is a risk that any of our product candidates regulated as a biologic and licensed under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies are developing biosimilars in other countries that could compete with any biologic products that we develop. If competitors are able to obtain marketing approval for biosimilars referencing any biologic products that we develop, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired. As a result, we could face more litigation and administrative proceedings with respect to the validity and/or scope of patents relating to our biologic products.

If our future pharmaceutical product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.

In the future, we may develop pharmaceutical product candidates using our therapeutics pipeline that require FDA approval of a New Drug Application ("NDA"), or a BLA before marketing or sale in the United States. In the NDA or BLA process, we, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective, or in the case of biologics, safe, pure, and potent, for a defined indication before they can be approved for commercial distribution. The FDA or foreign regulatory authorities may disagree with our clinical trial designs and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity, and novelty of the product candidate, and involve the expenditure of substantial resources for research, development, and testing. The FDA and foreign regulatory authorities have substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, may lead to increased uncertainty regarding the approvability of new drugs.

Applications for our drug or biologic product candidates could fail to receive regulatory approval for many reasons, including, but not limited to, the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our or our collaborators' clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we or our collaborators may be unable to demonstrate to the FDA, or comparable foreign regulatory authorities that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would seriously harm our business. In addition, the FDA may recommend advisory committee meetings for certain new molecular entities, and if warranted, require a Risk Evaluation and Mitigation Strategy ("REMS"), to assure that a drug's benefits outweigh its risks. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on the use and/or distribution of such product.

In addition, in order to market any pharmaceutical or biological product candidates that we develop in foreign jurisdictions, we, or our collaborative partners, must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's or other regulatory authorities' review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

The marketing authorization process is expensive, time-consuming, and uncertain, and we may not be able to obtain or maintain authorizations for the commercialization of some or all of our product candidates.

The product candidates associated with our therapeutics pipeline and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, export, and import, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency and comparable regulatory authorities in other countries. We have not received authorization to market any of our product candidates from regulatory authorities in any jurisdiction. Failure to obtain marketing authorization for a product candidate will prevent us from commercializing the product candidate.

Securing marketing authorizations may require the submission of extensive preclinical and clinical data and other supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy, or in the case of product candidates regulated as biologics, such product candidate's safety, purity, and potency. Securing regulatory authorization generally requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing authorization or prevent or limit commercial use.

The process of obtaining marketing authorizations, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if authorization is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing authorization policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application we submit, or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing authorization of a product candidate. Any marketing authorization we or our collaborators ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or our collaborators experience delays in obtaining authorization or if we or they fail to obtain authorization of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for the review and approval of INDs, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory authorization, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if granted.

The use of our product candidates could be associated with side effects or adverse events, which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory authorization by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects such as toxicity or other safety issues and could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which would harm our business and financial results. In such an event, we may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated or our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any other regulatory agency in a timely manner, if ever, which could harm our business, operating results, financial condition and prospects.

Additionally, product quality characteristics have been shown to be sensitive to changes in process conditions, manufacturing techniques, equipment or sites and other such related considerations, hence any manufacturing process changes we implement prior to or after regulatory authorization could impact product safety and efficacy.

Product-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims. We currently carry product liability insurance and we are required to maintain product liability insurance pursuant to certain of our agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability, or such insurance coverage may not be sufficient to cover all losses. A successful product liability claim or series of claims brought against us could adversely affect our business, operating results, and financial condition. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if authorized for commercial sale. Additionally, if one or more of our product candidates receives marketing authorization, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including, but not limited to:

- regulatory authorities may suspend, limit or withdraw marketing authorizations for such products, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require additional warnings on the label including "boxed" warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- the product may become less competitive;

- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, operating results, financial condition, and prospects.

If we receive marketing authorization, regulatory agencies including the FDA and foreign authorities enforce requirements that we report certain information about adverse medical events. For example, under FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of our device (or any similar future product) were to recur. We may fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to investigate and report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, including any legal action taken against us, will require us to devote significant time and capital to the matter, distract management from operating our business, and may harm our reputation and financial results.

We may not comply with laws regulating the protection of the environment and health and human safety.

Our research and development involves, or may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Insurance may not provide adequate coverage against potential liabilities, and we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state, and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Unfavorable global economic conditions, whether brought about by global crises, health epidemics, military conflicts and war, geopolitical and trade disputes or other factors, may have a material adverse effect on our business and financial results.

Our business is sensitive to global economic conditions, which can be adversely affected by public health crises (including the COVID-19 pandemic) and epidemics, political and military conflicts, trade and other international disputes, significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers.

For example, military conflicts or wars (such as the ongoing conflicts between Russia and Ukraine and Israel and surrounding areas) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter-sanctions, or retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. It is not possible to predict the short and long-term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber-attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets.

Additionally, our operations and facilities, as well as operations of our service providers and manufacturers, may be located in areas that are prone to earthquakes and other natural disasters. Such operations and facilities are also subject to the risk of interruption by fire, drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, telecommunication failure, labor disputes, public health crises (including the COVID-19 pandemic) and other events beyond our control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Because we rely on a single or limited sources for the supply and manufacture of many

critical components, a business interruption affecting such sources would exacerbate any negative consequences on our business. We may not carry sufficient business interruption insurance to compensate us for all losses that may occur.

Any public health crises, including the COVID-19 pandemic, may affect our operations and those of third parties on which we rely, including our business partners and suppliers. To date, we are aware of certain suppliers for our R&D activities who have experienced operational delays directly related to the COVID-19 pandemic. In the past three years, the COVID-19 pandemic has caused, and likely will continue to cause, significant volatility and uncertainty in U.S. and international markets, disruptions to our business and delays in our preclinical studies, clinical trials and timelines, including as a result of impacts associated with protective health measures that we, other businesses and governments are taking or might have to take again in the future to manage the pandemic. The extent to which the COVID-19 pandemic and measures taken in response thereto impact our business, results of operations and financial condition will depend on future developments which are highly uncertain and difficult to predict.

Our operating results may fluctuate significantly, which could adversely impact the value of our common stock.

Our operating results, including our revenues, gross margin, profitability, and cash flows, have varied in the past and may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, our results should not be relied upon as an indication of future performance. Our operating results, including quarterly financial results, may fluctuate as a result of a variety of factors, many of which are outside of our control. Fluctuations in our results may adversely impact the value of our common stock. Factors that may cause fluctuations in our financial results include, without limitation, those listed elsewhere in this “Risk Factors” section. In addition, as we increase our research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders, or reduce our financial resources.

We have in the past entered into, and may in the future enter into, transactions to acquire other businesses, products, or technologies. Successful acquisitions require us to correctly identify appropriate acquisition candidates and to integrate acquired products or operations and personnel with our own.

Should we make an error in judgment when identifying an acquisition candidate, should the acquired operations not perform as anticipated, or should we fail to successfully integrate acquired technologies, operations, or personnel, we will likely fail to realize the benefits we intended to derive from the acquisition and may suffer other adverse consequences. Acquisitions involve a number of other risks, including:

- we may not be able to make such acquisitions on favorable terms or at all;
- the acquisitions may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors;
- we may decide to incur debt with debt repayment obligations that we are unable to satisfy or that could otherwise require the use of a significant portion of our cash flow;
- we may decide to issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders;
- we may incur losses resulting from undiscovered liabilities of the acquired business that are not covered by any indemnification we may obtain from the seller;
- the acquisitions may reduce our cash available for operations and other uses;
- the acquisitions may divert of the attention of our management from operating our existing business; and
- the acquisitions may result in charges to earnings in the event of any write-down or write-off of goodwill and other assets recorded in connection with acquisitions.

We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our business, operating results, and financial condition.

The development and expansion of our business through joint ventures, licensing and other strategic transactions may result in similar risks that reduce the benefits we anticipate from these strategic alliances and cause us to suffer other adverse consequences.

We may be significantly impacted by changes in tax laws and regulations or their interpretation.

U.S. and foreign governments continue to review, reform and modify tax laws. Changes in tax laws and regulations could result in material changes to the domestic and foreign taxes that we are required to provide for and pay. In addition, we are subject to regular

audits with respect to our various tax returns and processes in the jurisdictions in which we operate. Errors or omissions in tax returns, process failures, or differences in interpretation of tax laws by tax authorities and us may lead to litigation, payments of additional taxes, penalties, and interest. On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("TCJA"), was passed into law. The TCJA has given rise to significant one-time and ongoing changes, including, but not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, limitations on interest expense deductions, the immediate expensing of certain capital expenditures, the adoption of elements of a partially territorial tax system, new anti-base erosion provisions, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017 and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable tax laws and regulations, or their interpretation and application, could have a material and adverse effect on our business, operating results, and financial condition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had net operating loss ("NOL") carryforwards of approximately $504.8 million for federal income tax purposes, and $246.3 million for state income tax purposes. The federal NOLs will be carried forward indefinitely and the state NOLs begin expiring in 2028. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Some of these NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by 5% stockholders over a rolling three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the TCJA, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely but generally may not be carried back and the deductibility of such NOLs is limited to 80% of taxable income.

Reimbursement Risks Related to Our Historical Testing Business

Billing disputes with third-party payors may decrease realized revenue and may lead to requests for recoupment of past amounts paid.

Prior to the shutdown of our Laboratory Operations, which occurred in 2021, we operated clinical laboratories and billed for tests. Payors dispute our billing or coding from time to time and we deal with requests for recoupment from third-party payors from time to time in the ordinary course of our business (see Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information regarding current recoupment requests). We continue to receive recoupment requests and we expect these disputes and requests for recoupment may continue for a period of time in the future. Third-party payors may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We have entered into settlement agreements with government and commercial payors in order to settle claims related to past billing practices that have since been discontinued. For more information on these disputes, see Part I, Item 1. “Business—Commercial Third-Party Payors” in our Annual Report. Additionally, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 (collectively, the "ACA"), enacted in March 2010, requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws and the healthcare enforcement authorities, of Office of Inspector General of the Department of Health and Human Services ("OIG"). Claims for recoupment also require the time and attention of our management and other key personnel, which can be a distraction from operating our business.

If a third-party payor successfully challenges that payment to us for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup payment, which amounts could be significant and would impact our operating results and financial condition. We may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment. In the past, we have negotiated and settled these types of claims with third-party payors. We may be required to resolve further disputes in the future. For example, after the closure of our Laboratory Operations, we received several managed Medicaid payor recoupment requests aggregating to $1.1 million, which we dispute. We can provide no assurance that we will not receive similar claims for recoupment from other third-party payors in the future. For more information on this claim, see Part I, Item 1. “Business —Reimbursement—Payor Dispute” in our Annual Report. Any of these outcomes, including recoupment or reimbursements, might also require us to restate our financials from a prior period, any of which could have a material and adverse effect on our business, operating results, and financial condition.

If the validity of an informed consent from a patient is challenged, we could be forced to refund amounts previously paid by third-party payors, or to exclude a patient's data from clinical trial results.

We are required to ensure that all clinical data and/or patient specimens that we receive have been collected from subjects who have provided appropriate informed consent for us to perform testing in clinical trials. We seek to ensure that the subjects from whom the data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. A subject's informed consent could be challenged in the future, and the informed consent could prove invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our partners, could deny us access to, or force us to stop, testing samples in a particular area or could call into question the results of our clinical trials. In addition, we could be requested to refund amounts previously paid by third-party payors for tests where an informed consent is challenged. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our operating results.

We may be unable to obtain or maintain third-party payor coverage and reimbursement for our future tests or products.

Our future success will depend on our or our potential partners' ability to obtain or maintain adequate reimbursement coverage from third-party payors. Third-party reimbursement for our testing historically represented a significant portion of our revenues, and we expect third-party payors such as third-party commercial payors and government healthcare programs to be a source of revenue in the future. It is to be determined whether and to what extent certain of our products under development will be covered or reimbursed. If we or our potential partners are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our future tests or other products, our ability to generate revenues will be limited. For example, healthcare providers may be reluctant to order our tests or other products due to the potential of a substantial cost to the patient if coverage or reimbursement is unavailable or insufficient.

Regulatory and Legal Risks Related to Our Business

If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.

We are subject to healthcare fraud and abuse regulation and enforcement by both the U.S. federal government and the states in which we conduct our business, including:

- federal and state laws and regulations governing the submission of claims, as well as billing and collection practices, for healthcare services;
- the federal Anti-Kickback Statute, which prohibits, among other things, the knowing and willful solicitation, receipt, offer or payment of remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid; a person does not need to have knowledge of the statute or specific intent to violate it to have committed a violation; a violation of the Anti-Kickback Statute may result in imprisonment for up to ten years and significant fines for each violation and administrative civil money penalties, plus up to three times the amount of the remuneration paid; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which, among other things, prohibits knowingly or willfully paying, offering to pay, soliciting or receiving any remuneration (including any kickback, bribe, or rebate), whether directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory, or in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory; violation of EKRA may result in significant fines and imprisonment of up to 10 years for each occurrence;
- the federal False Claims Act which prohibits, among other things, the presentation of false or fraudulent claims for payment from Medicare, Medicaid, or other government-funded third-party payors discussed in more detail below;
- federal laws and regulations governing the Medicare program, providers of services covered by the Medicare program, and the submission of claims to the Medicare program, as well as the Medicare Manuals issued by Centers for Medicare and Medicaid Services ("CMS") and the local medical policies promulgated by the Medicare Administrative Contractors with respect to the implementation and interpretation of such laws and regulations;
- the federal Stark Law, also known as the physician self-referral law, which, subject to certain exceptions, prohibits a physician from making a referral for certain designated health services covered by the Medicare program (and according to case law in some jurisdictions, the Medicaid program as well), including laboratory and pathology services, if the

physician or an immediate family member has a financial relationship with the entity providing the designated health services; a person who attempts to circumvent the Stark Law may be fined up to approximately $165,000 for each arrangement or scheme that violates the statute; in addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to significant civil monetary penalties, plus up to three times the amount of reimbursement claimed;

- the federal Civil Monetary Penalties Law, which, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program; any violation of these prohibitions may result in significant civil monetary penalties for each wrongful act;
- the prohibition on reassignment by the program beneficiary of Medicare claims to any party;
- The federal Healthcare Fraud Statute, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making false, fictitious or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to PHI upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve PHI; HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians, various other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members; we believe that we are currently exempt from these reporting requirements; we cannot assure you, however, that regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business;
- federal and state laws and regulations governing informed consent for genetic testing and the use of genetic material;
- state law equivalents of the above U.S. federal laws, such as the Stark Law, Anti-Kickback Statute and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; and
- similar healthcare laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Furthermore, a development affecting our industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability for, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government for violations of the False Claims Act and permit such individuals to share in any amounts paid by the defendant to the government in fines or settlement.

When an entity is determined to have violated the False Claims Act, it is subject to mandatory damages of three times the actual damages sustained by the government, plus significant mandatory civil penalties for each false claim. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and in some cases apply more broadly because many of these state laws apply to claims made to private payors and not merely governmental payors.

The evolving interpretations of these laws and regulations by courts and regulators increase the risk that we may be alleged to be, or in fact found to be, in violation of these or other laws and regulations, including pursuant to private qui tam actions brought by individual whistleblowers in the name of the government as described above.

Our inability to obtain, on a timely basis or at all, any necessary marketing authorizations for new device products or improvements could adversely affect our future product commercialization and operating results.

Our product candidates are expected to be subject to regulation by the FDA, and numerous other federal and state governmental authorities. The process of obtaining regulatory approvals or clearances to market a medical device, particularly from the FDA and regulatory authorities outside the United States, can be costly and time-consuming, and approvals or clearances might not be granted for future products on a timely basis, if at all. To ensure ongoing customer safety, regulatory agencies such as the FDA may re-evaluate their current approval or clearance processes and may impose additional requirements. In addition, the FDA and other regulatory authorities may impose increased or enhanced regulatory inspections for domestic or foreign facilities involved in the manufacture of medical devices.

We may develop new medical devices in connection with our therapeutics pipeline and new molecular test candidates that are regulated by the FDA as medical devices. Unless otherwise exempted, medical devices must receive one of the following marketing authorizations from the FDA before being marketed in the United States: “510(k) clearance,” de novo classification, or PMA. The FDA determines whether a medical device will require 510(k) clearance, de novo classification, or the PMA process based on statutory criteria that include the risk associated with the device and whether the device is similar to an existing, legally marketed product. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. The process to obtain either 510(k) clearance or PMA will likely be costly, time-consuming, and uncertain. However, we believe the PMA process is generally more challenging. Even if we design a product that we expect to be eligible for the 510(k) clearance process, the FDA may require that the product undergo the PMA process. There can be no assurance that the FDA will approve or clear the marketing of any new medical device product that we develop. Even if regulatory approval or clearance is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of the new medical device product.

If a medical device is novel and has not been previously classified by the FDA as Class I, II, or III, it is automatically classified into Class III regardless of the level of risk it poses. The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the “Request for Evaluation of Automatic Class III Designation,” or the de novo classification procedure. This procedure allows a manufacturer whose novel device would automatically be classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application.

FDA marketing authorization could not only be required for new products we develop, but also could be required for certain enhancements we may seek to make to our future products. Delays in receipt of, or failure to obtain, marketing authorizations could materially delay or prevent us from commercializing our products or result in substantial additional costs that could decrease our profitability. In addition, even if we receive FDA or other regulatory marketing authorizations for a new or enhanced product, the FDA or such other regulator may condition, withdraw, or materially modify its marketing authorization.

We are subject to costly and complex laws and governmental regulations.

Our therapeutics product candidates are subject to a complex set of regulations and rigorous enforcement, including by the FDA, United States Department of Justice ("DOJ"), HHS, and numerous other federal, state, and non-U.S. governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our product candidates, if approved. As a part of the regulatory process of obtaining marketing authorization for new products and modifications to products, we may conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials or the market’s or FDA’s perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate, and our business, operating results, and financial condition. We cannot guarantee that we will be able to obtain or maintain marketing authorization for our product candidates and/or enhancements or modifications to products, and the failure to maintain or obtain marketing authorization in the future could have a material and adverse effect on our business, operating results, financial condition.

Both before and after a product is commercially released, we and our products are subject to ongoing and pervasive oversight of government regulators. For instance, in the case of any product candidates subject to regulation by the FDA, including those products

candidates in connection with our therapeutics pipeline, our facilities and procedures and those of our suppliers will be subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. If the FDA or a non-U.S. regulatory agency were to conclude that we are not in compliance with applicable laws or regulations, or that any of our product candidates, if authorized for marketing, are ineffective or pose an unreasonable health risk, the FDA or such other non-U.S. regulatory agency could ban products, withdraw marketing authorizations for such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending marketing applications, require certificates of non-U.S. governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The FDA and other non-U.S. regulatory agencies may also assess civil or criminal penalties against us, our officers, or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future marketing authorizations, and could result in a substantial modification to our business practices and operations. Furthermore, we occasionally receive investigative demands, subpoenas, or other requests for information from state and federal governmental agencies, and we cannot predict the timing, outcome, or impact of any such investigations. See Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report. Any adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties, and/or administrative remedies, including exclusion from government reimbursement programs and/or amendments to our corporate integrity agreement with the OIG. In addition, resolution of any of these matters could involve the imposition of additional, costly compliance obligations. These potential consequences, as well as any adverse outcome from government investigations, could have a material and adverse effect on our business, operating results, and financial condition.

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation and regulation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. For example, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("IRA"), which, contains provisions intended to lower beneficiary drug spending. Beginning in 2023, the IRA authorizes the CMS to negotiate Medicare reimbursement rates for certain prescription drug products, which may put limits on prices paid for drugs by government health programs. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

We and our commercial partners and contract manufacturers are subject to significant regulation with respect to manufacturing medical devices and therapeutic products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

Entities involved in the preparation of medical devices and/or therapeutic products for clinical studies or commercial sale, including our manufacturers for the therapeutic products that we may develop, are subject to extensive regulation. Components of a finished medical device or therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP and/or QSR requirements. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of an NDA, a BLA, a PMA, a 510(k) application, a request for de novo classification, or a Marketing Authorization Application ("MAA"), on a timely basis and must adhere to cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers may have never produced a commercially approved pharmaceutical product and therefore have not been subject to the review of the FDA and other regulators. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug and biologic product candidates and may be subject to inspection in connection with a MAA for any of our other potential product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee our contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, such contract manufacturing partners for compliance with these regulatory requirements. If these facilities do not pass a pre-approval plant inspection, marketing authorizations for the

products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval or clearance of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility.

Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate, withdrawal of a marketing authorization or suspension of production. As a result, our business, operating results, and financial condition may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer will need to be qualified and we may need to obtain marketing authorization for a change in the manufacturer through submission of a PMA supplement, 510(k) pre-market notification, NDA or BLA supplement, MAA variation or other regulatory filing to the FDA or other foreign regulatory agencies, which could result in further delay.

These factors could cause us to incur additional costs and could cause the delay or termination of clinical studies, regulatory submissions, required marketing authorizations or commercialization of our products under development. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing proprietary product candidates, such as BT-600, a GI-targeted tofacitinib, for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. We expect that BT-600 will be regulated as a drug-device combination product under the drug provisions of the FD&C Act, enabling us to submit NDAs for approval of this product candidate. The Hatch-Waxman Act added Section 505(b)(2) to the FD&C Act. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FD&C Act, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidate by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional nonclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for this product candidate, and complications and risks associated with this product candidate, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidate, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidate will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval.

Moreover, even if our product candidate is approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

The misuse or off-label use of our product candidates may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, and any of these consequences could be costly to our business.

We are developing certain therapeutics product candidates, including pharmaceutical products and medical devices, which if authorized for marketing by the FDA or other regulatory authorities, will be authorized for use in specific indications and patient populations. We expect to train our marketing personnel and direct sales force not to promote our product candidates for uses outside of the FDA-approved or -cleared indications for use, which are sometimes referred to as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized for marketing by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Risks Related to Our Intellectual Property

New third-party claims of intellectual property infringement could result in litigation or other proceedings, which would be costly and time-consuming, and could limit our ability to commercialize our products under development.

Our success depends in part on our freedom-to-operate with respect to the patents or intellectual property rights of third parties. We operate in industries in which there have been substantial litigation and other proceedings regarding patents and other intellectual property rights. For example, we have identified a number of third-party patents that may be asserted against us with respect to certain of our future products, and have identified pending patent applications for which the ultimate claim scope and validity are uncertain. We believe that we do not infringe the relevant claims of these third-party patents and/or that the relevant claims of these patents are likely invalid or unenforceable. We may choose to challenge the validity of these patents, though the outcome of any challenge that we may initiate in the future is uncertain. We may also decide in the future to seek a license to those third-party patents, but we might not be able to do so on reasonable terms. Certain third parties, including our competitors or collaborators, may in the future assert that we are employing their proprietary technology without authorization or that we are otherwise infringing their intellectual property rights. The risk of intellectual property proceedings may increase as the number of products and the level of competition in our industry segments grows. Defending against infringement claims is costly and may divert the attention of our management and technical personnel. If we are unsuccessful in defending against patent infringement claims, we could be required to stop developing or commercializing products, pay potentially substantial monetary damages, and/or obtain licenses from third parties, which we may be unable to do on acceptable terms, if at all, and which may require us to make substantial royalty payments. In addition, we could encounter delays in product introductions while we attempt to develop alternative non-infringing products. Any of these or other adverse outcomes could have a material and adverse effect on our business, operating results, and financial condition. See Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for more information regarding a patent infringement suit filed by Ravgen, Inc. related to our discontinued historical laboratory developed test business, which is no longer in operation. There can be no assurance that we will prevail in the Ravgen matter. For example, in a patent infringement suit filed by Ravgen against another laboratory asserting the same patents, a Texas jury found the laboratory liable for infringement and awarded significant damages.

As we move into new markets and develop enhancements to and new applications for our product candidates, competitors have asserted and may in the future assert their patents and other proprietary rights against us as a means of blocking or slowing our entry into such markets or our sales of such new or enhanced products or as a means to extract substantial license and royalty payments from us. Our competitors and others may have significantly stronger, larger, and/or more mature patent portfolios than we have, and

additionally, our competitors may be better resourced and highly motivated to protect large, well-established markets that could be disrupted by our product candidates. In addition, future litigation may involve patent holding companies or other patent owners or licensees who have no relevant product revenues and against whom our own patents may provide little or no deterrence or protection.

In addition, our agreements with some of our collaborators, suppliers, and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, and financial condition.

Because the industries in which we operate are particularly litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our products under development or conducting our business.

There is a substantial amount of litigation over patent and other intellectual property rights in the industries in which we operate, including, but not limited to, the biotechnology, life sciences, pharmaceuticals, and medical device industries. Whether a product infringes a patent involves complex legal and factual issues that may be open to different interpretations. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our future products may infringe. In addition, our competitors or other parties may assert that our product candidates and the methods they employ may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling it unless we can obtain a license or redesign the product to avoid infringement. A license may not always be available or may require us to pay substantial royalties. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and could divert our management's attention from operating our business.

Any inability to effectively protect our proprietary technologies could harm our competitive position.

Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and elsewhere. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights in certain jurisdictions outside of the United States. In addition, the proprietary positions of companies in the industries in which we operate generally are uncertain and involve complex legal and factual questions. This is particularly true in the life sciences area where the U.S. Supreme Court has issued a series of decisions setting forth limits on the patentability of natural phenomena, natural laws, abstract ideas and their applications (see, Mayo Collaborative v. Prometheus Laboratories (2012), Association for Molecular Pathology v. Myriad Genetics (2013), and Alice Corporation v. CLS Bank (2014), which has made it difficult to obtain certain patents and to assess the validity of previously issued patents). This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any finding that our patents or patent applications are invalid or unenforceable could harm our ability to prevent others from practicing the related technology. We cannot be certain that we were the first to invent the inventions covered by pending patent applications or that we were the first to file such applications, and a finding that others have claims of inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms, if at all. There may be times when we choose to retain advisors with academic employers who limit their employees' rights to enter into agreements which provide the kind of confidentiality and assignment provisions congruent with our consulting agreements. We may decide that obtaining the services of these advisors is worth any potential risk, and this may harm our ability to obtain and enforce our intellectual property rights. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing similar or alternative competing products, or design around our patented technologies, and may therefore fail to provide us with any competitive advantage. Furthermore, as our issued patents expire, we may lose some competitive advantage as others develop competing products that would have been covered by the expired patents, and, as a result, may adversely affect our business, operating results, and financial condition.

We may be required to file or defend infringement lawsuits and other contentious proceedings, such as inter partes reviews, reexaminations, oppositions, and declaratory judgment actions, to protect our interests, which can be expensive and time-consuming. We cannot assure you that we would prevail over an infringing third party, and we may become subject to counterclaims by such third parties. Our patents may be declared invalid or unenforceable, or narrowed in scope, as a result of such litigation or other proceedings. Some third-party infringers may have substantially greater resources than us and may be able to sustain the costs of complex infringement litigation more effectively than we can. Even if we have valid and enforceable patents, competitors may still choose to offer products that infringe our patents.

Further, preliminary injunctions that bar future infringement by the competitor are not often granted; therefore, remedies for infringement are not often immediately available. Even if we prevail in an infringement action, we cannot assure you that we would be fully or partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the third parties on terms less profitable or otherwise less commercially acceptable to us than those negotiated between a willing licensee and a willing licensor. Any inability to stop third-party infringement could result in the future in a loss in market share of our products under development, or lead to a delay, reduction, and/or inhibition of our development, manufacture, or sale of some of our products. A product produced and sold by a third-party infringer may not meet our or other regulatory standards or may not be safe for use, which could cause irreparable harm to the reputation of our products, which in turn could result in substantial loss in our market share and profits.

There is also the risk that others, including our competitors in the targeted and systemic therapeutics fields, may independently develop similar or alternative technologies, ingestible devices, or design around our patented or patent pending technologies, and our competitors or others may have filed, and may in the future file, conflicting patent claims covering technology similar or identical to ours. The costs associated with challenging conflicting patent claims could be substantial, and it is possible that our efforts would be unsuccessful and may result in a loss of our patent position and the issuance or validation of the competing claims. Should such competing claims cover our technology, we could be required to obtain rights to those claims at substantial cost.

Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products under development.

“Submarine” patents may be granted to our competitors, which may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term “submarine” patent is used to denote a patent issuing from an application that was not published, publicly known or available prior to its grant. Submarine patents add substantial risk and uncertainty to our business. Submarine patents may issue to our competitors covering our product candidates and thereby cause significant market entry delay, defeat our ability to market our product candidates or cause us to abandon development and/or commercialization of a product candidate.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a product candidate or other product into the U.S. market.

If we are not able to adequately protect our trade secrets, know-how, and other proprietary information, the value of our technology and products under development could be significantly diminished.

We rely on trade secret protection and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to protect this information. These measures, however, may not provide adequate protection for our trade secrets, know-how, or other proprietary information. For example, although we have a policy of requiring our consultants, advisors and collaborators to enter into confidentiality agreements and our employees to enter into invention, non-disclosure and, where lawful, noncompete agreements, we cannot assure you that such agreements will provide for a meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information, including as a result of breaches of our physical or electronic security systems, or as a result of our employees failing to abide by their confidentiality obligations during or upon termination of their employment with us. Any action to enforce our rights is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States. Any unauthorized use or disclosure of, or access to, our trade secrets, know-how or other proprietary information, whether accidentally or through willful misconduct, could have a material and adverse effect on our programs, our business strategy, and on our ability to compete effectively.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, particularly for a company of our size, and time-consuming, and we may not be successful. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

Our pending trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other companies in the industries in which we operate, including biotechnology, pharmaceutical or medical device companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or willfully used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that our employees' former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property.

Even if we are successful, litigation could result in substantial costs to us and could divert the time and attention of our management and other employees.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has fluctuated in the past, and is likely to continue to be volatile, which could subject us to litigation.

The market price of our common stock has fluctuated and is likely to be subject to further wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this "Risk Factors" section and others including:

- actual or anticipated variations in our and our competitors' operating results;
- announcements by us or our competitors of new products, product development results, significant acquisitions or divestitures, strategic and commercial partnerships and relationships, joint ventures, collaborations or capital commitments;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- periodic fluctuations in our revenue;
- actual or anticipated changes in regulatory oversight of our products under development;
- developments or disputes concerning our intellectual property or other proprietary rights or alleged infringement of third party's rights by us or our products under development;
- commencement of, or our involvement in, litigation or other proceedings;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- any major change in our management; and
- general economic conditions and slow or negative growth of our markets, including slow or negative growth in the biotechnology industry generally.

In addition, if the stock market experiences uneven investor confidence, the market price of our common stock could decline for reasons unrelated to our business, operating results, or financial condition. The market price of our common stock might also decline in reaction to events that affect other companies within, or outside, our industry even if these events do not directly affect us. Some companies that have experienced volatility in the trading price of their stock have been the subject of securities class action litigation. If we are the subject of such litigation, it could result in substantial costs and a diversion of our management's attention and resources.

We may fail to qualify for continued listing on the Nasdaq Global Market, which could make it more difficult for our stockholders to sell their shares.

We are required to satisfy the continued listing requirements of the Nasdaq Global Market ("Nasdaq") to maintain such listing, including, among other things, the maintenance of a market value of our common stock of at least $50 million.

For example, on April 4, 2023, we received formal notice from Nasdaq indicating that we no longer satisfy the $50 million in total assets and $50 million in total revenue requirement for continued listing on Nasdaq or the alternative criteria under Nasdaq Listing Rule 5450(b).

While we were successful in regaining compliance with the continued listing requirements of Nasdaq, there can be no assurance that we will be able to maintain compliance in the future with Nasdaq's continued listing requirements. If our stock price does not increase or if we are unable to raise additional funds, and if our market capitalization does not meet the minimum standards, we may

not be able to maintain the standards for continued listing on Nasdaq. In the event that we do not maintain compliance with the Nasdaq Listing Rules in the future, we expect to receive written notification that our common stock is subject to delisting. If our common stock is delisted by Nasdaq, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;
- a determination that our shares are "penny stock," which will require brokers trading in our shares to adhere to more stringent shares, and which may limit demand for our common stock among certain investors;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our common stock may become the target of "short squeezes."

In the recent past, the securities of several companies have increasingly experienced significant and extreme volatility in stock price due to short sellers of shares of their stock and buy-and-hold decisions of other investors, resulting in what is sometimes described as a "short squeeze." Short squeezes have caused extreme volatility in the stock prices of those companies and in the market and have led to the price per share of some of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Sharp rises in a company's stock price may force traders in a short position to buy the stock to avoid even greater losses. Investors who purchase shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. Market activity suggests that we have been the target of a short squeeze, and this could occur again at any time, and stockholders may lose a significant portion or all of their investment if they purchase our shares at a rate that is significantly disconnected from our underlying value.

The issuance of shares of our common stock upon conversion of the Convertible Notes and exercise of warrants will dilute the ownership interests of our stockholders and could depress the trading price of our common stock.

We must settle conversions of our outstanding Convertible Notes and exercise of our outstanding warrants in shares of our common stock, together with cash in lieu of issuing any fractional share in the case of the Convertible Notes. The issuance of shares of our common stock upon conversion of the Convertible Notes or exercise of the warrants will dilute the ownership interests of our stockholders, which could depress the trading price of our common stock. In addition, the market's expectation that conversions or exercises may occur could depress the trading price of our common stock even in the absence of actual conversions or exercises. Moreover, the expectation of conversions or exercises could encourage the short selling of our common stock, which could place further downward pressure on the trading price of our common stock.

Hedging activity by investors in the Convertible Notes and warrants could depress the trading price of our common stock.

We expect that many investors in our outstanding Convertible Notes and warrants will seek to employ an arbitrage strategy. Under this strategy, investors typically short sell a certain number of shares of our common stock and adjust their short position over time while they continue to hold the Convertible Notes or warrants. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of, or in addition to, short selling shares of our common stock. This market activity, or the market's perception that it will occur, could depress the trading price of our common stock.

Provisions in the Indenture governing our outstanding Convertible Notes could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in our Convertible Notes and the Indenture governing the Convertible Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a "fundamental change" (which is defined in the Indenture to include certain change-of-control events and the delisting of our common stock), then noteholders will have the right to require us to repurchase their Convertible Notes for cash. In addition, if a takeover constitutes a "make-whole fundamental change" (which is defined in the Indenture to include, among other events, fundamental changes and certain additional business combination transactions), then we may be required to temporarily increase the conversion rate for the Convertible Notes. In either case, and in other cases, our obligations under the Convertible Notes and the Indenture could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of our common stock may view as favorable.

We may be unable to raise the funds necessary to repurchase the Convertible Notes for cash following a fundamental change or to pay any cash amounts due upon conversion, and our other indebtedness may limit our ability to repurchase our outstanding Convertible Notes.

Noteholders may require us to repurchase their Convertible Notes following a "fundamental change" (which is defined in the Indenture governing the Convertible Notes to include certain change-of-control events and the delisting of our common stock) at a

cash repurchase price generally equal to the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any. Furthermore, additional cash amounts may be due upon conversion in certain circumstances if the number of shares that we deliver upon conversion of the Convertible Notes is limited by Nasdaq listing standards. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Convertible Notes or pay these cash amounts upon their conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the Convertible Notes or pay these cash amounts upon their conversion. Our failure to repurchase Convertible Notes when required or pay these cash amounts upon their conversion will constitute a default under the Indenture governing the Convertible Notes. A default under the Indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Convertible Notes.

The accounting method for the Convertible Notes could adversely affect our reported financial results.

The accounting method for reflecting the underlying shares of our common stock in our reported diluted earnings per share may adversely affect our reported earnings and financial condition. We expect that, under applicable accounting principles, the shares underlying our Convertible Notes will be reflected in our diluted earnings per share using the "if-converted" method. Under that method, diluted earnings per share would generally be calculated assuming that all the Convertible Notes were converted into shares of common stock at the beginning of the reporting period, unless the result would be anti-dilutive. The application of the if-converted method may further increase our reported diluted loss per share.

Furthermore, the conversion features in our Convertible Notes are accounted for as a free-standing embedded derivative bifurcated from the principal balance of the Convertible Notes. The embedded derivative liability is remeasured at fair value each reporting period with positive or negative changes in fair value recorded in our consolidated statement of operations, which may adversely affect our reported earnings and financial condition and result in significant fluctuations in our future financial performance.

General Risk Factors

Insiders have substantial control over us and will be able to influence corporate matters.

As of September 30, 2023, our current directors and executive officers, together with their affiliates, have significant ownership of our outstanding common stock. As a result, these stockholders, if they act, will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying, deterring or preventing a third party from acquiring control over us, depriving our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company, and could negatively impact the value and market price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

In the future, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, directors, and consultants pursuant to our equity incentive plans. If we sell common stock, convertible securities, or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

Sales of a substantial number of shares of our common stock in the public market, including through our ATM Facility or by our existing stockholders, or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as are

required of other public companies that are not emerging growth companies, which may make comparison of our consolidated financial information to those of other public companies more difficult.

For as long as we continue to be an emerging growth company, however, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and experience decreases.

We will remain an emerging growth company until the earliest of (a) the end of the fiscal year (i) following the fifth anniversary of the closing of our IPO, (ii) in which the market value of our common stock that is held by non-affiliates exceeds $700 million and (iii) in which we have total annual gross revenues of $1.235 billion or more during such fiscal year, and (b) the date on which we issue more than $1 billion in non-convertible debt in a three-year period.

We have previously identified material weaknesses in our internal control over financial reporting. If additional material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results, which could adversely affect our stock price and result in an inability to maintain compliance with applicable stock exchange listing requirements.

We previously concluded that there were matters that constituted material weaknesses in our internal control over financial reporting that have since been remediated. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weaknesses related to a lack of (i) controls, as related to our historical testing business prior to our Strategic Transformation, designed to reconcile tests performed and recognized as revenue to billed tests and (ii) appropriately designed or effectively operating controls over the proper recording of accounts payable and accrued liabilities.

If additional material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results. If we are unable to successfully remediate any material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts provide coverage of us, or if industry analysts cease coverage of us, the trading price and volume for our common stock could be adversely affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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

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

- authorize the issuance of “blank check” preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibit stockholder action by written consent, which requires stockholder actions to be taken at a meeting of our stockholders, except for so long as specified stockholders hold in excess of 50% of our outstanding common stock;
- prohibit stockholders from calling special meetings of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings;

- provide the board of directors with sole authorization to establish the number of directors and fill director vacancies; and
- provide that the board of directors is expressly authorized to make, alter, or repeal our second amended and restated bylaws.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay, or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our eighth amended and restated certificate of incorporation, as amended to date, provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our eighth amended and restated certificate of incorporation, as amended to date, and our second amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our eighth amended and restated certificate of incorporation, as amended to date, provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our eighth amended and restated certificate of incorporation, as amended to date, and our second amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

None.

Item 3. Default Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT NO.	DESCRIPTION
4.1	Form of Pre-Funded Warrant (filed with the SEC as Exhibit 4.1 to the registrant's Form 8-K filed on September 19, 2023).
4.2	Form of September 2023 Warrant (filed with the SEC as Exhibit 4.2 to the registrant's Form 8-K filed on September 19, 2023).
4.3	Amendment No. 4 to Fourth Amended and Restated Investors' Rights Agreement, dated September 18, 2023, by and among Biora Therapeutics, Inc., and certain of its stockholders (filed with the SEC as Exhibit 4.3 to the registrant's Form 8-K filed on September 19, 2023).
10.1	Convertible Notes Exchange Agreement for Common Stock and Warrants, dated September 18, 2023, by and among the Company, Athyrium Opportunities III Acquisition LP and Athyrium Opportunities III Co-Invest 1 LP (filed with the SEC as Exhibit 10.1 to the registrant's Form 8-K filed on September 19, 2023).
10.2*	Purchase and Sale Agreement, dated October 6, 2023, by and among Biora Therapeutics, Inc. and Lynxdx, Inc.
31.1*	Certification of principal executive officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
31.2*	Certification of principal financial officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934
32.1†	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

† Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Exchange Act, and shall not be deemed to be incorporated by reference into any filing under the Securities Act.

SIGNATURES

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

Date: November 13, 2023

BIORA THERAPEUTICS, INC.

By: /s/ Aditya P. Mohanty
Aditya P. Mohanty
Chief Executive Officer
(principal executive officer)

By: /s/ Eric d'Esparbes
Eric d’Esparbes
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 10.2

PURCHASE AND SALE AGREEMENT

THIS PURCHASE AND SALE AGREEMENT (this "**Agreement**") is entered into and made effective as of October 6, 2023 (the "**Effective Date**"), by and between BIORA THERAPEUTICS, INC. (formerly known as Progenity, Inc.), a Delaware corporation ("**Seller**") and LYNXDX, INC., a Michigan corporation, or its permitted assigns ("**Purchaser**").

Background

Purchaser desires to acquire from Seller, and Seller desires to convey to Purchaser, the Property (as defined below). The parties desire to consummate such transactions in accordance with the terms and conditions set forth herein.

Agreement

NOW, THEREFORE, IN CONSIDERATION OF THE MUTUAL COVENANTS AND CONDITIONS SET FORTH HEREIN, THE PARTIES AGREE AS FOLLOWS:

1. Property. Purchaser shall purchase and Seller shall convey the Property in accordance with the terms and conditions set forth herein. The Property shall include the following (hereafter referred to collectively as the "**Property**"): (a) all those certain tracts or parcels of land commonly known as 5230 State Street, Ann Arbor, Michigan, and more particularly described on the attached **Exhibit A** (the "**Land**"); (b) all improvements, structures and fixtures located upon the Land (the "**Improvements**"); (c) all rights, easements and interests, water, air and mineral rights, streets, public ways or rights-of-way, privileges, tenements, hereditaments, licenses, appurtenances and other rights and benefits belonging or in any way related or appurtenant to the Land, if any and to the extent owned by Seller; and (d) all rights to divisions under the Michigan Land Division Act (if any).

(a) In addition, Seller agrees to provide a general assignment at Closing that assigns and transfers its interest, if any, in: (i) all unexpired transferable guarantees and warranties given, made or issued by any contractors, subcontractors, suppliers, manufacturers and installers relating to the construction of the Improvements on the Property and the materials and equipment installed or located on the Property, if any; and (ii) all transferable occupancy certificates, consents, authorizations, variances, waivers, licenses, permits, and approvals from or issued by any governmental or quasi-governmental agency, department, board, commission, bureau and any guarantees thereof or other entity or instrumentality in respect of the Property and/or relating to the use, development, maintenance or operation of the Property traffic and zoning or hereafter held by or granted to Seller, if any.

(b) Seller also agrees, and Purchaser shall accept and receive, all right, title and interest of Seller in and to all personal property located upon the Land and/or within the Improvements, including, without limitation, those specific items listed on **Exhibit B** attached hereto (collectively, the "**Personal Property**"), and Seller shall not be obligated to remove any Personal Property or other fixtures or items from the Property. With respect to Personal Property that necessitates third-party approval for transfer to the Purchaser (specifically, the Qiagen QIAsymphony and Illumina MiSeq equipment, which require the transfer of ownership from the vendor, Qiagen and Illumina, respectively, to the Purchaser), the Seller hereby agrees to actively cooperate with and provide support to the Purchaser in their efforts to solicit such third-party approvals.

2. Purchase Price. The purchase price for the Property shall be Two Million Seven Hundred Fifty Thousand and No/100 Dollars ($2,750,000.00) (the "**Purchase Price**"). The Purchase Price, less the

Deposit defined below, and adjusted by other charges and credits as set forth herein, shall be delivered at Closing in immediately available funds subject to the terms and conditions of this Agreement.

3. Deposit. Purchaser shall deliver to First American Title Insurance Company ("**Title Company**") the sum of Fifty Thousand and No/100 Dollars ($50,000.00) by wire transfer or certified, cashier's or corporate check (the "**Deposit**") within three (3) business days of the execution of this Agreement by both parties. The Deposit shall be credited against the Purchase Price at Closing or otherwise returned to Purchaser or released to Seller in accordance with the terms of this Agreement.

4. Investigation Period. The "**Investigation Period**" shall commence on the date of this Agreement and shall expire twenty one (21) days from the date hereof at 5:00 p.m. eastern time, unless extended as provided below. During the Investigation Period, Purchaser and/or its agents and representatives, shall have the right to enter the Property and have the Property and Improvements inspected, evaluated, analyzed, tested, appraised and/or assessed for any matter whatsoever, including but not limited to, condition of Improvements including structure, plumbing and mechanical systems and the presence of wood destroying insects; survey and boundaries of the Property including any easements serving the Property; the service agreements related to the Property; market value; soil conditions; location of flood plains; presence of wetlands and necessary mitigation, if any; storm water drainage systems; presence of environmental contamination, including a Phase I environmental assessment; health and safety conditions; access to utilities; access to public roads; signage; zoning; compliance with laws, codes and ordinances, and any other matter desired by Purchaser. Solely in the event that Purchaser's phase one environmental assessment ("**Phase I Environmental Assessment**") and/or Survey (as defined below) is/are not complete as of the end of the Investigation Period, Purchaser shall have the unilateral right to extend the Investigation Period solely for purposes of completion and review of the Phase I Environmental Assessment and/or Survey for an additional twenty one (21) days in order to complete such investigations by giving Seller written notice thereof prior to the expiration of the initial twenty one (21) day Investigation Period.

Notwithstanding the foregoing, to the extent Purchaser desires to undertake a Phase II environmental assessment of the Property that includes invasive sampling, soil borings, groundwater testing, monitoring wells or invasive sampling or testing techniques during the Investigation Period, as it may be extended (collectively, the **"Phase II Environmental Assessments**"), the parties agree that the Phase II Environmental Assessments shall be undertaken and performed only with Seller's prior approval (which approval shall not be unreasonably conditioned, withheld or delayed). Seller shall provide written notice of its approval or disapproval of any plan for Phase II Environmental Assessments within two (2) business days of Purchaser's written request. If Seller fails to respond to such request by Purchaser, Seller shall be deemed to have approved Purchaser's plans for its Phase II Environmental Assessments and Purchaser may proceed with such investigations in accordance with the terms of this Agreement. If Seller disapproves of Purchaser's plans for its Phase II Environmental Assessments, Purchaser shall have the right to terminate this Agreement and receive a refund of the Deposit. If, for any reason, this Agreement terminates or if the Property is not transferred to Purchaser for any reason, the results, conclusions, reports and information regarding the environmental condition of the Property shall be held strictly confidential by Purchaser and Purchaser's consultants and may only be disclosed to any third party after obtaining the prior written consent of Seller, unless such disclosure is required by law. Disclosures to Purchaser's principals, employees, officers, shareholders, attorneys, accountants, advisors, consultants or investors shall be deemed authorized disclosures. Purchaser shall indemnify and hold Seller harmless from any and all claims, actions, losses, liabilities that arise from the unauthorized disclosure of any such information. The parties agree this obligation and indemnity shall survive termination of the Agreement.

Purchaser agrees to pay all costs and expenses associated with the Purchaser's inspections conducted pursuant to this Section 4, and Purchaser further agrees to repair and restore any damage to the Property and/or to any portions thereof resulting from or arising out of the Purchaser's inspections if the transaction contemplated by this Agreement does not close. Purchaser and Seller agree to work together in good faith to determine the timing of Purchaser's inspections to minimize interference with the operation of Seller's business at the Property. Seller shall provide Purchaser or its representatives access to the Property during normal business hours with 24 hours' notice thereof from Purchaser.

In the event that, after conducting its investigations, Purchaser desires not to proceed with the Purchase of the Property for any reason or no reason at all, in its sole discretion, Purchaser shall have the right to terminate this Agreement by delivery of written notice of termination to Seller and the Title Company prior to the expiration of the initial Investigation Period (and excluding an extension of the Investigation Period, which is addressed below) ("**Termination Notice**"). In the event Purchaser terminates this Agreement pursuant to its rights under this Section, and the Termination Notice is delivered before the expiration of the Investigation Period (excluding an extension of the Investigation Period, which is addressed below), then, (i) the full amount of the Deposit shall be promptly refunded to Purchaser, (ii) at the direction of Seller, Purchaser shall return or destroy the Property Information (as defined below), and (iii) all rights, liabilities and obligations of the parties hereunder shall immediately and forever terminate with the exception of those rights, liabilities and obligations that are expressly intended to survive termination of this Agreement.

In the event that Purchaser extends the Investigation Period due to the need for additional time to complete the Phase I Environmental Assessment and/or the Survey, Purchaser shall forever, waive release and discharge the right to terminate this Agreement based on this Section 4 as to any other matter, including as to the Phase I Environmental Assessment and/or Survey, if either have been delivered prior to expiration of the initial Investigation Period. In the event that Investigation Period is extended in accordance with the provisions of this Section 4, and the Phase I Environmental Assessment or Survey disclose material adverse conditions or defects (the finding of any "recognized environmental condition" in the Phase I Environmental Assessment shall constitute a material adverse condition for purposes of this paragraph), then Purchaser shall have the right to terminate this Agreement by delivery of written notice to Seller prior to expiration of the extended Investigation Period that states the grounds for such termination and includes a copy of the report (ie the Phase I Environmental Assessment or Survey) that discloses the defect being relied upon to terminate this Agreement. In the event such right to terminate is timely and properly exercised, then (i), (ii) and (iii) of the preceding paragraph shall apply.

5. Title and Survey Matters.

A. Purchaser acknowledges that, prior to the Effective Date, it received a commitment (the "**Title Commitment**") for the Property from the Title Company to issue to Purchaser, at the Closing, an ALTA owner's title insurance policy in the amount of the Purchase Price (the "**Title Insurance Policy**"), and with such endorsements as Purchaser may require, to the extent reasonably available (any such endorsements shall be at Purchaser's sole cost and expense except to the extent that the same relate to the cure of a title objection), free and clear of any liens and encumbrances except for (i) real estate taxes and/or assessments, not yet due and payable as of the date of Closing, (ii) matters that would be revealed or disclosed by an accurate ALTA/NSPS survey of the Property, (iii) all building and zoning laws and ordinances and municipal codes and regulations, and any state, county or federal regulations affecting the Property, and (iv) matters set forth in the Title Commitment not objected to by Purchaser, as permitted hereunder, or objected to by Purchaser but waived by Purchaser or the Title Company or insured over by the Title Company (collectively, the "**Permitted Exceptions**"). Notwithstanding anything contained in this Section to the contrary, Seller covenants and agrees that it shall pay and discharge on or before Closing, if necessary from the proceeds of the Purchase Price, and Permitted Exceptions shall not include: (i) mortgages, liens

or other encumbrances of a liquidated nature and an ascertainable monetary amount; and (ii) mortgages, liens or other encumbrances created by the act or omission of Seller or any agent or contractor of Seller.

B. Within five (5) business days after the Effective Date, Purchaser may order a survey of the Property in such form as Purchaser may desire (the "**Survey**") at Purchaser's sole cost and expense which Purchaser shall cause to also be certified to the Title Company.

C. If written objection to title and/or Survey matters is made by Purchaser, no later than the earlier of: (i) seven (7) days after Purchaser's receipt of the Survey, or (ii) the expiration of the Investigation Period, as it may be extended for completion of the Survey, that the title and/or Survey is not acceptable to Purchaser, Seller shall have ten (10) days from the date that it received written notice of each of the particular defects (with reasonable specificity), in order, in Seller's sole and absolute discretion, to notify ("**Title Defect Notice**") Purchaser of its proposed cure for each defect or to provide Purchaser with a revised Title Commitment evidencing that such defects have been remedied (or, with Purchaser's approval, insured over) to the satisfaction of Purchaser, it being expressly understood that Seller shall have no obligation to remedy any such defect. If Seller is unable or unwilling to obtain such revised Title Commitment or does not elect to cure such defects within such ten (10) day period, Purchaser shall have the option (i) to proceed with the purchase of the Property without any reduction in the Purchase Price, in which event such defects or objections will be deemed Permitted Exceptions or (ii) to terminate this Agreement by delivery of written notice of termination to Seller and the Title Company prior to Closing, whereupon (A) Purchaser shall promptly receive a refund of the Deposit, (B) at the direction of Seller, Purchaser shall return or destroy the Property Information (as defined below), and (C) all rights, liabilities and obligations of the parties hereunder shall immediately and forever terminate with the exception of those rights, liabilities and obligations that are expressly intended to survive termination of this Agreement. Failure of Purchaser to timely deliver such written notice of termination to Seller shall be deemed an election by Purchaser to choose the foregoing option (i).

6. Property Information. Within five (5) days after the Effective Date, Seller agrees to deliver to Purchaser the documents and materials listed on **Exhibit C** attached hereto (collectively, the "**Property Information**"). Notwithstanding the foregoing, Purchaser acknowledges and agrees that it is relying exclusively on its own investigations and due diligence of the Property in relation to determining whether it will exercise its right to terminate this Agreement prior to the expiration of the Investigation Period. The parties further acknowledge and agree that Seller makes no representations or warranties regarding the accuracy or completeness of the Property Information, or any other documents or information that Seller provides to Purchaser (except as set forth in Section 11 hereof or in the Deed or other documents delivered by Seller at Closing) and that Purchaser agrees it is not, and shall not, rely on the Property Information and that Purchaser is relying exclusively on its own investigations, due diligence and information.

7. Closing. The sale shall be closed (the "Closing") at the offices of the Title Company, or in escrow by mail, on the date which is fourteen (14) days after the expiration of the Investigation Period, or such other date as the parties may agree to in writing (the "**Closing Deadline**"). If Purchaser provides Seller with a timely Title Defect Notice pursuant to Section 5C above, and the Closing Deadline is scheduled to occur prior to the end of Seller's ten (10) day response period, then the Closing Deadline shall automatically be extended to occur fourteen (14) days from the date that Purchaser provides Seller with its Title Defect Notice. At Closing, Seller shall make the Seller Deliveries described herein and Purchaser shall make the Purchaser Deliveries described herein.

8. Seller's Closing Deliveries. At the Closing, Seller shall deliver to Title Company for delivery to Purchaser, the following items:

A. A Covenant Deed (the "**Deed**") conveying to Purchaser title to the Property, subject only to the Permitted Exceptions, executed and acknowledged by Seller in recordable form, along with a Real Estate Transfer Tax Valuation Affidavit.

B. An affidavit of ownership as is acceptable to Seller in its commercially reasonable discretion and as the Title Company may reasonably require to remove its standard printed exceptions from the Title Insurance Policy relating to, among other things, construction liens and rights of parties in possession, but not with respect to matters of survey.

C. Authority documents as the Title Company may require.

D. A 'marked-up' Title Commitment or pro forma and title instruction letter for a Title Insurance Policy dated as of the later of the Closing and recording of the Deed, issued by the Title Company in the amount of the Purchase Price, showing fee simple title to the Property in Purchaser, subject only to the Permitted Exceptions, with the requirements to issuance and standard exceptions deleted (except for those exceptions related to survey in the event the Purchaser fails to furnish the Title Company with a sufficient Survey).

E. A certificate in such form as may be required by the Internal Revenue Service pursuant to Section 1445 of the Internal Revenue Code of 1986, as amended, or the regulations issued pursuant thereto, certifying as to the non-foreign status of a transferor.

F. A general assignment, assigning any interest of Seller in and to the Property items listed in Sections 1(a) hereof, which general assignment shall be made without any representation or warranty.

G. A bill of sale with respect to the Personal Property, which bill of sale shall be made with representations and warranties as to ownership and absence of liens (provided, however, Seller's representations and warranties as to ownership of the Qiagen QIAsymphony and Illumina MiSeq equipment may be qualified as applicable).

H. Such other documents, including a signed closing statement, as are necessary and appropriate for the consummation of this transaction by Seller.

9. Purchaser's Closing Deliveries. At the Closing, Purchaser shall deliver to the Title Company for delivery to Seller, the following items:

A. The Purchase Price adjusted by the Deposit and other credits and debits as set forth on the closing statement to be prepared by Title Company.

B. A certificate certifying that all of Purchaser's representations and warranties contained in this Agreement are true and correct.

C. Such other documents, including a signed closing statement, as are necessary and appropriate for the consummation of this transaction by Purchaser.

10. Closing Costs and Prorations. Seller shall pay (i) all transfer and/or conveyance taxes assessed in connection with the Closing, (ii) the base premium for the Title Insurance Policy (excluding costs related to removal of the standard exceptions which require a Survey for their removal), (iii) one half of the Title Company's closing fee in connection with this transaction and (iv) all costs related to Seller's

professionals and consultants. Purchaser shall pay (A) all recording costs for recordation of the Deed, (B) all costs and expenses associated with Purchaser's inspections conducted pursuant to this Agreement and Purchaser's professionals and consultants, (C) any endorsements issued with the Title Insurance Policy (except for those used by Seller to cure any title objections), (D) the cost of the Survey, if any, and (E) one half of the Title Company's closing fee connection with this transaction.

Seller shall be responsible for and will pay at or prior to Closing all ad valorem property taxes and installments of special assessments that are due and payable prior to Closing. Current ad valorem property taxes and installments of special assessments shall be prorated as of the date of Closing on a due date basis.

All utilities should be apportioned based on final meter readings and final invoices as of the date of Closing. Seller shall request each utility serving the Property to render a final bill as of Closing so that utility charges may be separately billed for the periods before and after Closing. In the event that Seller is unable to obtain final meter readings for water as of the Closing Date, then Seller agrees to place funds in escrow with the Title Company pursuant to a customary water escrow agreement (the amount of such escrow to be satisfactory to the parties based upon the historical water bills). Utility accounts, are to be closed or transfer to Purchaser as of the date of Closing, with Seller responsible for all charges prior to the date of Closing.

Other regular and customary costs and expenses related to the Property shall also be prorated based on the date of Closing. To the extent appropriate for the adjustment of the foregoing amounts to achieve the requirements of this Section, the terms of this Section shall survive Closing.

11. Representations and Warranties of Seller. Seller hereby represents and warrants to Purchaser, which representations and warranties shall survive Closing for a period of 90 days, that as of the date hereof, and on the date of Closing:

A. Seller has the right, power and authority to enter into this Agreement and to sell the Property in accordance with the terms hereof. Seller has the right, power and authority to enter into all of the agreements, assignments and other documents contemplated by this Agreement. The individuals signing this Agreement and all other documents executed or to be executed pursuant hereto on behalf of Seller are and shall be duly authorized to sign the same on Seller's behalf and to bind Seller thereto.

B. There are no leases, agreements, rights of first refusal, rights of first offer, options or other instruments or agreements in effect with respect to the Property to which Seller is a party.

C. There are no service agreements, contracts, agreements, obligations, or other rights of third parties affecting any portion of the Property that will not terminate at Closing.

D. The execution and delivery of, and the performance of all obligations under this Agreement by Seller do not and will not require any consent or approval of any person or entity, and do not and will not result in a breach of any agreement or instrument to which Seller is a party or to which any portion of the Property is subject.

E. There is no litigation, proceeding or investigation pending or, to Seller's knowledge, threatened against or involving Seller or any portion of the Property.

F. Seller has not received written notice that the Property or any portion thereof is situated, used, or operated in violation of any law, court order, regulation, ordinance or requirement of any city, county, state or federal governmental authority.

G. No property tax appeals are pending with respect to all or any part of the Property.

H. Seller has not made any commitments to any governmental authority, utility company, school board, homeowners association or other organization which would impose an obligation on Purchaser or its successors or assigns to make any contributions or dedications of money or land or to Seller's knowledge to construct, install or maintain any improvements of a public or private nature on or off the Property, and no governmental authority has imposed any requirement that any developer of the Property pay directly or indirectly any special fees, charges or contributions (including impact fees) in connection with the development of the Property.

I. Subject to information or matters disclosed in the Phase I Environmental Assessment, the Phase II Environmental Assessment (if obtained) and the Existing Environmental Report (defined in Exhibit C), to Seller's actual current knowledge: (i) there are no Hazardous Materials situated upon or buried in the Land, and (ii) neither Seller nor any user nor its or their respective agents or employees, or any prior owner or occupant of the Property are in violation of any Environmental Laws.

> For the purposes of this Agreement, "**Hazardous Materials**" shall include, but shall not be limited to, chemical waste, toxic or hazardous substances, chemicals or wastes, solid waste and any other substances or materials regulated by any Environmental Laws, and shall include substances defined as "hazardous substances" or "toxic substances" in CERCLA, RCRA (as such acronyms are defined below), the Hazardous Materials Transportation Act and those substances defined as hazardous or contaminated waste in any federal, state or local laws and the regulations adopted and publications promulgated pursuant to said laws. For purposes of this Agreement the term "**Environmental Laws**" shall mean and include any and all laws, statutes, ordinances, rules, regulations, orders or determinations of any federal, state or local governmental authority existing as of the date hereof pertaining to health, air or water quality, hazardous substances, hazardous waste, waste disposal, air emissions or the environment, and relating to the Property, including without limitation, the Clean Air Act, as amended, the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, ("**CERCLA**"), the Federal Water Pollution Control Act Amendments, the Occupational Safety and Health Act of 1970, as amended, the Resource Conservation and Recovery Act of 1976, as amended, ("**RCRA**"), the Hazardous Materials Transportation Act of 1975, as amended, the Safe Drinking Water Act, as amended, and the Toxic Substances Control Act, as amended. Likewise, the terms "hazardous substance", "release" and "threatened release" shall have the meanings specified in CERCLA and the terms "solid waste" and "disposal" (or "disposed") shall have the meanings specified in RCRA; provided that, to the extent the laws of the state where the Property is located establish a meaning for "hazardous substance", "release", "solid waste" or "disposal" which is broader than that currently specified in CERCLA or RCRA, such broader meaning shall apply with regard to the Property.

The continuing truth and correctness of the foregoing representations and warranties shall be conditions precedent to Purchaser's obligation to close under this Agreement.

12. Representations and Warranties of Purchaser. Purchaser hereby represents and warrants to Seller, which representations and warranties shall survive Closing for a period of 90 days, that as of the date hereof, and on the date of Closing:

A. Purchaser has the full power and authority to execute, deliver and perform this Agreement and all of Purchaser's obligations under this Agreement; and

B. The individuals signing this Agreement and all other documents executed or to be executed pursuant hereto on behalf of Purchaser are and shall be duly authorized to sign the same on Purchaser's behalf and to bind Purchaser thereto.

The continuing truth and correctness of the foregoing representations and warranties shall be conditions precedent to Seller's obligation to close under this Agreement.

13. Indemnification.

A. Seller agrees to indemnify and hold Purchaser harmless from and against any and all liabilities, claims, demands, and expenses, of any kind or nature, including but not limited to, all expenses related thereto, including, without limitation, court costs and attorney's fees for matters arising from or related to the inaccuracy or breach of any of Seller's representations and warranties in Section 11 hereof up to an amount not to exceed $275,000.00, provided, however, such cap shall not apply in instances of fraud.

B. Purchaser agrees to indemnify and hold Seller harmless from and against any and all liabilities, claims, demands, and expenses, of any kind or nature, including but not limited to, all expenses related thereto, including, without limitation, court costs and attorney's fees for matters arising from or related to the inaccuracy or breach of any of Purchaser's representations and warranties in Section 12 hereof up to an amount not to exceed $275,000.00, provided, however, such cap shall not apply in instances of fraud.

C. In the event either party hereto receives notice of a claim or demand for which the other party may be entitled to indemnification pursuant to this Section, such party shall promptly give notice thereof to the other party. The indemnifying party shall immediately take such measures as may be reasonably required to properly and effectively defend such claim, and may defend same with counsel of its own choosing and approved by the other party (which approval shall not be unreasonably withheld or delayed). In the event the indemnifying party refuses to defend such claim or fails to properly and effectively defend such claim, then the other party may defend such claim with counsel of its own choosing at the expense of the indemnifying party. In such event, the indemnified party may settle such claim without the consent of the indemnifying party. It is expressly stipulated, covenanted, and agreed that the provisions of this Section shall survive the Closing for a period of 90 days (provided, however, representations and warranties that are the basis for claims asserted under this Agreement prior to the expiration of said ninety (90) day period shall also survive until the final resolution of those claims).

14. Condemnation; Casualty. Purchaser shall have the right to terminate this Agreement if any part of the Property is destroyed without fault of Purchaser or any part of the Property is taken or is threatened to be taken by eminent domain. Purchaser shall give written notice of Purchaser's election to terminate this Agreement within ten (10) business days after Purchaser receives written notice from Seller of any such damage or threatened condemnation. In the event of such a termination by Purchaser, the Title Company shall promptly refund to Purchaser the Deposit, at Seller's direction, Purchaser shall return or destroy the Property Information, and the rights and obligations of the parties hereunder shall terminate, with the exception of those rights and obligations that are expressly intended to survive termination of this Agreement. If Purchaser does not elect to so terminate this Agreement, (i) in the case of a condemnation or taking, the Purchase Price shall not be reduced, and at Closing Seller shall assign to Purchaser all rights to any condemnation award, and (ii) in the case of a casualty, Seller shall turn over to Purchaser on the date of Closing all casualty insurance proceeds collected by Seller on account of said casualty, plus Seller's

deductible or other self-insured amount, and to the extent such proceeds are not so collected, assign to Purchaser the right to receive and settle same.

15. Default and Remedies.

A. Purchaser's Default; Seller's Remedy. If, prior to Closing, Purchaser breaches this Agreement and such default continues for ten (10) days after written notice thereof from Seller to Purchaser without cure by Purchaser (except such notice and cure period shall not apply to a failure to close), then Seller may terminate this Agreement by written notice thereof to Purchaser and the Deposit shall promptly be paid to Seller as liquidated damages, as Seller's sole and exclusive remedy, and upon payment to Seller of the Deposit, this Agreement and all rights and obligations of the parties shall terminate, with the exception of those rights and obligations that are expressly intended to survive termination of this Agreement. The parties agree that it would be impracticable and extremely difficult to ascertain the actual damages suffered by Seller as a result of Purchaser's failure to complete the purchase of the Property and that under the circumstances existing as of the date of this Agreement, the liquidated damages provided for in this Section represents a reasonable estimate of the damages which Seller will incur as a result of such failure. The parties acknowledge that the payment of such liquidated damages is not intended as a forfeiture or penalty but is intended to constitute liquidated damages to Seller. Except with respect to a breach of any of Purchaser's representations or warranties under Section 12 hereof or any other obligations of Purchaser that expressly survive termination of this Agreement, Seller hereby unconditionally and irrevocably waives, to the greatest extent permitted by law, any claim for monetary damages against Purchaser arising out of a default by Purchaser hereunder, which waiver will survive the termination of this Agreement.

B. Seller's Default; Purchaser's Remedies. If, prior to Closing, Seller breaches this Agreement and such default continues for ten (10) days after written notice from Purchaser to Seller thereof (except such notice and cure period shall not apply to a failure to close) then Purchaser shall, as its sole remedy, have the right to either (i) terminate this Agreement by written notice thereof to Seller, in which event Purchaser shall (A) receive a refund of the Deposit, (B) upon Seller's direction, return or destroy the Property Information, and (C) neither party shall have any further liability under this Agreement except for liability which expressly survives termination as provided herein, or (ii) seek specific performance of Seller's obligations hereunder and to recover its attorneys' fees and costs as set forth in paragraph C hereof, except that in the event the remedy of specific performance is not available to Purchaser due to Seller's fraud, Purchaser shall, in addition to the foregoing remedies, be permitted to pursue any and all rights and remedies available to Purchaser at law or in equity on account of Seller's breach. Except with respect to a breach of any of Seller's representations or warranties under Section 11 or in the Deed or other documents delivered by Seller at Closing, or any Surviving Purchaser Claims, Purchaser hereby unconditionally and irrevocably waives, to the greatest extent permitted by law, any claim for monetary damages against Seller arising out of a default by Seller hereunder, which waiver will survive the termination of this Agreement. Notwithstanding anything to the contrary contained herein, in the event Purchaser has not commenced an action for specific performance pursuant to the foregoing subclause (ii) within sixty (60) days after the date of Seller's default, Purchaser shall be deemed to have waived its right to pursue and obtain specific performance pursuant to such foregoing subclause (ii).

As used in this Agreement, the "**Surviving Purchaser Claims**" shall mean any and all claims, expenses, losses, costs, damages and liabilities suffered by Purchaser after the date of Closing, as a result of, on account of or arising from Seller's fraud.

C. Attorneys' Fees. The prevailing party in any legal proceeding brought under or with relation to this Agreement or transaction shall be entitled to recover court costs, reasonable attorneys' fees and all other litigation expenses from the non-prevailing party.

16. Assignment of Agreement. Purchaser shall not assign this Agreement or its rights hereunder without the prior written consent of Seller, which consent may be withheld in its sole discretion. Notwithstanding the foregoing, Purchaser shall have the right to assign its rights in this Agreement, without Seller's consent, to an affiliate of Purchaser that is owned, in whole or in majority part, and controlled by Purchaser or Purchaser's principal owners. Notwithstanding any assignment, Purchaser shall not be released from any, and Purchaser shall cause all, of its obligations hereunder to be performed. Purchaser shall provide Seller not less than three (3) business days' notice of any such assignment, such notice to include the name and signature block of the assignee and reasonable evidence of the relationship of Purchaser to such assignee.

17. AS-IS. Purchaser acknowledges that, with the exception of the representations and warranties of Seller set forth in Section 11 above and in the Deed and other documents delivered by Seller with Closing, Seller (i) has made no representations or warranties whatever with respect to the Property, (ii) specifically disclaims any and all express and implied representations and warranties with respect to the Property, including without limitation, any representations with respect to the physical or environmental condition of the Property, the construction of the improvements located thereon, the fitness of the Property for a particular purpose, or whether the Property complies with any laws, and (iii) the inspection, due diligence and investigation rights set forth herein are sufficient to enable Purchaser to inspect the Property to determine that they are satisfactory to Purchaser. Accordingly, except for any the representations and warranties of Seller set forth in Section 11 above and in the Deed and other documents delivered by Seller with Closing, Purchaser is acquiring the Property in its "as is" "where is" condition, with all faults.

18. Miscellaneous.

A. TIME IS OF THE ESSENCE OF THIS AGREEMENT.

B. This Agreement shall be governed by and construed under the laws of the state in which the Property is located.

C. This Agreement may be executed in any number of counterparts, each of which, when taken together, shall be deemed to be one and the same instrument. Executed copies of this Agreement may be delivered between the parties via electronic mail.

D. Should any provision of this Agreement require judicial interpretation, it is agreed that the court interpreting or construing the same shall not apply a presumption that the terms hereof shall be more strictly construed against one party by reason of the rule of construction that a document is to be construed more strictly against the party who itself or through its agent prepared the same, it being agreed that the agents of all parties have participated in the preparation hereof.

E. This Agreement supersedes all prior discussions and agreements between Seller and Purchaser with respect to the conveyance of the Property and all other matters contained herein and constitutes the sole and entire agreement between Seller and Purchaser with respect thereto. This Agreement may not be modified or amended unless such amendment is set forth in writing and signed by both Seller and Purchaser. Failure by Purchaser or Seller to insist upon or enforce any of its rights under this Agreement shall not constitute a waiver thereof. The terms, conditions, provisions, agreements, representations and warranties contained in this Agreement shall not merge into the Deed and shall survive the Closing as set forth herein.

F. All notices, payments, demands or requests required or permitted to be given pursuant to this Agreement shall be in writing and shall be deemed to have been properly given or served and shall be immediately effective upon personal delivery, or upon sending of an e-mail, or upon the second (2nd)

business day after being deposited in the United States mail, postpaid and registered or certified with return receipt requested; or when sent by private courier service for same-day delivery or one day after being sent by private courier service for next-day delivery. The time period in which a response to any notice, demand or request must be given shall commence on the date of receipt by the addressee thereof. Rejection or other refusal to accept delivery or inability to deliver because of changed address, of which no notice has been given, shall constitute receipt of the notice, demand or request sent. Any such notice, demand or request shall be sent to the respective addresses set forth below:

To Seller:

Eric d'Esparbes
Biora Therapeutics, Inc.
4330 La Jolla Village Drive, # 300
San Diego, California 92122

With Copy to:

Honigman, LLP
c/o J. Patrick Lennon
650 Trade Centre Way
Suite 200
Kalamazoo, Michigan 49002
(269) 337-7712
lennon@honigman.com

To Purchaser:

LynxDx, Inc.
120 W Main St STE 300,
Northville MI 48167
Attn: Steve Riggs
steve@lynxdx.com

With Copy to:

Bodman PLC
c/o Kelly Lockman
1901 St. Antoine Street
Sixth Floor at Ford Field
Detroit, Michigan 48226
klockman@bodmanlaw.com

Any notice under this Agreement may be given by an attorney of the respective party.

G. This Agreement shall inure to the benefit of and bind the parties hereto and their respective heirs, legal representatives, successors and permitted assigns.

H. If any date of performance hereunder falls on a Saturday, Sunday or legal holiday, such date of performance shall be deferred to the next day which is not a Saturday, Sunday or legal holiday.

I. In case one or more of the provisions contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect by a court of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provisions hereof and this Agreement shall be construed as if such invalid, illegal or unenforceable provision is severed and deleted from this Agreement.

J. With the exception of Colliers International who shall be paid in full for all compensation and expenses by Seller, Seller and Purchaser shall be responsible for any compensation owing to any broker or consultant that they created in connection with the transaction contemplated by this Agreement and the party creating any such obligation agrees to indemnify and hold the other party harmless against any and all liability, loss, cost, damage and expense (including, but not limited to, attorneys' fees and costs of litigation) that the other party shall ever suffer or incur because of any claim by any such broker or consultant. These obligations will survive closing or termination of this Agreement.

K. If either party wishes to include the transaction contemplated by this Agreement in a Section 1031 like kind exchange transaction, that party shall give the other party written notice of that intention. The other party shall cooperate with the party that wishes to undertake a Section 1031 transaction, at no cost to the other party. The other party will not be required to take title to any other property that is included in the Section 1031 transaction or to delay the closing of the transaction contemplated by this Agreement in order to accommodate the Section 1031 transaction.

19. Intentionally Deleted.

20. No Sale of Business; No Successor Liability. The parties acknowledge that this transaction contemplates only the sale and purchase of the Property and that Seller is not selling a business nor do the parties intend that Purchaser be deemed a successor of Seller with respect to any liabilities of Seller to any third party. The provisions of this Section shall survive Closing.

21. Operation of Property Prior to Closing. Until the earlier of the Closing or the termination of this Agreement, Seller shall: (a) not take any action outside the ordinary course of business or create or allow to be created any easement, mortgage, lien, security interest, encumbrance or other interest in the Property or take any action which may adversely affect the Property, Seller's title to the Property, Seller's ability to comply with the terms of this Agreement or cause any material change in the Property; (b) insure the Property in the ordinary course of business; (c) promptly comply and furnish Purchaser with a copy of any and all notices of violation of laws or municipal ordinances, regulations, orders or requirements of departments of housing, building, fire, labor, health, or other state, or municipal departments or other governmental authorities having jurisdiction over the Property or the use or operation thereof; (d) promptly disclose in writing to Purchaser any change in any facts or circumstances which would make any of the representations or warranties in Section 11 inaccurate or false to the detriment of Purchaser; (e) pay and perform all of its obligations under or with respect to the Permitted Exceptions, pay, or cause to be paid, all contractors, laborers, materialmen and all other involved in the construction of the Property, and cause all liens arising out of such work to be discharged by payment, bond or otherwise, in a manner satisfactory to the Purchaser, promptly after the filing of any such liens; (f) not construct any improvements on the Property or undertake any activities that would result in a construction lien; and (g) not enter into any lease or occupancy agreement with respect to all or any part of the Property, without Purchaser's prior written consent. Seller's compliance with this Section shall be a condition to Purchaser's obligation to close under this Agreement.

22. Intentionally Deleted.

Signatures on following page

IN WITNESS WHEREOF, the parties hereto have executed this Agreement to be effective as of the Effective Date.

SELLER:

BIORA THERAPEUTICS, INC.,
a Delaware corporation

By:_____
Name: Adi Mohanty
Its: Chief Executive Officer

PURCHASER:

LynxDx, Inc., a Michigan corporation

By:_____
Name: Steve Riggs
Its: President

EXHIBIT "A"

THE PROPERTY

The Land referred to herein below is situated in the Township of Pittsfield, County of Washtenaw, State of Michigan, and is described as follows:

Unit 2 of STATE STREET EXECUTIVE PARK, a Condominium according to the Master Deed recorded in Liber 4741, Page 401 and First Amendment to Master Deed recorded in Liber 5102, page 841 as amended, and designated as Washtenaw County Condominium Subdivision Plan No. 577, together with rights in the general common elements and the limited common elements as shown on the Master Deed and as described in Act 59 of the Public Acts of 1978, as amended.

EXHIBIT “B”

PERSONAL PROPERTY INFORMATION

Any and all personal property including but not limited to furniture, lab equipment, benches, hoods, the backup generator, all refrigeration and freezer units, the Illumina MiSeq and the 5 Qiagen Symphonies in the building as of the signing of the Letter of Intent entered into by and between the parties dated September 19, 2023 shall remain in the building and be conveyed to the Purchaser at closing for the sum of $1.00 and other good and valuable consideration.

EXHIBIT C

Property Information

Phase I Environmental Site Assessment prepared by PM Environmental Inc. dated February 16, 2022 (the “Existing Environmental Report”).

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Aditya P. Mohanty, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biora 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:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 13, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty, Chief Executive Officer

(principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric d'Esparbes, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biora 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:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 13, 2023

By: /s/ Eric d'Esparbes

Eric d'Esparbes, Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Biora Therapeutics, Inc. (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report 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: November 13, 2023

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty, Chief Executive Officer
(principal executive officer)

By: /s/ Eric d'Esparbes

Eric d'Esparbes, Chief Financial Officer
(principal financial and accounting officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Biora Therapeutics, Inc. and will be retained by Biora Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.