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

FORM 10-Q

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

For the quarterly period ended June 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: 001-36284

Biocept, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**80-0943522**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

9955 Mesa Rim Road, San Diego, California
(Address of principal executive offices)

92121
(Zip Code)

(858) 320-8200
(Registrant's telephone number, including area code)

Not Applicable
(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 $0.0001 per share	BIOC	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "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 by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 8, 2023, there were 2,626,026 shares of the Registrant's common stock outstanding.

BIOCEPT, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED
June 30, 2023

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IMPORTANT NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements included or incorporated by reference in this Quarterly Report other than statements of historical fact, are forward-looking statements. You can identify these and other forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue," "plan," "estimate," "potentially," "predict," "should" or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements.

Forward-looking statements may include, but are not limited to, statements about:

- *the performance of our products, assays and services;*
- *the ability of our products, assays and services to become a key component of the standard of care for personalized cancer treatment;*
- *our ability to generate revenue, grow our business and increase sales of our products, assays and services;*
- *our ability to develop and commercialize new products, diagnostic assays, services and enhance our current products, assays and services and future products, assays, and services;*
- *our plans to launch a series of cancer diagnostic assays for different predictive biomarkers;*
- *our ability to effectively compete with other products, diagnostic assays, methods and services that now exist or may hereafter be developed;*
- *our ability to expand our international business and commercialize our products and assays in other countries;*
- *market adoption of our products and assays and our ability to successfully complete clinical utility studies;*
- *our FORESEE trial, including anticipated timelines for progressing and completing the trial;*
- *the potential for CNSide to be included in NCCN guidelines;*
- *our ability to obtain coverage and adequate reimbursement from governmental and other third-party payors for assays and services;*
- *our expectations regarding our material cash requirements, contractual obligations and commitments and the use of our existing cash;*
- *our ability to enter into and leverage agreements with commercialization partners for the sales, marketing and commercialization of our current products, assays and services, and our planned future products, assays and services;*
- *our ability to satisfy any applicable United States and international regulatory requirements with respect to products, assays and services;*
- *our ability to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned products, assays and services;*
- *potential effects of an epidemic or pandemic on our business;*
- *our estimates regarding the period of time for which our current capital resources will be sufficient to fund our continued operations;*
- *our expectations and estimates regarding our future use of cash, expenses and costs and needs for additional financing; and*
- *our ability to maintain a strong internal control environment and remediate internal control deficiencies.*

Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in this report under the "Management's Discussion and Analysis" and "Risk Factors" headings.

Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made except as required by law. Readers should, however, review the factors and risks we describe in the reports we file from time to time with the SEC. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date the statement is made, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Biocept, Inc.
Condensed Balance Sheets
(In thousands, except share and per share data)

	June 30, 2023	December 31, 2022
Assets	(unaudited)	
Current assets:		
Cash	$ 6,633	$ 12,897
Accounts receivable	800	2,151
Inventories, net	551	757
Prepaid expenses and other current assets	876	538
Total current assets	8,860	16,343
Fixed assets, net	2,395	2,572
Lease right-of-use asset - operating	8,190	8,486
Lease right-of-use assets - finance	2,272	3,086
Other non-current assets	386	386
Total assets	$ 22,103	$ 30,873
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,467	$ 1,523
Accrued liabilities	1,529	2,249
Current portion of lease liability - operating	565	518
Current portion of lease liabilities - finance	815	1,099
Financed insurance premiums	526	117
Total current liabilities	4,902	5,506
Non-current portion of lease liability - operating	8,849	9,175
Non-current portion of lease liabilities - finance	836	1,200
Payor liability	6,149	6,132
Warrant liability	1,077	—
Total liabilities	21,813	22,013
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; 2,090 shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized; 2,407,381 shares and 568,994 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively.	—	—
Additional paid-in capital	309,503	307,298
Accumulated deficit	(309,213)	(298,438)
Total stockholders' equity	290	8,860
Total liabilities and stockholders' equity	$ 22,103	$ 30,873

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

Biocept, Inc.
Condensed Statements of Operations
(In thousands, except shares and per share data)
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Net revenues	$ 589	$ 5,819	$ 1,262	$ 25,763
Costs and expenses:				
Cost of revenues	2,550	8,023	5,578	18,357
Research and development expenses	409	1,729	1,449	3,574
General and administrative expenses	3,494	4,300	6,482	10,556
Sales and marketing expenses	250	1,656	965	5,314
Total costs and expenses	6,703	15,708	14,474	37,801
Loss from operations	(6,114)	(9,889)	(13,212)	(12,038)
Other income (expense):				
Interest expense, net	(50)	(155)	(96)	(217)
Other income, net	91	—	91	—
Change in fair value of warrant liability	2,442	—	2,442	—
Total other income (expense):	2,483	(155)	2,437	(217)
Loss before income taxes	(3,631)	(10,044)	(10,775)	(12,255)
Income tax expense	—	—	—	—
Net loss	(3,631)	(10,044)	(10,775)	(12,255)
Net loss attributable to common stockholders	$ (3,631)	$ (10,044)	$ (10,775)	$ (12,255)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders:				
Basic	1,036,529	563,528	813,180	562,561
Diluted	1,036,529	563,528	813,180	562,561
Net loss per common share:				
Basic	$ (3.50)	$ (17.82)	$ (13.25)	$ (21.78)
Diluted	$ (3.50)	$ (17.82)	$ (13.25)	$ (21.78)

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

Biocept, Inc.
Condensed Statements of Stockholders' Equity
(In thousands, except for shares)
(Unaudited)

	Common Stock		Series A Convertible Preferred Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2022	568,994	$ —	2,090	$ —	$ 307,298	$ (298,438)	$ 8,860
Stock-based compensation expense	—	—	—	—	316	—	316
Shares issued for ATM transaction, net of issuance costs	23,903	—	—	—	396	—	396
Net loss	—	—	—	—	—	(7,144)	(7,144)
Balance at March 31, 2023	592,897	$ —	2,090	$ —	$ 308,010	$ (305,582)	$ 2,428
Stock-based compensation expense	—	—	—	—	209	—	209
Shares issued for May 2023 financing transaction, net of issuance costs	1,176,470	—	—	—	484	—	484
Shares issued for exercise of May 2023 warrants	638,014	—	—	—	800	—	800
Net loss	—	—	—	—	—	(3,631)	(3,631)
Balance at June 30, 2023	2,407,381	$ —	2,090	$ —	$ 309,503	$ (309,213)	$ 290

	Common Stock		Series A Convertible Preferred Stock				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2021	561,652	$ —	2,106	$ —	$ 303,831	$ (266,351)	$ 37,480
Stock-based compensation expense	—	—	—	—	1,759	—	1,759
Shares issued upon conversion of preferred stock	12	—	(16)	—	—	—	—
Net loss	—	—	—	—	—	(2,210)	(2,210)
Balance at March 31, 2022	561,664	$ —	2,090	$ —	$ 305,590	$ (268,561)	$ 37,029
Stock-based compensation expense	—	—	—	—	585	—	585
Shares issued for ATM transaction, net of issuance costs	2,424	—	—	—	94	—	94
Net loss	—	—	—	—	—	(10,044)	(10,044)
Balance at June 30, 2022	564,088	$ —	2,090	$ —	$ 306,269	$ (278,605)	$ 27,664

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

Biocept, Inc.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	For the Six Months Ended June 30,	
	2023	**2022**
Cash Flows from Operating Activities		
Net loss	$ (10,775)	$ (12,255)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	984	810
Noncash operating lease expense	296	268
Stock-based compensation	525	2,344
Loss on disposal of fixed assets	36	—
Gain on finance lease termination	(125)	—
Other non-cash	2	—
Transaction costs allocated to warrants	505	—
Change in fair value of warrant liability	(2,442)	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	1,351	1,203
Inventory	206	402
Prepaid expenses and other current assets	500	6
Other non-current assets	—	(41)
Accounts payable	308	(2,852)
Accrued liabilities	(389)	(281)
Operating lease liability	(279)	(230)
Payor liability	17	5,654
Net cash used in operating activities	(9,280)	(4,972)
Cash Flows from Investing Activities:		
Purchases of fixed assets	(188)	(315)
Proceeds from sale of fixed assets	75	—
Net cash used in investing activities	(113)	(315)
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock (ATM)	396	94
Net proceeds from issuance of common stock and warrants (May 2023 offering)	3,558	—
Net payments on finance leases	(394)	(501)
Payments on financed insurance premiums	(431)	(242)
Net cash provided by (used in) financing activities	3,129	(649)
Net decrease in cash	(6,264)	(5,936)
Cash at Beginning of Period	12,897	28,864
Cash at End of Period	$ 6,633	$ 22,928

	For the Six Months Ended June 30,	
Supplemental cash flow information:	**2023**	**2022**
Cash paid for interest	$ 96	$ 217
Supplemental disclosure of non-cash activities		
Initial measurement of warrants issued in connection with May 2023 offering	$ 4,319	$ —
Unpaid issuance costs in accounts payable and accrued liabilities	$ 741	$ —
Fair value of cashless warrants exercised	$ 800	$ —
Unpaid fixed asset purchases in accounts payable	$ 45	$ 361
Right-of-use assets obtained in exchange for operating lease liabilities	$ 23	$ —

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

1. The Company, Business Activities and Basis of Presentation

The Company and Business Activities

Biocept, Inc., the Company, was founded in California in May 1997 and is a molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell and circulating cell-free tumor DNA assays utilizing a standard blood sample, or liquid biopsy. The Company's current and planned assays are intended to provide information to aid healthcare providers to identify specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy at diagnosis, progression or for monitoring to identify specific resistance mechanisms. Sometimes traditional procedures, such as surgical tissue biopsies, result in tumor tissue that is insufficient and/or unable to provide the molecular subtype information necessary for clinical decisions. The Company's assays, performed on cerebral spinal fluid, have the potential to provide more contemporaneous information on the characteristics of a patient's disease when compared with tissue biopsy and radiographic imaging.

The Company operates a clinical laboratory that is CLIA-certified (under the Clinical Laboratory Improvement Amendment of 1988) and CAP-accredited (by the College of American Pathologists), and manufactures cell enrichment and extraction microfluidic channels, related equipment and certain reagents to perform the Company's diagnostic assays in a facility located in San Diego, California. CLIA certification and accreditation are required before any clinical laboratory performs testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, treatment of disease, or assessment of health. The assays the Company offers are classified as laboratory developed tests (LDT) under the CLIA regulations.

In July 2013, the Company effected a reincorporation to Delaware by merging itself with and into Biocept, Inc., a Delaware corporation, which had been formed to be and was a wholly owned subsidiary of the Company since July 23, 2013.

In January 2020, the Company adapted and validated its proprietary blood-based liquid biopsy technology for commercial and clinical research use in CSF to identify tumor cells that have metastasized to the central nervous system, or CNS, in patients with advanced lung cancer or breast cancer. CNSide has been designed to improve the clinical management of patients with suspected metastatic cancer involving the CNS by enabling the quantitative analysis and molecular characterization of tumor cells and cell-free tumor DNA and RNA in the CSF. Since then, we have worked extensively with leading neuro-oncologists and other cancer experts to further define and characterize the use of this unique assay.

In June 2020, we launched a COVID-19 diagnostic test (assay manufactured by Thermo-Fisher) which broadened our assay menu to meet the community testing needs due to the emergence of COVID-19. In February 2023, due to reduced demand, the Company ceased COVID-19 testing services.

Basis of Presentation

The accompanying unaudited condensed financial statements and notes are prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, and are prepared on the basis that the Company will continue as a going concern (see Note 2). The accompanying unaudited condensed financial statements and notes do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

The unaudited condensed financial statements included in this Form 10-Q have been prepared in accordance with the U.S. Securities and Exchange Commission, or SEC, instructions for Quarterly Reports on Form 10-Q. Accordingly, the unaudited condensed financial statements are do not contain all the information required by GAAP to be included in a full set of financial statements. The balance sheet at December 31, 2022 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for a complete set of financial statements. The audited financial statements for the year ended December 31, 2022, filed with the SEC with our Annual Report on Form 10-K on April 17, 2023, include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

On May 16, 2023 (the "Effective Date"), the Company filed a Certificate of Amended and Restated Certificate of Incorporation (the "Amendment") with the Secretary of State of the State of Delaware to effect a 1-for-30 reverse stock split of its outstanding common stock. As of the Effective Date, every 30 shares of the Company's issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in par value per share. The reverse split affected all shares of the Company's common stock outstanding immediately prior to the Effective Date. As a result of the reserve stock split, proportionate adjustments are made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options and warrants issued by the Company and outstanding immediately prior to the Effective Date, which will result in a proportionate decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options and warrants, and, in the case of stock options and warrants, a proportionate increase in the exercise price of all such stock options and warrants. In addition, the number of shares reserved for issuance under the Company's equity compensation plans immediately prior to the Effective Date will be reduced proportionately.

No fractional shares were issued as a result of the reverse stock split. Stockholders of record who were otherwise entitled to receive a fractional share received a cash payment (without interest) in lieu thereof. The reverse stock split affected all stockholders proportionately and will not affect any stockholder's percentage ownership of the Company's common stock (except to the extent that the reverse stock split results in any stockholder owning only a fractional share).

All references to share and per share amounts in these unaudited condensed financial statements and accompanying notes have been retroactively restated to reflect the 1-for-30 reverse stock split, except for the authorized number of shares of the Company's common stock, which was not affected by the one-for-30 reverse stock split.

Significant Accounting Policies

The Company's accounting policy surrounding fair value measurement is considered a significant accounting policy as of and for the three and six months ended June 30, 2023 as a result of the common warrants issued in the Company's May 2023 underwritten public offering (see Note 3). There were no changes to our significant accounting policies as described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

ASC 820, Fair Value Measurement ("ASC 820"), established a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumption about the inputs that market participants would use in pricing the asset or liability. These are developed based on the best information available under the circumstances.

ASC 820 identified fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 established a three-tier fair value hierarchy that distinguishes between the following:

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

Level 2—Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3—Unobservable inputs developed using estimates or assumptions developed by the Company, which reflect those that a market participant would use.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Revenue Recognition and Accounts Receivable

The Company's commercial revenues are generated from diagnostic services provided to patients' physicians and billed to third-party insurance payors such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*, which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

Contracts

For its commercial revenues, while the Company markets directly to physicians and other healthcare providers, the Company provides services that benefit the patient. Patients do not typically enter into direct agreements with the Company; however, a patient's insurance coverage requirements would dictate whether or not any portion of the cost of the tests would be patient responsibility. Accordingly, the Company establishes contracts with commercial insurers in accordance with customary business practices, as follows:

- Approval of a contract is established via the order and accession, which are submitted by the patient's physician.
- The Company is obligated to perform its diagnostic services upon receipt of a sample from a physician, and the patient and/or applicable payor are obligated to reimburse the Company for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with the Centers for Medicare & Medicaid Services, or CMS, and applicable reimbursement contracts established between the Company and payors, unless the patient is a self-pay patient, whereby the Company bills the patient directly after the services are provided.
- Once the Company delivers a patient's assay result to the ordering physician, the contract with a patient has commercial substance, as the Company is legally able to collect payment and bill an insurer and/or patient, regardless of payor contract status or patient insurance benefit status.
- Consideration associated with commercial revenues is considered variable and constrained until fully adjudicated, with net revenues recorded to the extent that it is probable that a significant reversal will not occur.

The Company's development services revenues are supported by contractual agreements and generated from assay development services provided to entities, such as pharma or biotech organizations, as well as certain other diagnostic services provided to physicians, and revenues are recognized upon delivery of the performance obligations in the contract.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service, or a bundle of goods or services, to the customer. For its commercial and development services revenues, the Company's contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the delivery of a patient's assay result(s) to the ordering physician or entity. The duration of time between accession receipt and delivery of a valid assay result to the ordering physician or entity is typically less than two weeks, and for our RT-PCR COVID-19 testing, was typically 48 hours or less. Accordingly, the Company elected the practical expedient and therefore, does not disclose the value of unsatisfied performance obligations.

Transaction Price

The transaction price is the amount of consideration that the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties, such as sales taxes. The consideration expected from a contract with a customer may include fixed amounts, variable amounts, or both. The Company's gross commercial revenues billed, and corresponding gross accounts receivable, subject to price concessions to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected and is deemed to be variable although the variability is not explicitly stated in any contract. Rather, the variability is due to several factors, such as the payment history or lack thereof for third-party payors, reimbursement rate changes for contracted and non-contracted payors, any patient co-payments, deductibles or compliance incentives, the existence of secondary payors and claim denials. The Company estimates the amount of variable consideration using the most likely amount approach to estimating variable consideration for third-party payors, including direct patient bills, whereby the estimated reimbursement for services is established by payment histories on CPT codes for each payor, or similar payor types. When no payment history is available, the value of the account is estimated at Medicare rates, with additional other payor-specific reserves taken as appropriate. Collection periods for billings on commercial revenues range from less than 30 days to several months, depending on the contracted or non-contracted nature of the payor, among other variables. The estimates of amounts that will ultimately be realized from commercial diagnostic services for non-contracted payors require significant judgment by management.

The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. Revenue is recognized up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of implicit price concessions and are included in the period in which such revisions are made. The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more consideration than it originally estimated for a contract with a customer, it will account for the change as an increase in the estimate of the transaction price in the period identified as an increase to revenue. Similarly, if the Company subsequently determines that the

amount it expects to collect from a customer is less than it originally estimated, it will generally account for the change as a decrease in the estimate of the transaction price as a decrease to revenue.

Allocate Transaction Price

For the Company's commercial revenues, the entire transaction price is allocated to the single performance obligation contained in a contract with a customer. For the Company's development services revenues, the contracted transaction price is allocated to each single performance obligation contained in a contract with a customer as performed.

Point-in-time Recognition

The Company's single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient's successful assay result is delivered to the patient's ordering physician or entity. The Company considers this date to be the time at which the patient obtains control of the promised diagnostic assay service.

Contract Balances

The timing of revenue recognition, billings and cash collections results in accounts receivable recorded in the Company's condensed balance sheets. Generally, billing occurs subsequent to delivery of a patient's test result to the ordering physician or entity, resulting in an account receivable.

Practical Expedients

The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period is one year or less. These costs are recorded within sales and marketing expenses.

The Company incurs certain other costs regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications. These costs are expensed as incurred and recorded within general and administrative expenses.

Disaggregation of Revenue and Concentration of Risk

The composition of the Company's net revenues recognized during the three and six months ended June 30, 2023, disaggregated by source and nature, are as follows (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Net revenues from non-contracted payers	$ 190	$ 767	$ 341	$ 8,029
Net revenues from contracted payers*	347	4,960	824	17,605
Net commercial revenues	537	5,727	1,165	25,634
Development services revenues	37	92	82	129
Kits & BCT	15	—	15	—
Total net revenues	$ 589	$ 5,819	$ 1,262	$ 25,763

*Includes Medicare, Medicare Advantage and CARES Act as reimbursement amounts are fixed.

As of June 30, 2023, there were no unbilled accounts receivable.

Concentrations of credit risk with respect to revenues are primarily limited to geographies to which the Company provides a significant volume of its services, and to specific third-party payors of the Company's services such as Medicare, insurance companies, and other

third-party payors. The Company’s client base consists of many geographically dispersed clients diversified across various customer types.

The Company's third-party payors that represent more than 10% of total net revenues in any period presented during the three and six months ended June 30, 2023 and 2022 were as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Medicare and Medicare Advantage/CARES Act	28%	12%	21%	36%
Blue Cross Blue Shield	17%	16%	15%	16%
Kaiser Permanente	1%	23%	3%	16%

The Company's third-party payors that represent more than 10% of total accounts receivable at June 30, 2023 and December 31, 2022 were as follows:

	June 30, 2023	December 31, 2022
Blue Cross Blue Shield	28%	23%

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 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 period. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments- Credit Losses*, which included an amendment of the effective date. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022. The Company adopted this standard on January 1, 2023, which did not have an impact on its unaudited condensed financial statements.

In September 2022, the FASB issued ASU 2022-04, *Liabilities-Supplier Finance Programs*, to enhance the transparency of supplier finance programs. The main objective of this standard requires a buyer in a supplier finance program to disclose sufficient information about the program to allow a user of financial statements to understand the program’s nature, activity during the period, changes from period to period, and potential magnitude. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted this standard on January 1, 2023, which did not have an impact on its unaudited condensed financial statements.

2. Liquidity

As of June 30, 2023, cash totaled $6.6 million, and the Company had an accumulated deficit of $309.2 million. For the six months ended June 30, 2023 and 2022, the Company incurred net losses of $10.8 million and $12.3 million, respectively.

The Company has historically funded its operations primarily through sales of its equity securities. During the first quarter of 2023, we received net proceeds of approximately $0.4 million from the sale of our common stock from our Sales Agreement (see Note 3). On May 26, 2023, the Company received net cash proceeds of approximately $3.6 million from an underwritten public offering ("May 2023 Offering") of shares of common stock and pre-funded warrants to purchase shares of common stock.

During the three and six months ended June 30, 2023, net revenues were approximately $0.6 million and approximately $1.3 million, respectively, compared with approximately $5.8 million and approximately $25.8 million for the same period in the prior year. In February 2023, the Company ceased COVID-19 testing services.

The Company incurred net operating losses for the six months ended June 30, 2023 and 2022. The Company does not anticipate it will be profitable until, if ever, it has commercial expansion of its proprietary clinical diagnostic laboratory assays designed to identify rare tumor cells from cerebrospinal fluid, trademarked as CNSide. Accordingly, management performed the required going concern assessment and determined substantial doubt exists about the Company's ability to continue as a going concern within one year after the issuance date of this Quarterly Report on Form 10-Q. We currently expect that our existing resources will only be sufficient to fund our

planned operations and expenditures into the fourth quarter of 2023. Management intends to continue its efforts to contain costs and to raise additional capital until it ultimately generates sufficient cash to support operations from commercial sales. Management's plans are based on events that are not within its control and therefore substantial doubt about the Company's ability to continue as a going concern has not been alleviated.

3. Sales of Equity Securities

On May 12, 2021, the Company entered into a Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Sales Agent"), under which the Company could issue and sell from time to time up to $25.0 million of its common stock through or to the Sales Agent, as sales agent or principal. The issuance and sale of these shares under the Sales Agreement, if any, is subject to the continued effectiveness of a shelf registration statement on Form S-3 cover the sale of such shares. Our shelf registration statement on Form S-3, filed with the SEC on April 24, 2020, is no longer available and we will not be able to file a new Form S-3 until, at the earliest, September 1, 2023. Sales of the Company's common stock, under the Sales Agreement are made at market prices by any method that is deemed to be an "at the market offering ("ATM")" as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. Each time the Company wishes to issue and sell common stock under the Sales Agreement, it notifies the Sales Agent of the number of shares to be issued, the dates on which such sales are anticipated to be made and any minimum price below which sales may not be made. Once the Company has so instructed the Sales Agent, unless the Sales Agent declines to accept the terms of the notice, the Sales Agent has agreed to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such shares up to the amount specified on such terms.

The obligations of the Sales Agent under the Sales Agreement to sell the Company's common stock are subject to a number of conditions that the Company must meet. The offering of common stock pursuant to the Sales Agreement will terminate upon the earlier of (1) the sale of all common stock subject to the Sales Agreement and (2) termination of the Sales Agreement as permitted therein. The Sales Agreement may be terminated by either party at any time upon ten days' prior notice. The Sales Agent is entitled to compensation from the Company at a fixed commission rate equal to 3.0% of the gross sales price per share of any common stock sold under the Sales Agreement.

During the first quarter of 2023, we received net proceeds of approximately $0.4 million from the sale of our common stock and issued 23,903 shares of our common stock at a weighted average purchase price of $17.08 pursuant to the Sales Agreement. We are not eligible to use Form S-3 as of the filing of the Company's most recently filed Annual Report on Form 10-K and consequently may not make any further sales under the Sales Agreement unless and until we file, and the SEC has declared effective, a new shelf registration statement on Form S-3.

On May 26, 2023, the Company received net cash proceeds of approximately $3.6 million from an underwritten public offering ("May 2023 Offering") of 876,470 shares of common stock and pre-funded warrants to purchase 300,000 shares of common stock, and accompanying warrants to purchase up to an aggregate of 2,352,940 shares of common stock ("common warrants"), at a combined offering price of $4.25 per share and accompanying warrants or $4.2499 per pre-funded warrant and accompanying warrants. The pre-funded warrants had an exercise price of $0.0001 per share. As of June 30, 2023, all pre-funded warrants were exercised for cash.

The common warrants expire on May 25, 2028.

4. Fair Value Measurement

Assumptions Used in Determining the Fair Value of Warrant Liability

Under the guidance in ASC 815-40, *Derivatives and Hedging–Contracts in Entity's Own Equity,* the common warrants do not meet the criteria for equity treatment. As such, the common warrants were recorded as a liability on the condensed balance sheet at fair value as a result of an "alternative cashless exercise" feature, as described further below.

An initial valuation was required as of May 26, 2023 and was subject to re-measurement at the balance sheet date. With each re-measurement, the common warrant valuation will be adjusted to fair value, with the changes in fair value recognized in the Company's condensed statement of operations.

The Company's warrant liability is based on valuation models utilizing inputs from observable and unobservable markets with less volume and transaction frequency than active markets. As such, the fair value of the warrant liability is classified within Level 3 of the fair value hierarchy.

The common warrant agreement stipulates that if a Fundamental Transaction (as defined within the warrant to purchase common stock agreement) that is within the Company's control and approved by the Company's board of directors occurs, the common warrants are entitled to receive a cash payment based on the Black-Scholes Option Pricing Model ("BSOPM") and the assumptions utilized should be based on the following:

- A risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the expiration date,
- An expected volatility equal to the 100 day volatility as obtained from the Bloomberg (determined utilizing a 365 day annualization factor) as of the trading day immediately following the public announcement of the applicable contemplated Fundamental Transaction
- The underlying price per share used in such calculation shall be the volume-weighted average price ("VWAP") during the period beginning on the trading day immediately preceding the public announcement of the applicable contemplated Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the trading day immediately prior to the consummation of such Fundamental Transaction
- Remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Expiration Date
- A zero cost of borrow

If the Fundamental Transaction is not within the Company's control, holders of the common warrants will only be entitled to receive the same type or form of consideration (and in the same proportion) that is offered and paid to the holders of common stock in connection with the Fundamental Transaction, as if the holders exercised their common warrants upon such Fundamental Transaction

In addition to exercising the common warrants for cash, commencing on June 23, 2023, the holders of the common warrants became entitled to exercise the common warrants pursuant to an "alternative cashless exercise" provision, which 'provides that the warrant holder is entitled to receive, for no additional consideration, a number of shares of common stock that is equal to the product of (x) the aggregate number of shares that would be issuable upon exercise of the warrant by means of a cash exercise and (y) 0.50.

These features were modeled using the Monte-Carlo Simulation ("MCS") methodology that uses the Geometric-Brownian Motion ("GBM") framework to estimate the fair value of the common warrants. For each trading day until the contractual 'common warrants expiration date, the common stock price was simulated and the resulting payoffs under the "alternative cashless exercise" and the "held until remaining maturity" were compared to arrive at the optimal decision for a hypothetical investor holding the common warrants. The payoff under the elected scenario at a particular day was then discounted back at an appropriate present value factor to conclude on the payoff for that particular trial. This process was repeated for 50,000 trials to conclude on the average payoff to the investor.

The following inputs were used as of June 30, 2023 and as of May 26, 2023:

	As of June 30, 2023	As of May 26, 2023
Underlying stock price	$ 1.21	$ 2.16
Exercise price	$ 4.25	$ 4.25
Expected volatility	135%	140%
Risk-free rate	4.15%	3.92%
Expected dividend yield	0.00%	0.00%
Expiration life (years)	4.9	5.0

As of May 26, 2023, the fair value of the common warrants was approximately $4.3 million and the fair value of the common stock and prefunded warrants was approximately $0.7 million. Offering costs associated with the common warrants was approximately $1.2 million, while costs associated with the common stock and prefunded warrants was approximately $0.2 million. The offering costs allocated to the warrants were expenses and recorded within general and administrative expenses for the three and six months ended June 30, 2023. The offering costs allocated to the common stock and prefunded warrants are included within additional paid-in capital.

As of June 30, 2023, the fair value of the common warrants was approximately $1.1 million. The change in fair value of approximately $2.4 million is included within the other income (expense) section of the Company's condensed statement of operations for the three and six months ended June 30, 2023. As of June 30, 2023, the value of common stock issued upon exercise of the common warrants was $0.8 million.

5. Balance Sheet Details

The following provides certain balance sheet details (in thousands):

	June 30, 2023	December 31, 2022
	(unaudited)	
Inventories		
Raw materials	$ 970	$ 1,564
Subassemblies	110	401
Finished goods	6	36
	$ 1,086	$ 2,001
Less: inventory reserve	(535)	(1,244)
Total inventories, net	$ 551	$ 757
Fixed Assets		
Machinery and equipment	$ 3,781	$ 3,183
Furniture and office equipment	161	160
Computer equipment and software	4,042	3,824
Leasehold improvements	700	689
Construction in process	39	39
	$ 8,723	$ 7,895
Less: accumulated depreciation and amortization	(6,328)	(5,323)
Total fixed assets, net	$ 2,395	$ 2,572
Accrued Liabilities		
Accrued salaries and benefits	792	1,766
Accrued issuance costs	310	—
Accrued other	427	483
Total accrued liabilities	$ 1,529	$ 2,249

6. Payor Liability

In March 2022, the U.S. Health Resources and Services Administration, or HRSA, informed providers that, after March 22, 2022, it would stop accepting claims for testing and treatment for uninsured individuals under the HRSA COVID-19 Uninsured Program and that claims submitted prior to that date would be subject to eligibility and availability of funds. HRSA's procedure for recouping credits due from service providers had been to net these amounts against reimbursements for services provided. Given that no further payments are expected from HRSA, there is no longer a mechanism for recoupments. The Company has therefore recorded a liability for outstanding HRSA credits which were previously netted against accounts receivable.

7. Leases

Finance Leases

The Company leases certain laboratory equipment under arrangements classified on the Company's balance sheet as lease right-of-use assets-finance and related lease liabilities, and depreciated on a straight-line basis over the lease term ranging from approximately 3 to 7 years. The total gross value of equipment capitalized under such lease arrangements was approximately $4.8 million and $7.2 million at June 30, 2023 and December 31, 2022, respectively. Total accumulated depreciation related to equipment under finance leases was approximately $2.5 million and $4.1 million at June 30, 2023 and December 31, 2022, respectively. Total depreciation expense related to equipment under finance leases during the three months ended June 30, 2023 and 2022 was approximately $0.3 million and $0.2 million, respectively. Total depreciation expense related to equipment under finance leases during the six months ended June 30, 2023 and 2022 was approximately $0.6 million and $0.4 million, respectively.

During the six months ended June 30, 2023, the Company entered into a finance lease for a capital amount of approximately $23,000. Under the terms of the financing agreement, the principal balance plus interest for the equipment are to be paid in 48 monthly installments of approximately $600 totaling approximately $28,000 through June 2027.

During the six months ended June 30, 2022, the Company entered into a finance lease for a capital amount of approximately $107,000. Under the terms of the financing agreement, the principal balance plus interest for the equipment are to be paid in 60 monthly installments of approximately $2,000 totaling approximately $111,000 through August 2027.

Operating Lease

On June 1, 2020, the Company entered into a lease for a 39,000 square foot headquarters, manufacturing and laboratory facility at 9955 Mesa Rim Road in San Diego, California. The lease commenced on December 1, 2020 and is for a term of 127 months from the commencement date.

The following schedule represents the components of lease expense for the three and six months ended June 30, 2023 and 2022 (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Finance lease cost				
Amortization of right-of-use assets	$ 310	$ 214	$ 578	$ 440
Interest on lease liabilities	41	58	90	106
Operating lease cost	415	414	829	829
Total	$ 766	$ 686	$ 1,497	$ 1,375

The following schedule represents maturities of operating and finance lease liabilities as of June 30, 2023 (in thousands):

	Finance Minimum Lease Payments	Operating Minimum Lease Payments
2023 (Remaining 6 months)	$ 484	$ 816
2024	729	1,672
2025	404	1,715
2026	199	1,762
2027	17	1,805
Thereafter	—	6,714
Total payments	1,833	14,484
Less amount representing interest	(182)	(5,070)
Present value of payments	$ 1,651	$ 9,414

The following schedule sets forth supplemental cash flow information related to operating and finance leases for the six months ended June 30, 2023 and 2022 (in thousands):

	For the Six Months Ended June 30,	
	2023	2022
Other information		
Operating cash flows from finance leases	$ 90	$ 106
Operating cash flows from operating leases	$ 813	$ 791
Financing cash flows from finance leases	$ 546	$ 501

The aggregate weighted average remaining lease term was 2.4 years on finance leases and 8.0 years on operating leases as of June 30, 2023. The aggregate weighted average discount rate was 8.4% on finance leases and 12% on operating leases as of June 30, 2023.

8. Stock-Based Compensation

Equity Incentive Plans

The Company has two equity incentive plans: The Amended and Restated 2013 Equity Incentive Plan, or the 2013 Plan, and the 2007 Equity Incentive Plan, or the 2007 Plan. The 2013 Plan includes a provision that shares available for grant under the Company's 2007 plan become available for issuance under the 2013 Plan and are no longer available for issuance under the 2007 Plan.

At the Company's annual meeting of stockholders held on July 16, 2021, the Company's stockholders approved amendments to the 2013 Plan, which included an increase in the number of non-inducement shares of common stock authorized for issuance under the 2013 Plan by 1,300,000 shares. On February 14, 2022 and March 22, 2022, the board of directors approved an increase of 1,000,000 and 500,000 shares, respectively, in the inducement shares of common stock authorized for issuance under the 2013 Plan.

Stock Options

A summary of stock option activity for the six months ended June 30, 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term in Years
Outstanding at December 31, 2022	75,336	$ 98.46	8.86
Granted	—	—	
Cancelled/forfeited/expired	(35,313)	109.44	
Outstanding at June 30, 2023	40,023	88.78	8.56
Vested and unvested expected to vest, June 30, 2023	39,659	$ 89.12	7.45

The intrinsic values of options outstanding, options exercisable, and options vested and unvested expected to vest were $0 at both June 30, 2023 and December 31, 2022.

Stock-based Compensation Expense

The following table presents the effects of stock-based compensation related to equity awards to employees and non-employees on the unaudited condensed statements of operations during the periods presented (in thousands):

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Stock Options				
Cost of revenues	$ 61	$ 184	$ 134	$ 391
Research and development expenses	16	49	50	210
General and administrative expenses	108	245	288	1,497
Sales and marketing expenses	24	107	53	246
Total expenses related to stock options	$ 209	$ 585	$ 525	$ 2,344

As of June 30, 2023, total unrecognized share-based compensation expense related to unvested stock options was $1.2 million and is expected to be recognized over a weighted-average period of approximately 2.34 years.

9. Common Stock Warrants Outstanding

A summary of common stock warrant activity for the six months ended June 30, 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2022	28,149	$ 690.57	1.25
Issued	2,352,940	$ 4.25	
Exercised	(1,276,031)	$ 4.25	
Expired	(1,865)	$ 104.85	
Outstanding at June 30, 2023	1,103,192	$ 21.48	4.81

All warrants outstanding at June 30, 2023 and December 31, 2022 are exercisable. The outstanding warrants have expiration dates ranging from August 2023 to May 2028.

The intrinsic value of equity-classified common stock warrants outstanding were $0 at both June 30, 2023 and December 31, 2022.

10. Net Loss per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common stockholders for the six months ended June 30, 2023 and 2022, the outstanding RSUs, warrants, and common stock options have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding for the periods presented, as they would be anti-dilutive:

	For the Six Months Ended June 30,	
	2023	2022
Common warrants outstanding	1,103,192	28,575
RSUs outstanding	—	1
Convertible preferred stock outstanding (number of common stock equivalents)	1,519	1,519
Common options outstanding	40,023	106,783
Total anti-dilutive common share equivalents	1,144,734	136,878

11. Commitments and Contingencies

In the normal course of business, the Company may be involved in legal proceedings or threatened legal proceedings. The Company is not party to any legal proceedings or aware of any threatened legal proceedings except as provided in the paragraph below, and except for those proceedings that are not expected to have a material adverse effect on the Company’s financial condition, results of operations or liquidity.

On June 9, 2023, the Company received a notice of default from its landlord under the terms of the Company's lease agreement due to the roof warranty being voided as a direct result of construction work completed after the Company moved into the building. On August 11, 2023, the default was cured by mutual agreement between the landlord and the Company. As of June 30, 2023, the Company has accrued expenses of approximately $0.1 million to remedy the default.

The Company was in mediation with former employees regarding disputed claims for certain sales commissions. Although the Company was not in agreement with their interpretations or claims, the Company entered into settlement negotiations related to the disputed commissions. The matter was resolved in June 2022 for approximately $1.7 million and was recorded within sales and marketing expense.

12. Related Party Transactions

A former member of the Company's management is the controlling person of Aegea Biotechnologies, Inc., or Aegea. On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement, or the Cross-License Agreement, with Aegea. On December 11, 2019, the Company entered into a First Amendment to Assignment and Exclusive Cross-License Agreement with Aegea pursuant to which the Company obtained a royalty bearing license for a certain patent. On May 22, 2022, the Company entered into a Second Amendment to Assignment and Exclusive Cross-License Agreement with Aegea pursuant to which the Company obtained a royalty-free license for a certain patent and Aegea obtained certain patents. The Company agreed to pay Aegea, effective January 1, 2019, a royalty of 10% on the Company's sale of research use only, or RUO, and import research use only reagents and kits in the field of oncology, where the sample types are tissue, whole blood, bone marrow, cerebrospinal fluid or derivatives of any of the foregoing. As of June 30, 2023 and December 31, 2022, and for the three and six months ended June 30, 2023 and 2022, no royalties have been accrued and no expenses have been incurred by the Company related to this arrangement.

13. Subsequent Events

The Company has evaluated subsequent events and determined that there have been no events that have occurred that would require adjustments to our disclosures in the condensed financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission, or SEC, on April 17, 2023. Past operating results are not necessarily indicative of results that may occur in future periods.

Company Overview

We are a molecular oncology diagnostics company that develops and commercializes proprietary clinical diagnostic laboratory assays designed to identify rare tumor cells and cell-free tumor DNA from blood and cerebrospinal fluid, or CSF. The identification and characterization of tumor cells and cell-free tumor DNA in CSF has now become our only development focus following our early commercial expansion into CSF in 2020. This product was branded and trademarked as CNSide™ in April 2021.

The identification of circulating tumor cells, or CTCs, and circulating cell-free tumor DNA and ctDNA, deriving from solid tumors such as breast cancer or lung cancer using a standard blood sample has been described as a "liquid biopsy." This term reflects the ease with which peripheral blood can be drawn compared to performing a surgical biopsy on a primary tumor site, but this technology is not limited to a peripheral blood approach.

In January 2020, we adapted and validated our proprietary blood-based liquid biopsy technology for commercial and clinical research use in CSF to identify tumor cells that have metastasized to the central nervous system, or CNS, in patients with advanced lung cancer or breast cancer. CNSide has been designed to improve the clinical management of patients with suspected metastatic cancer involving the CNS by enabling the quantitative analysis and molecular characterization of tumor cells and ctDNA in the CSF. Since then, we have worked extensively with leading neuro-oncologists and other cancer experts to further define and characterize the use of this unique assay.

Our efforts have culminated in the presentation of our early clinical experience at several leading academic forums, including most recently the San Antonio Breast Cancer Symposium, or SABCS, in December 2021, the American Academy of Neurology in April 2022, and the Annual Society of Neuro Oncology, or SNO, meeting in November 2022. We believe these presentations have illustrated the feasibility of this assay to inform three critical questions important for the care of patients with suspected or confirmed metastatic cancer involving the CNS: Is there tumor (diagnosis)? Is there target (presence of a biomarker to aid treatment selection)? Is there trend (a response to therapy)? We are also starting to see presentations and peer reviewed journal papers from research groups not associated with Biocept that utilize CNSide and where our assay favorably compares to existing standard of care testing, for example, in the journal of clinical breast cancer in June 2022, or at the annual meeting of the American Society of Clinical Oncology in June 2023.

The question "Is there tumor?" is essential for the diagnostic work-up of these patients. Tumor cells in the blood can shed from either primary or metastatic tumors. They can be rapidly removed in the capillary beds of the spleen, liver, kidneys, lungs and other organs, so they are rarely found. They are the defining feature of metastasis to the leptomeningeal space within the CNS and hence define the presence or absence of leptomeningeal metastasis, or LM. To distinguish tumor cells derived from CSF and blood we often refer to tumor cells in CSF as CSF Tumor Cells, or CSFTCs, rather than CTCs.

Regarding the second clinical question, "Is there target?" our CNSide assay provides a vehicle for several different diagnostic assay profiles which combined with our molecular test menu and next generation sequencing (NGS) services can identify tumor cell biomarkers that are intended to help physicians make decisions related to the evolution or course of metastatic tumor that may inform treatment decisions. Cancer cells typically acquire genetic alterations which differ from that of normal cells. Metastatic cancers often acquire additional genetic alterations which distinguish them from the primary tumor site. This marked genetic variation between areas of tumor growth is termed "genetic heterogeneity," and findings related to this were featured in our SABCS presentation in December 2021 illustrating the value of CNSide in identifying "genetic heterogeneity" of a targetable biomarker called HER2.

Finally, regarding the third clinical question, “Is there trend?” over the past year we have gained considerable experience with cases that have been sampled multiple times over the course of a patient’s treatment. The association of quantitative CSF tumor cell counts with response to treatment has been noted in both lung and breast cancer, as well as other tumors examined. In August 2021, at the SNO Brain Metastases meeting, we presented data obtained from a single institution experience showing how serial monitoring of CSFTCs by CNSide was used to determine the response to treatment in patients with Non-Small Cell Lung Cancer having LM. In November 2021 at SNO, we presented the early findings of several patients with breast cancer having LM which had been followed with multiple CSF samples drawn at different time points on each patient. In April 2022 at the American Academy of Neurology (AAN) meeting, a year of CNSide data for a single breast cancer patient was presented that demonstrated the correlation between the initiation and cessation of therapy and decreases and increases in CSF tumor cells. The downward progression of tumor cell counts has been noted by several treating physicians to correlate with response to treatment and resolution of symptoms. Serial monitoring of genetic alterations present in CSF tumor cells may create opportunities to change the therapy of certain patients throughout treatment. These observations presented in abstracts and poster presentations in 2021 have informed our clinical study strategy which is the basis for our 2022 efforts to further explore these observations in a prospective clinical trial.

Our first CNSide multi-center prospective clinical trial, named FORESEE (NCT05414123) is now enrolling patients at three sites. The FORESEE trial is expected to have two portions. The first portion, which is enrolling now, is a feasibility study that will enroll approximately 32-40 subjects. The primary goal of the feasibility portion is to evaluate the performance of CNSide in monitoring the LM's response to treatment and to assess the impact of CNSide on treatment decisions made by physicians in two cohorts of patients, one with primary Breast cancer and one with primary non-small cell lung cancer lung cancer. In addition, we will assess correlation of CSF Tumor cells with clinical response and evaluate CNSide in its ability to help determine the course of treatment. The feasibility portion of the FORESEE trial is expected to be complete in the first half of 2024. Following the completion of the feasibility portion, we plan to initiate the second portion of the trial, which will be a validation study that will enroll approximately 40-100 subjects. The purpose of the validation study will be to confirm, on a larger patient population, the impact of CNSide in managing leptomeningeal metastases in patients with Breast or NSCLC as well as expand to add additional tumor types and end points. Assuming the results of the trial are favorable, we intend to pursue the inclusion of CNSide in the standard National Comprehensive Cancer Network, NCCN, guideline for diagnosis and monitoring of leptomeningeal metastases disease. With the help of a leading Clinical Research Organization, we have established the infrastructure for the trial, have opened three sites and are now in the process of opening at least three additional clinical sites where patients with breast or non-small cell lung cancer, NSCLC, who have suspicious or confirmed leptomeningeal metastases will be able to enroll.

COVID-19 Pandemic Response Summary

In June 2020, to respond to a national public health emergency precipitated by the COVID-19 pandemic, we introduced molecular testing for SARS-CoV2, the virus responsible for COVID-19, using a United States Food and Drug Administration, or FDA, Emergency Use Authorization, or EUA, based “RT-PCR” method developed by Thermo-Fisher.

During our COVID-19 testing program, we performed more than 1,000,000 assays for customers. We primarily marketed our COVID-19 testing services to skilled nursing facilities in the western United States and to certain community colleges within California.

As a result of increased vaccination and immunization levels, as well as decreased COVID-19 hospitalizations, reported cases and mandatory COVID-19 testing, we experienced reduced demand for our COVID-19 testing services during 2022. We ceased COVID-19 service offerings in February 2023.

Additional Oncology Testing Services

In addition to CNSide, we previously offered blood-based testing through our Target Selector technologies which enable detection of specific gene mutations, such as EGFR, KRAS or BRAF, in ctDNA from blood and CSF samples. In May 2022, after a thorough business review, we decided to discontinue certain unprofitable blood-based molecular testing services including our Target Selector offerings. We also offer, and received MolDX reimbursement approval for, certain specific protein and gene alterations, such as HER2 amplification, in tumor cells isolated from blood or present in CSF. We continue to offer these HER2 based tests as they are an important aspect of our CNSide offering. We will also continue to provide certain other blood-based testing services for biopharma partners and to support investigator-initiated studies involving CNSide. We believe our multi-modality combination of a proprietary cell capture and analysis method in combination with an extensive menu of molecular testing modalities that includes ICC, FISH, and NGS testing provides us with the necessary tools to service a broad range of diagnostic applications in patients with neurological metastatic cancers. We continue to seek other diagnostic modalities that may benefit neuro-oncology patients and their caregivers.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is CLIA-certified, CAP accredited and licensed by the California Department of Public Health. In this facility we also develop novel assays that are part of our project pipeline for future commercial launch, and we manufacture our microfluidic channels and various assay reagents used in our

testing processes. We also work closely with external manufacturers to outsource certain materials used in our assays such as transport tubes and to manufacture items that we intend to use in the near future to reduce costs and improve efficiency.

The assays we offer and intend to offer are classified as CLIA laboratory developed tests, or LDTs, under CLIA regulations. CLIA certification and state licensure in California and certain other states under the supervision of a qualified laboratory medical director is required before any clinical laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of health. In addition, we participate in and have received CAP accreditation, which includes rigorous bi-annual laboratory inspections and requires adherence to specific quality standards.

Commercial Strategy

Our primary commercial strategy is to engage neuro-oncologists, oncologists and other physicians in the United States at private and group practices, hospitals, laboratories and cancer centers to educate them about our unique products and services. In addition, we market our clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations.

Our revenue generating efforts are focused in the following areas:

- providing laboratory services to neuro-oncologists, oncologists and other physicians or healthcare providers treating patients with cancer who use the information we provide in order to determine the best treatment plan for their patients; and
- providing laboratory services using both our CSF tumor cell and ctDNA assays in order to help pharmaceutical and biopharmaceutical companies run clinical studies establishing the use of novel drug therapies used to treat cancer.

We plan to grow our business by directly offering our CNSide and molecular assays to neuro-oncologists, oncologists and other physicians or health care providers who treat patients with cancer. Based on our product development data, as well as discussions with our key collaborators, we believe that our planned future assays, particularly those related to CSF, should provide important information and clinical value to physicians and their patients.

We believe our ability to rapidly translate insights about the utility of cytogenetic, immunocytochemical and molecular biomarkers to provide information to neuro-oncologists, oncologists and other physicians for treatment decisions in the clinical setting will improve patient treatment and management, and that these assays will become a key component of the standard of care for personalized cancer treatment.

Key Factors Affecting our Results of Operations and Financial Condition

Our overall long-term growth plan depends on our ability to continue to develop and commercialize products and assays through our CLIA-certified, CAP-accredited, and state-licensed laboratory. We have now commercialized our CNSide assays for breast cancer, non-small cell lung cancer, small cell lung cancer, melanoma, esophageal cancer, gastric cancer, colorectal cancer, head and neck cancers, ovarian cancer, endometrial cancer, renal cancer, bladder cancer, prostate cancer, liver cancer, pancreatic cancer, neuroendocrine cancer, melanoma and plan to continue to launch a series of cancer diagnostic assays for different predictive biomarkers assays in the United States as LDTs performed in our laboratory and enhance revenue for these products through the efforts of our sales and marketing organization. Our sales strategy is to engage medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians in the United States at private and group practices, hospitals and cancer centers. We also have a research and development program focused on technology enhancements, novel platform development, and evaluating clinical applications for our cancer diagnostic tests in different cancer types and clinical settings.

To facilitate market adoption of our products and assays, we anticipate having to successfully complete additional clinical utility studies with clinical samples to generate clinical utility data and then publish our results in peer-reviewed scientific journals, including the FORESEE study for CNSide (NCT05414123). Our ability to complete such clinical studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research, to conduct the appropriate clinical studies and to obtain favorable clinical data. We currently collaborate with key thought leaders, physicians and clinical researchers across the country, including those at Sarah Cannon Research Institute, University of Colorado, Northwestern University Lurie Cancer Center, Stanford University, Penn State University, University of California, San Diego, St John's Cancer Institute at Santa Monica (formerly John Wayne Cancer Institute), Columbia University, Emory University, Johns Hopkins Medical Institute, University of Texas Southwestern Medical Center, Yale University, Ohio State University, Vanderbilt University, Georgetown University and many others and plan to expand our collaborative relationships to include other key thought leaders at other institutions for the cancer types we target with our CNSide commercialized assays and our planned future assays, as well as for our current and planned future products. Such relationships help us develop and validate the effectiveness and utility of our products, commercialized assays and our planned future assays in specific, clinical settings and provide us access to patient samples and data.

We believe that the factors discussed in the following paragraphs have had and are expected to continue to have a material impact on our results of operations and financial condition.

Revenues

Our commercial revenues are generated from diagnostic services provided to patient's physicians and billed to third-party insurance payors such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company recognizes revenue in accordance with Accounting Standards Codification (Topic 606), Revenue from Contracts with Customers, or ASC 606, which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

We bill third-party payors on a fee-for-service basis at our list price and third-party commercial revenue is recorded net of contractual discounts, payor-specific allowances and other reserves. Our development services revenues are supported by contractual agreements and generated from assay development services provided to entities, as well as certain other diagnostic services provided to physicians. Diagnostic services are completed upon the delivery of assay results to the prescribing physician, at which time we bill for the service.

Our gross commercial revenues billed are subject to estimated deductions for such contractual discounts, payor-specific allowances and other reserves to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected. These third-party payor discounts and sales allowances are estimated based on a number of assumptions and factors, including historical payment trends, seasonality associated with the annual reset of patient deductible limits on January 1 of each year, and current and estimated future payments. The estimates of amounts that will ultimately be realized from commercial diagnostic services require significant judgment by us. Patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that they have not met their annual deductible limit under their insurance policy, if any, or if their insurance otherwise declines to reimburse us. Adjustments to the estimated payment amounts are recorded at the time of final collection and settlement of each transaction as an adjustment to net revenue.

Costs and Expenses

We classify our costs and expenses into four categories: cost of revenues, research and development, sales and marketing, and general and administrative. Our costs and expenses principally consist of facility costs and overhead, personnel costs, outside services and consulting costs, laboratory consumables, development costs, and legal fees.

Cost of Revenues. Our cost of revenues consists principally of facility costs and overhead, personnel costs, and laboratory and manufacturing supplies and materials. We are pursuing various strategies to reduce and control our cost of revenues, including automating aspects of our processes, developing more efficient technology and methods, and attempting to negotiate improved terms and volume discounts with our suppliers.

Research and Development Expenses. We incur research and development expenses principally in connection with our efforts to develop and improve our tests. Our primary research and development expenses consist of direct personnel costs, laboratory equipment and consumables, and overhead expenses. We anticipate that research and development expenses will increase in the near-term, principally to develop and validate tests in our pipeline and to perform work associated with clinical utility studies, including the FORESEE study for CNSide, and development collaborations. In addition, we expect that our costs related to collaborations with research and academic institutions will increase. All research and development expenses are charged to operations in the periods in which they are incurred.

Sales and Marketing Expenses. During the periods presented, our sales and marketing expenses consisted principally of personnel and related overhead costs for our sales team and their support personnel, travel and entertainment expenses, and other selling costs including trade shows. As part of a reduction in force that was completed in the first quarter of 2023, we eliminated our field-based sales force in an effort to conserve our cash resources. Once we have adequate resources to do so, as part of our business strategy, we plan to hire and develop a field-based sales force to educate physicians directly on the benefits of our assays and the clinical data supporting them, as well as provide support to and serve as technical specialists for our partners, which will increase our sales and marketing expenses.

General and Administrative Expenses. General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, insurance costs, and other general expenses. We expect that our general and administrative expenses will remain relatively flat for the foreseeable future.

Other Income and Expense. Other Income and Expense consist principally of interest expense and the change in fair value of warrant liability. We expect that our other income and expense will decrease as the warrants are exercised and then remain relatively flat for the foreseeable future.

Results of Operations

For the three months ended June 30, 2023 and 2022

The following table sets forth certain information concerning our results of operations for the periods shown (dollars in thousands):

	For the Three Months Ended June 30,		Change	
	2023	2022	$	%
Net revenues	$ 589	$ 5,819	$ (5,230)	(90%)
Costs and expenses:				
Cost of revenues	2,550	8,023	(5,473)	(68%)
Research and development expenses	409	1,729	(1,320)	(76%)
General and administrative expenses	3,494	4,300	(806)	(19%)
Sales and marketing expenses	250	1,656	(1,406)	(85%)
Total costs and expenses	6,703	15,708	(9,005)	(57%)
Loss from operations	(6,114)	(9,889)	3,775	(38%)
Other income (expense):				
Interest expense, net	(50)	(155)	105	(68%)
Other income, net	91	—	91	100%
Change in fair value of warrant liability	2,442	—	2,442	100%
Total other income (expense):	2,483	(155)	2,638	(1,702%)
Loss before income taxes	(3,631)	(10,044)	6,413	(64%)
Income tax expense	—	—	—	0%
Net loss	$ (3,631)	$ (10,044)	$ 6,413	(64%)

Net Revenues

Net revenues were approximately $0.6 million for the three months ended June 30, 2023, compared with approximately $5.8 million for the same period in 2022. The decrease was due to a decrease in COVID-19 testing. In February 2023, the Company ceased COVID-19 testing services.

The net estimated revenue per commercial accession delivered during the three months ended June 30, 2023 was $1,667, based on 322 commercial accessions delivered, while during the three months ended June 30, 2022 it was $74 based on 77,779 commercial accessions delivered. The increase in net revenue per commercial accessions delivered was due to commercial accessions for the three months ended June 30, 2022 being primarily related to COVID-19 testing, whereas for the three months ended June 30, 2023, all commercial accessions were oncology related.

The following table sets forth certain information regarding commercial accessions received during the three months ended June 30, 2023 and 2022:

	For the Three Months Ended June 30,		Change	
	2023	2022	# / $	%
# Commercial accessions delivered	322	77,779	(77,457)	(100%)
$ Value estimated per commercial accession delivered	$ 1,667	$ 74	1,593	2,153%

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately $2.6 million for the three months ended June 30, 2023, compared with approximately $8.0 million for the same period in 2022. The decrease in costs is primarily associated with our COVID-19 testing ending in February 2023 and a reduction headcount and the associated decrease in salary- and benefit-related expenses. There was approximately a $2.4 million decrease in direct materials and supplies, approximately a $2.2 million decrease in labor costs, and approximately a $0.4 million decrease in freight costs.

Research and Development Expenses. Research and development expenses were approximately $0.4 million for the three months ended June 30, 2023, compared with approximately $1.7 million for the same period in 2022. The decrease is primarily due to a reduction in headcount and an associated decrease in salary- and benefit-related expenses of approximately $0.7 million, as well as approximately a $0.5 million decrease in materials and supplies for non-clinical trial related projects.

General and Administrative Expenses. General and administrative expenses were approximately $3.5 million for the three months ended June 30, 2023, compared with approximately $4.3 million during the same period in 2022. The decrease is primarily due to a reduction in headcount and an associated decrease in salary- and benefit-related expenses of approximately $0.4 million, as well as a decrease in consulting related expenses of approximately $0.2 million as we continue efforts to reduce costs.

Sales and Marketing Expenses. Sales and marketing expenses were approximately $0.3 million for the three months ended June 30, 2023, compared with approximately $1.7 million for the same period in 2022. The decrease is primarily due to a reduction in headcount and an associated decrease in salary- and benefit-related expenses of approximately $0.9 million. Further, a decrease of $0.4 million due to a decrease in consulting, promotion, and outside service-related expenses as we continue efforts to reduce costs.

Other Income (Expense). Other income (expense) was approximately $2.5 million of income for the three months ended June 30, 2023, compared with approximately $0.2 million of expense for the same period in 2022. The increase is primarily due to the $2.4 million gain associated with the change in the fair value of warrant liability. No warrant liability existed for the three months ended June 30, 2022.

Results of Operations

For the six months ended June 30, 2023 and 2022

The following table sets forth certain information concerning our results of operations for the periods shown (dollars in thousands):

	For the Six Months Ended June 30,		Change	
	2023	2022	$	%
Net revenues	$ 1,262	$ 25,763	$ (24,501)	(95%)
Costs and expenses:				
Cost of revenues	5,578	18,357	(12,779)	(70%)
Research and development expenses	1,449	3,574	(2,125)	(59%)
General and administrative expenses	6,482	10,556	(4,074)	(39%)
Sales and marketing expenses	965	5,314	(4,349)	(82%)
Total costs and expenses	14,474	37,801	(23,327)	(62%)
Loss from operations	(13,212)	(12,038)	(1,174)	10%
Other (expense) income:				
Interest expense, net	(96)	(217)	121	(56%)
Other income, net	91	—	91	100%
Change in fair value of warrant liability	2,442	—	2,442	100%
Total other expense:	2,437	(217)	2,654	(1,223%)
Loss before income taxes	(10,775)	(12,255)	1,480	(12%)
Income tax expense	—	—	—	0%
Net loss	$ (10,775)	$ (12,255)	$ 1,480	(12%)

Net Revenues

Net revenues were approximately $1.3 million for the six months ended June 30, 2023, compared with approximately $25.8 million for the same period in 2022. The decrease was due to a decrease in COVID-19 testing. In February 2023, the Company ceased COVID-19 testing services.

The net estimated revenue per commercial accession delivered during the six months ended June 30, 2023 was $342, based on 3,407 commercial accessions delivered, while during the six months ended June 30, 2022 it was $111, based on 230,835 commercial accessions delivered. The increase in net revenue per commercial accessions delivered was primarily due to an increase in the proportion of oncology based accessions.

The following table sets forth certain information regarding commercial accessions received during the six months ended June 30, 2023 and 2022:

	For the Six Months Ended June 30,		Change	
	2023	2022	# / $	%
# Commercial accessions delivered	3,407	230,835	(227,428)	(99%)
$ Value estimated per commercial accession delivered	$ 342	$ 111	231	208%

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately $5.6 million for the six months ended June 30, 2023, compared with approximately $18.4 million for the same period in 2022. The decrease in costs is primarily associated with our COVID-19 testing ending in February 2023 and a reduction in headcount and the associated decrease in salary- and benefit-related expenses. There was approximately a $6.6 million decrease in direct materials and supplies, approximately a $4.1 million decrease in labor costs, and approximately a $1.3 million decrease in freight costs.

Research and Development Expenses. Research and development expenses were approximately $1.4 million for the six months ended June 30, 2023, compared with approximately $3.6 million for the same period in 2022. The decrease is primarily due to a reduction in headcount and an associated decrease in salary-and benefit-related expenses of approximately $1.1 million, as well as approximately a

$0.6 million decrease in materials and supplies for non-clinical trial related projects. Furthermore, outside service related expenses decreased by approximately $0.2 million as we continue efforts to reduce costs.

General and Administrative Expenses. General and administrative expenses were approximately $6.5 million for the six months ended June 30, 2023, compared with approximately $10.6 million during the same period in 2022. The decrease is predominately due to non-recurring severance and stock-based compensation expenses of approximately $0.9 million and $1.1 million, respectively, incurred in 2022, due to the resignation of our former Chief Executive Officer and Chief Financial Officer. Complying with the terms of their separation agreements, which required, among other terms, payment of salary, annual bonus, COBRA premiums and an acceleration of stock options previously granted. Further, legal expenses decreased by approximately $1.2 million primarily due to costs associated with the sales commission settlement that occurred in 2022. Furthermore, outside service related expenses decreased by $1.1 million as we continue efforts to reduce costs.

Sales and Marketing Expenses. Sales and marketing expenses were approximately $1.0 million for the six months ended June 30, 2023, compared with approximately $5.3 million for the same period in 2022. Sales and marketing expenses decreased primarily due to a reduction in commissions expense of approximately $1.8 million as a result of the commissions settlement that occurred in 2022 and approximately a $1.4 million decrease in salary- and benefit-related expenses due to reduction in sales personnel. Further, a decrease of $0.8 million due to consulting, promotion, and outside service-related expenses as we continue efforts to reduce costs.

Other Income (Expense). Other income (expense) was approximately $2.4 million of income for the six months ended June 30, 2023, compared with approximately $0.2 million of expense for the same period in 2022. The increase is primarily due to the $2.4 million gain associated with the change in the fair value of warrant liability. No warrant liability existed for the six months ended June 30, 2022.

Income Tax Expense

Over the past several years we have generated operating losses in all jurisdictions in which we may be subject to income taxes. As a result, we have accumulated significant net operating losses and other deferred tax assets. Because of our history of losses and the uncertainty as to the realization of those deferred tax assets, a full valuation allowance has been recognized. We do not expect to report a provision for income taxes until we have a history of earnings, if ever, that would support the realization of our deferred tax assets. We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future, however, we believe multiple ownership changes likely occurred. As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

Liquidity and Capital Resources

We are actively working to improve our financial position and enable the growth of our business, by raising new capital and generating revenues. As of June 30, 2023, our cash totaled $6.6 million.

Cash Flows

Our net cash flow from operating, investing and financing activities for the periods below were as follows (dollars in thousands):

Cash Flows - Summarized

Our net cash flow from operating, investing and financing activities for the periods below were as follows:

	For the Six Months Ended June 30,	
	2023	2022
Cash provided by (used in):		
Operating activities	$ (9,280)	$ (4,972)
Investing activities	(113)	(315)
Financing activities	3,129	(649)
Net decrease in cash	$ (6,264)	$ (5,936)

Cash Used in Operating Activities. Net cash used in operating activities was approximately $9.3 million for the six months ended June 30, 2023, compared with net cash used by operating activities of approximately $5.0 million for the same period in 2022. The

increase in cash used by operating activities is primarily due to a decrease in cash provided by the payor liability of approximately $5.7 million.

Cash Used in Investing Activities. Net cash used in investing activities was approximately $0.1 million for the six months ended June 30, 2023, compared with approximately $0.3 million in the same period in 2022. The decrease in cash used in investing activities relates to a decrease in purchases of property and equipment of approximately $0.1 million. During the six months ended June 30, 2023, we had cash provided of $0.1 million from the sale of property and equipment. There was no equipment sold during the six months ended June 30, 2022.

Cash Provided by (Used in) Financing Activities. Net cash provided by financing activities was approximately $3.1 million for the six months ended June 30, 2023, compared with net cash used in financing activities of approximately $0.6 million for the same period in 2022. The increase in cash provided by financing activities was primarily due to the net cash proceeds of $3.6 million from the underwritten public offering of common stock and pre-funded warrants.

Liquidity, Capital Resources and Material Cash Requirements

We expect to continue to incur substantial operating losses in the future. We expect that we will use the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our assays, acquire equipment, implement automation and scale our capabilities to prepare for significant assay volume, for general corporate purposes and to fund ongoing operations and the expansion of our business, including the increased costs associated with expanded commercial activities. We may also use the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, and our revenues from operations to acquire or invest in businesses, technologies, services or products, although we do not have any current plans to do so.

In May 2021, we entered into the Sales Agreement with the Sales Agent, under which we may issue and sell from time to time up to $25.0 million of our common stock through or to the Sales Agent, as sales agent or principal. Sales of our common stock under the Sales Agreement are made at market prices by any method that is deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. During the first quarter of 2023, we received net proceeds of approximately $0.4 million from the sale of our common stock and issued 23,903 shares of our common stock at a weighted average price of $17.08 pursuant to the Sales Agreement. We are not eligible to use Form S-3 as of the filing of the Company's most recently filed Annual Report on Form 10-K and consequently may not make any further sales under the Sales Agreement unless and until we file, and the SEC has declared effective, a new shelf registration statement on Form S-3.

On May 26, 2023, we received net cash proceeds of approximately $3.6 million from an underwritten public offering of 876,470 shares of common stock and pre-funded warrants to purchase up to 300,000 shares of common stock, and accompanying common warrants to purchase up to an aggregate of 2,352,940 shares of common stock, at a combined offering price of $4.25 per share and accompanying common warrants or $4.2499 per pre-funded warrant and accompanying common warrants. The pre-funded warrants had an exercise price of $0.0001 per share. As of June 30, 2023, all of the pre-funded warrants were exercised for cash.

As of June 30, 2023, our cash totaled $6.6 million.

We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. If we are unable to raise a sufficient amount of financing in a timely manner, we would likely need to further scale back our general and administrative activities and certain of our research and development activities. Our forecast pertaining to our current financial resources and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

- our ability to secure financing and the amount thereof;
- the costs of operating and enhancing our laboratory facilities;
- the costs of developing our anticipated internal sales and marketing capabilities;
- the scope, progress and results of our research and development programs, including clinical utility studies;
- the scope, progress, results, costs, timing and outcomes of the clinical utility studies for our diagnostic assays;
- our ability to manage the costs for manufacturing our microfluidic channels;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

- our ability to obtain adequate reimbursement from governmental and other third-party payors for our assays and services;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources, as a result of becoming a public company;
- our ability to collect revenues; and
- other risks discussed in this report.

To fund our current and planned operations in the short-term (within the next 12 months) and long-term (beyond 12 months), we may seek to raise additional capital through public or private equity offerings, debt financing, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by us could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders, including potentially due to increased cash payments that may be made to warrant holders in the event of a fundamental transaction. Given the risks associated with our business, including our unprofitable operating history and our ability or inability to develop additional assays, additional capital may not be available when needed on acceptable terms, or at all. There is no assurance that we will be able to raise adequate funds when needed or on favorable terms. If adequate funds are not available when needed, we will need to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, pursue an acquisition of our company at a price that may result in a significant loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets.

Critical Accounting Policies and Significant Judgments and Estimates

For a discussion of accounting policies that we consider critical to our business operations and understanding of our results of operations, and that affect the more significant judgments and estimates used in the preparation of our financial statements, please see the information listed in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” contained in our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes to our critical accounting policies and estimates from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2022.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are not required to include the information contemplated by this Item 3 because we are a smaller reporting company.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective as of June 30, 2023, due to the material weaknesses in internal control over financial reporting described below, which have not yet been fully remediated.

Material Weakness in Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Following the original issuance of our unaudited condensed financial statements for the three and nine months ended September 30, 2021 included in our quarterly report on Form 10-Q, filed with the SEC on November 15, 2021 (the "Original September 30, 2021 Financial Statements"), we discovered that we had failed to accrue for, and reflect in the Original September 30, 2021 Financial Statements, certain expenses incurred during the third quarter of 2021 in the amount of approximately $1.1 million. This resulted in the restating of our unaudited condensed financial statements as of and for the nine months ended September 30, 2021. We determined that our review control over the completeness and accuracy of our accounts payable did not operate effectively, resulting in a material error in the Original September 30, 2021 Financial Statements.

In connection with the preparation of our Annual Report on Form 10-K for the year ended December 31, 2021 and the preparation of our Quarterly Report on Form 10-Q as of and for the three month period ended March 31, 2022, we discovered additional material weaknesses related to the (i) operating effectiveness of our internal controls to determine certain estimates and the timely review of such estimates and (ii) operating effectiveness of our internal controls to review and approve certain revenue related manual journal entries, including the review of the completeness and accuracy of information used.

While preparing our financial statements as of and for the year ended December 31, 2022, we discovered that there was an error in the inputs used within the black-scholes calculation for options granted in April 2019. Further, we discovered there was an error associated with the acceleration of stock-based compensation recorded in the unaudited condensed financial statements included in our quarterly report on Form 10-Q for the quarter ended March 31, 2022 (the "Original March 31, 2022 Financial Statements"). We determined that our review control over the completeness and accuracy of information used when calculating stock-based compensation expense did not operate effectively, resulting in a material error in the Original March 31, 2022 Financial Statements.

In addition, we discovered an error in our revenue and accounts receivable reconciliation process, such that the correct accounts receivable and corresponding revenue activity was not properly reflected in the unaudited condensed financial statements included in our quarterly report on Form 10-Q for the quarter ended June 30, 2022 (the "Original June 30, 2022 Financial Statements"). We also discovered through our revenue recognition and accounts reconciliation process that changes in payor class and implicit price concessions were not appropriately reflected in our unaudited condensed financial statements included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (the "Original September 30, 2022 Financial Statements"), which is the period in which they were known. We determined that our review control over the completeness and accuracy of data used in estimating net revenues and accounts receivable, as well as our control over the reconciliation process did not operate effectively, resulting in a material error in the Original June 30, 2022 Financial Statements and the Original September 30, 2022 Financial Statements.

None of these material weaknesses has been remediated.

A material weakness, as defined in Rule 12b-2 under the Exchange Act, is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any changes in our internal control over financial reporting that occurred during the three and six months ended June 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We are in the process of implementing certain remedial measures related to our material weaknesses, as described below under "Remediation Actions to Date".

Remediation Actions to Date

As of June 30, 2023, we implemented certain improvements to our internal control and financial reporting processes to address the material weaknesses identified above. These improvements include the following:

- During the first quarter of 2022, we engaged a “Big Four” accounting firm under an advisory engagement to be conducted under the AICPA Standards for Consulting Services to assist management with their internal controls review.
- During the second quarter of 2022, we began the process for designing and implementing the recommendations from the internal control review done during the first quarter of 2022.
- During the second and third quarters of 2022, our accounting department was substantially overhauled.
- During the second half of 2022 and during the first half of 2023, we continued the process of designing and implementing controls based off the recommendation from the "Big Four" internal controls review. This includes controls within the purchasing and payables, revenue and receivables, period-end financial reporting, equity and stock-based compensation business processes. Management has begun to test the operating effectiveness of the controls implemented to determine if the stated material weaknesses can be considered remediated.

We are committed to maintaining a strong internal control environment and implementing measures to ensure that the control deficiencies identified above are remediated as soon as possible. Management is in the process of implementing a remediation plan, which includes steps to design and implement new controls and expand the review of any potential unrecorded liabilities.

We have implemented certain aspects of our remediation plan but will need to design and implement additional controls related to the material weaknesses identified above. Moreover, we do not believe that any of our remedial controls have been fully implemented or operated for a sufficient period of time or number of occurrences to allow for sufficient testing to determine the controls’ operating effectiveness.

The remediation actions are being monitored by the Audit Committee of our Board of Directors.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

RISK FACTOR SUMMARY

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors", and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our common stock.

- We are a molecular oncology diagnostics company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.
- We need to raise additional capital to continue as a going concern.
- We expect to continue to incur significant expenses to develop and market products and diagnostic assays, which could make it difficult for us to achieve and sustain profitability.
- If we are unable to increase clinical utilization and reimbursement of our current products, assays and services or successfully develop and commercialize other products, assays and services, our revenues will be insufficient for us to achieve profitability.
- If we cannot develop products, assays and services to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.
- If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our products and diagnostic assays and pursue our research and development efforts may be jeopardized.
- Clinical utility studies are important in demonstrating to both customers and payors an assay's clinical relevance and value. If the results of those studies do not demonstrate that an assay provides clinically meaningful information and value, commercial adoption of such assay may be slow, which would negatively impact our business.
- The loss of key members of our executive management team could adversely affect our business.
- There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite skills, we may be unable to successfully execute our business strategy.
- Our failure to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for our products and diagnostic assays, to expand geographically and to successfully commercialize any other products or assays we may develop.
- We depend on third parties for the supply of samples and other biological materials that we use in our research and development efforts. If the costs of such samples and materials increase or our third-party suppliers terminate their relationship with us, our business may be materially harmed.
- We currently rely on third-party suppliers for our specimen collection and transport tubes, or STTs, shipping kits, and critical materials needed to perform our current assays, as well as our planned future products, assays and services, and any problems experienced by them could result in a delay or interruption of their supply to us.
- Our commercial success could be compromised if hospitals or other clients do not pay our invoices or if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our current assays and our planned future assays.
- We expect to depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our current assays and our planned future assays, our revenues could decline.
- Because of certain Medicare billing policies, we may not receive complete reimbursement for assays provided to Medicare patients. Medicare reimbursement revenues are an important component of our business model, and private payors

sometimes look to Medicare determinations when making their own payment determinations; therefore, incomplete or inadequate reimbursement from Medicare would negatively affect our business.

- Long payment cycles of Medicare, Medicaid and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.
- If we were required to conduct additional clinical studies or trials before continuing to offer assays that we have developed or may develop as laboratory developed tests, or LDTs, those studies or trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.
- If we are unable to maintain effective proprietary rights for our products or services, we may not be able to compete effectively in our markets.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.
- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.
- General economic or business conditions may have a negative impact on our business.

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained elsewhere in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on April 17, 2023.

Risks Relating to Our Financial Condition and Capital Requirements

We are a molecular oncology diagnostics company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.*

We have historically incurred substantial net losses, including a net loss of approximately $3.6 million and $10.8 million for the three and six months ended June 30, 2023. We experienced reduced demand for our COVID-19 testing services and stopped offering these services in February 2023. We will continue to incur net losses and negative cash flows from operations for the foreseeable future. At June 30, 2023, our accumulated deficit was approximately $309.2 million.

We expect our losses to continue as a result of costs relating to our laboratory operations as well as sales and marketing costs and research and development expenses. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

We need to raise additional capital to continue as a going concern.*

We expect to continue to incur losses for the foreseeable future and will have to raise additional capital to fund our planned operations and to meet our long-term business objectives. We currently expect that our existing resources will only be sufficient to fund our planned operations and expenditures into the fourth quarter of 2023. Management intends to continue its efforts to contain costs and to raise additional capital until we can generate sufficient cash from commercial sales to support operations, if ever. Until we can generate significant cash from operations, including product and assay revenues, we expect to continue to fund our operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. General market conditions resulting from high inflation, high interest rates, global supply chain issues, the Russia-Ukraine conflict, health epidemics or pandemics, bank failures, general economic uncertainty and other macroeconomic factors, as well as market conditions affecting companies in the life sciences industry in general, may make it difficult for us to obtain financing from the capital

markets on attractive terms, or at all. Failure to raise additional capital in sufficient amounts when needed would significantly impact our ability to continue as a going concern. The actual amount of funds that we will need and the timing of any such investment will be determined by many factors, some of which are beyond our control. To fund our current and planned operations in the short- and long-term, we may seek to raise additional capital through public or private equity offerings, debt financing, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by us could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability or inability to develop additional assays, and the current volatility in the equity markets, additional capital may not be available when needed on acceptable terms, or at all. There is no assurance that we will be able to raise adequate funds when needed or on favorable terms. If adequate funds are not available when needed, we will need to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses (through reductions in our workforce or otherwise), sell assets (potentially at a discount to their fair value or carrying value), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, pursue an acquisition of our company at a price that may result in a significant loss on investment to our stockholders, file for bankruptcy, seek other protection from creditors, or liquidate all of our assets.

We expect to continue to incur significant expenses to develop and market products and diagnostic assays, which could make it difficult for us to achieve and sustain profitability.*

In recent years, we have incurred significant costs in connection with the development of our products and diagnostic assays. For the six months ended June 30, 2023 and the year ended December 31, 2022, our research and development expenses were $1.4 million and $6.2 million, respectively, and our sales and marketing expenses were $1.0 million and $7.1 million, respectively. We expect our expenses to be significantly more than our revenues for the foreseeable future and increase as we conduct studies of our current products, assays and services and our planned future products, assays and services, establish our sales and marketing organization, drive adoption of and reimbursement for our products and diagnostic assays and develop new products, assays and services. As a result, we will need to generate significant revenues in order to achieve sustained profitability.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our financial condition, business strategy and long-term operating plans. For example, we completed a reduction in our workforce in the first quarter of 2023, including our entire field-based salesforce. Subject to obtaining sufficient funding, we plan to hire and develop a field-based sales organization in the future as part of our long-term business strategy.

Any restructuring activities we undertake in the future may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we have undertaken or undertake in the future will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If any internal restructuring activities we have undertaken or undertake in the future fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.*

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (“FDIC”) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.*

We maintain the majority of our cash in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. As noted above, the FDIC recently took control of SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Risks Relating to Our Business and Strategy

If we are unable to increase clinical utilization and reimbursement for our current products, assays and services or successfully develop and commercialize other products, assays and services, our revenues will be insufficient for us to achieve profitability.*

We currently derive substantially all our revenues from reimbursement for our diagnostic assays. We began offering our assays through our Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified CAP accredited, and state-licensed laboratory in 2014. We are in varying stages of research and development for other products and diagnostic assays that we may offer. If we are unable to increase reimbursement for our existing products and diagnostic assays or successfully develop and commercialize other products and diagnostic assays, we will not produce sufficient revenues to become profitable.

If we are unable to execute our strategy for clinical adoption and utilization of our products and diagnostic assays and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.*

We are an early-stage molecular oncology diagnostics company and have engaged in only limited sales and marketing activities for the diagnostic assays we currently offer through our CLIA-certified, CAP accredited, and state-licensed laboratory. Except for net income generated in the first quarter of 2021 as a result of our former COVID-19 testing, our revenue has been insufficient to fund operations.

Although we believe that our current assays and our planned future assays represent a promising commercial opportunity, our products or assays may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our products and diagnostic assays and build that market through physician education, awareness programs and the publication of prospective clinical trial results. Gaining acceptance in medical communities requires, among other things, publications in leading peer-reviewed journals of results from studies using our current products, assays and services and/or

our planned future products, assays and services. Publications in leading medical journals are subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our current products, assays and services and our planned future products, assays and services.

Our ability to successfully obtain reimbursement for the products and diagnostic assays that we have developed, and may develop in the future, will depend on numerous factors, including:

- the success of our FORESEE clinical study to evaluate the clinical utility of CNSide in LM patients, and our ability to conduct clinical utility studies of CNSide or other assays in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether CNSide is included in NCCN or other treatment guidelines;
- whether private health insurers, government health programs and other third-party payors will adopt CNSide in their guidelines, or cover such diagnostic assays in their fee schedules, and, if so, whether they will adequately reimburse us.
- whether healthcare providers believe such diagnostic assays provide clinical utility;
- whether the medical community accepts that such diagnostic assays are sufficiently sensitive and specific to be meaningful in-patient care and treatment decisions;
- our ability to continually source raw materials, STTs, shipping kits, and other products that we sell or consume in our manufacturing process that are of sufficient quality and supply;
- our ability to successfully hire and develop a field-based sales force in the future, and the success of any such sales force; and
- our ability to fund sales and marketing activities.

Failure to achieve widespread market acceptance of our current products, assays and services, as well as our planned future products, assays and services, would materially harm our business, financial condition and results of operations.

If we cannot develop products, assays and services to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.*

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. Several new cancer cell and gene therapies have been approved, as well as numerous new cancer drugs, and the pipeline of new oncology drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new products and diagnostic assays and enhance any existing products, assays and services to keep pace with evolving standards of care. Our current products, assays and services and our planned future products, assays and services could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring or prognosis of patients with neurological metastatic cancer. New cancer therapies typically have only a few years of clinical data associated with them, which limits our ability to develop products and diagnostic assays based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the applicability of our current products, assays and services and our planned future products, assays and services to new treatments, by incorporating important biomarker analysis, sales of our products, assays and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

If our current products, assays and services and our planned future products, assays and services do not continue to perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that we can continue to provide reliable, high-quality products and assay results. We believe that our customers are likely to be particularly sensitive to product or assay defects and errors. As a result, the failure of our current or planned future products or assays to perform as expected, including with respect to our ability to maintain the sensitivity, specificity, concordance or reproducibility of such assays, would significantly impair our reputation and the public image of our products and cancer assays, and we may be subject to legal claims arising from any defects or errors. This could also impact our ability to get paid or the amount we are paid.

If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide our products and diagnostic assays and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our diagnostic assays conducted in our CLIA-certified, CAP accredited, and state-licensed laboratory. We do not have any clinical reference laboratory facilities other than our facility in San Diego, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding and power outages, which may render it difficult or impossible for us to sell our products or perform our diagnostic assays for some period of time. The inability to sell our current or planned future products, or to perform our current assays and our planned future assays, or the backlog of assays that could develop if our facility is inoperable for even a short period of time, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

The San Diego area periodically experiences serious fires and power outages and is considered to lie in an area with earthquake risk.

Additionally, a key component of our research and development process involves using biological samples as the basis for our diagnostic assay development. In some cases, these samples are difficult to obtain. If the parts of our current or future laboratory facility where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our current or future CLIA-certified, CAP accredited, and state-licensed laboratory becomes inoperable or unqualified in any way we may not be able to license or transfer our technology to another facility with the necessary qualifications, including state licensure and CLIA certification, under the scope of which our current assays and our planned future assays could be performed. Even if we find a facility with such qualifications to perform our assays, it may not be available to us on commercially reasonable terms.

Our business is subject to risks arising from pandemic and epidemic diseases.*

A pandemic or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, courier delivery services and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The continued spread of an infectious disease and the measures taken by state and local governments could disrupt the supply chain of material needed for our assays, interrupt our ability to receive samples, impair our ability to perform or deliver the results from our tests, impede patient movement or interrupt healthcare services causing a decrease in test volumes, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our tests and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic previously resulted in a number of restrictions to reduce the spread of the disease, including executive orders in California, and several other state and local orders across the country, which, among other things, directed individuals to shelter at their places of residence, directed schools, businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. The effects of state and local stay-at-home orders may disrupt our business and delay our development programs and regulatory timelines and negatively impact our commercial activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations due to a health epidemic or pandemic could negatively impact our business, operating results and financial condition.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability.*

Our principal competition comes from established molecular diagnostic clinical testing services and products, used by medical oncologists, neuro-oncologists, surgical oncologists, radiation oncologists, pulmonologists, pathologists and other physicians, which are based on tumor tissue analysis. It may be difficult to change established clinical practices and behavior of medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians to get them to adopt the use of our CSF-based tumor cell and ctDNA assays, in their practices in conjunction with current standard of care.

Liquid biopsy molecular tests based on tumor cell and ctDNA assays for oncology applications represent a new area of science and medicine and we cannot predict what products or assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the products or assays we develop.

We face competition from specialty oncology diagnostic companies that are conducting research and development to develop proprietary CTC or ctDNA based assays and assay test panels for use in genomic profiling and monitoring solid tumor cancers. Competitors developing ctDNA based assays and assay panels include but are not limited to companies such as Guardant Health, Foundation Medicine, Tempus Laboratories, NeoGenomics, Invitae, Natera, Inivata and Biodesix. EPIC Sciences, Menarini Silicon Biosystems and Angle PLC offer CTC-based assays. These companies, in addition to operating research and development laboratories, have established CLIA-certified testing laboratories and have developed LDT (lab developed tests) that they market directly to oncologists and pathologists. A few of these companies, like Guardant Health and Foundation Medicine, have achieved FDA clearance for their proprietary laboratory tests.

There are several national and regional specialty diagnostic companies, such as Caris Life Sciences and CSI, which are focused on the oncology diagnostic market, who while not currently offering CTC or ctDNA assays are selling to oncologists and pathologists and could develop or offer ctDNA or CTC or assays. In addition, large laboratory services companies such as Quest and LabCorp which provide a broad array of cancer diagnostic assays and testing services could also offer CTC or ctDNA based clinical testing services.

Another new area of science and medicine is tumor cell and ctDNA assays performed from CSF samples for neuro-oncology applications and there is currently limited competition for our CSF-based tumor cell and ctDNA assays. There are no known specialty oncology diagnostic companies or large laboratory services companies that offer CSF-based tumor cell and ctDNA tests for neuro-oncology applications as a standard commercial clinical testing service. A few academic based pathology labs such as Memorial Sloan Kettering Cancer Center offer CSF-based testing mainly for research and internal purposes.

Companies like Abbott, Danaher and others could develop equipment or reagents in the future as well. Currently, companies like Streck, Roche and Exact Sciences offer STTs, and in the future, companies like Covidien, Beckton Dickinson, Thermo Fisher, and other large medical device companies may develop STTs as well.

There are a number of life science technology companies that are focused on the oncology diagnostic market, such as Thermo Fisher Scientific, Illumina, Abbott Molecular, Bio-Rad, Sysmex, Qiagen, and Roche Diagnostics, that are selling equipment and reagents kits for ctDNA assays and assay panels. These companies compete with our ctDNA assay kit products and STTs. Menarini Silicon Biosystems sells equipment and reagents kits for CTC assays. These companies market their products to specialty laboratories that offer molecular based testing for oncology applications, including national reference laboratory, regional laboratories and pathology laboratories that are part of academic medical centers and hospital systems. These laboratories may purchase these products and develop ctDNA and CTC based laboratory developed tests that are marketed to medical oncologists and pathologists that compete with our lab services.

Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex assays that payors, medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians could view as functionally equivalent to our current or planned future assays, which could force us to lower the list price of our assays and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced products or diagnostic tools that are more sensitive or specific or offer more content than ours may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized products or diagnostic assays similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned future products or assays, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect that biopharmaceutical companies will increasingly focus resources on development of targeted oncology therapies that may require a companion diagnostics test approved by the FDA. Biocept may face increasing competition from companies that offer CTC or ctDNA assays or products that are approved by the FDA as an IVD for companion diagnostic uses.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current or planned future products or assays in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their product or assay by physicians or patients in other countries.

If medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians decide not to order our current or planned future assays, or if laboratory supply distributors or their customers decide not to order our current or planned future products, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our current products, assays and services and our planned future products, assays and services, we will need to hire and develop a field-based sales organization to educate medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, and other physicians and other health care professionals, as well as laboratory and medical equipment suppliers, on the clinical utility, benefits and value of the products, assays and services we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we need to educate medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians of our ability to obtain and maintain coverage and adequate reimbursement from third-party payors. We will need to hire additional commercial, scientific, technical and other personnel to support this process. Unless an adequate number of medical practitioners order our current assays and our planned future assays, or unless an adequate number of laboratory supply distributors order our current and planned future products, we will likely be unable to create demand in sufficient volume for us to achieve sustained profitability.

Clinical utility studies are important in demonstrating to both customers and payors an assay's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that an assay provides clinically meaningful information and value, commercial adoption of such assay may be slow, which would negatively impact our business.

Clinical utility studies, including the FORESEE trial for CNSide, show when and how to use a clinical test or assay and describe the particular clinical situations or settings in which it can be applied and the expected results. Clinical utility studies also show the impact of the test or assay results on patient care and management. Clinical utility studies are typically performed with collaborating oncologists or other physicians at medical centers and hospitals, analogous to a clinical trial, and generally result in peer-reviewed publications. Sales and marketing representatives use these publications to demonstrate to customers how to use a clinical test or assay, as well as why they should use it. These publications are also used with payors to obtain coverage for a test or assay, helping to assure there is appropriate reimbursement.

We need to conduct additional studies for our assays, increase assay adoption in the marketplace and obtain coverage and adequate reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians, adoption of our assays could be impaired, and we may not be able to obtain coverage and adequate reimbursement for them.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The collective efforts of each member of the executive team and others working with them as a team are critical to us as we continue to develop our technologies, products, services, assays and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our executive management team each have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain "key person" life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

Our failure to obtain sufficient funding and to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for our products and diagnostic assays, to expand geographically and to successfully commercialize any other products or assays we may develop.

To succeed in selling our products and diagnostic assays and any other products or assays that we develop, we intend to hire and develop a U.S. based field-based sales organization in the future, subject to obtaining sufficient funding to do so. We will seek to recruit sales representatives with extensive experience in oncology and established relationships with medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, oncology nurses, and other physicians and hospital personnel, as well as laboratory supply distributors. To achieve our marketing and sales goals, we will need to build and develop a sales and commercial infrastructure. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire and retain the number of sales professionals with the right qualifications, scientific backgrounds and relationships with decision-makers at potential customers needed to achieve our sales goals. We expect to face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer.

Our dependence on commercialization partners for sales of products, assays and services could limit our success in realizing revenue growth.

We may seek to grow our business through the use of commercialization partners for the sales, marketing and commercialization of our current products, assays and services, as well as our planned future products, assays and services, and to do so we must enter into agreements with these partners to sell, market or commercialize our products, assays and services. These agreements may contain exclusivity provisions and generally cannot be terminated without cause during the term of the agreement. We may need to attract additional partners to expand the markets in which we sell products or assays. These partners may not commit the necessary resources to market and sell our products and diagnostics assays to the level of our expectations, and we may be unable to locate suitable alternatives should we terminate our agreement with such partners or if such partners terminate their agreement with us.

If future commercialization partners do not perform adequately, or we are unable to locate commercialization partners, we may not realize revenue growth.

We depend on third parties for the supply of samples and other biological materials that we use in our research and development efforts. If the costs of such samples and materials increase or our third-party suppliers terminate their relationship with us, our business may be materially harmed.*

We have relationships with suppliers and institutions that provide us with samples and other biological materials that we use in developing and validating our current assays and our planned future assays. If one or more suppliers terminate their relationship with us or are unable to meet our requirements for samples, we will need to identify other third parties to provide us with blood samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business. In addition, as we grow, our research and academic institution collaborators may seek additional financial contributions from us, which may negatively affect our results of operations. To the extent that the third parties supplying us with samples or other biological materials are impacted by a health epidemic or pandemic or supply chain issues, our costs and availability of such supplies may be impacted.

We currently rely on third-party suppliers for our STTs, shipping kits, and critical materials needed to perform our current assays, as well as our planned future products, assays and services, and any problems experienced by them could result in a delay or interruption of their supply to us.*

We currently purchase our STTs and raw materials for our microfluidic channels and assay reagents under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our STTs, shipping kits, materials or reagents, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in obtaining STTs, shipping kits, manufacturing the microfluidic channels,

or performing assays while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new STTs, shipping kits, materials, or reagents and in increased operating costs. Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to perform diagnostic assays in a timely manner and sell our products. If our third-party suppliers' operations are impacted by a health epidemic or pandemic or supply chain issues, we may experience supply delays or interruptions.

Some of the components used in our current or planned future products are currently sourced from a supplier for which alternative suppliers exist but we have not validated the products of such alternative suppliers, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by any one of our suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations or product sales. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products and current assays, as well our planned future products, assays and services, could lead to the filing of product liability claims against us if someone alleges that our products or assays failed to perform as designed. We may also be subject to liability for errors in the assay results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, result in the recall of products or assays, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

If we cannot support demand for our current products, assays and services, as well as our planned future products, assays and services, including successfully managing the evolution of our laboratory service, our business could suffer.*

As our product and assay volume grows, we will need to increase our assay capacity, implement automation, increase our scale and related processing, customer service, billing, collection and systems process improvements and expand our internal quality assurance program and technology to support assays on a larger scale. Examples of challenges we may face include, but are not limited to, maintaining the same validated sensitivity in our assays for both CTC and ctDNA analysis as our assay volume increases. We will also need additional clinical laboratory scientists and other scientific and technical personnel to process these additional assays. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional products, assays and services are commercialized, we may need to bring new equipment online, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement or maintain necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform assays on a timely basis, or procure STTs, shipping kits or other materials we sell, at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our assay results, or that we will respond successfully to the growing complexity of our operations. If we encounter difficulty meeting market demand or quality standards for our current products, assays and services and our planned future products, assays and services, including with respect to our assays our ability to maintain the sensitivity, specificity, concordance and reproducibility of such assays, our reputation could be harmed, and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations and cash flows.

Billing for our diagnostic assays is complex, and we must dedicate substantial time and resources to the billing process to be paid.

Billing for clinical laboratory assay services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, including Medicare, insurance companies and patients, all of which have different billing requirements. We generally bill third-party payors for our diagnostic assays and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of doubtful accounts and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the list price for our assays and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing Medicare;
- risk of government audits related to billing Medicare;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes and/or coverage policies that apply to our assays;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as Current Procedural Terminology, or CPT, codes, to bill for our diagnostic assays. These codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on our revenues. There can be no assurance that payors will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems and ours will not result in errors, delays in payments and a related increase in accounts receivable balances.

As we introduce new assays, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. These billing complexities, and the related uncertainty in obtaining payment for our assays, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We rely on third-party billing provider software, and an in-house billing function, to transmit claims to payors, and any delay in transmitting claims could have an adverse effect on our revenue.

While we manage the overall processing of claims, we rely on third-party billing provider software to transmit the actual claims to payors based on the specific payor billing format. We have previously experienced delays in claims processing when our third-party provider made changes to its invoicing system. Additionally, coding for diagnostic assays may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payors on a timely basis or are erroneously submitted, or if we are required to switch to a different software provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payors, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

We may encounter manufacturing problems or delays that could result in lost revenue.*

We currently manufacture our proprietary microfluidic channels at our San Diego facility and intend to continue to do so. We believe we currently have adequate manufacturing capacity for our microfluidic channels. If demand for our current products, assays and services and our planned future products, assays and services increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. If we or third-party manufacturers engaged by us fail to manufacture and deliver our microfluidic channels or certain reagents in a timely manner, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing, or quality control problems will not arise as we attempt to increase the production of our microfluidic channels or reagents or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot manufacture our microfluidic channels consistently on a timely basis because of these or other factors, it could have a significant negative impact on our ability to perform assays and generate revenues. We may encounter supply chain constraints in obtaining the raw materials needed to manufacture our products for a variety of reasons, including events outside of our control such as a health epidemic or pandemic and geopolitical events.

International expansion of our business would expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

As part of our long-term business strategy, we may pursue international expansion, including partnering with academic and commercial testing laboratories, and introducing our technology outside the United States as part of in vitro diagnostic, or IVD, test kits and/or testing systems utilizing our technologies. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products or assays and our planned future products or assays in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our current products or assays and our planned future products or assays cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;

- natural disasters, political and economic instability, including wars, invasions, other military actions, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, without limitation, regulatory investigations or actions, litigation, interruption to our operations, harm to our reputation, fines, penalties, liability, or a loss of revenues, customers or sales, or other adverse consequences.

In the ordinary course of our business, we may process proprietary, confidential and sensitive information, personal data (including health information), intellectual property, trade secrets, and other sensitive business information owned or controlled by ourselves or other parties (collectively, sensitive information).

Despite the implementation of security measures, we and the third parties upon whom we rely (including the Internet and related systems) face a variety of evolving threats related to sensitive information, including without limitation ransomware attacks, which could cause security incidents. Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel misconduct or error, employee theft or misuse, sophisticated nation-state and nation-state supported actors. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products.

We and the third parties upon whom we rely are subject to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), software bugs, malicious code (such as viruses and worms), denial-of-service attacks (such as credential stuffing), ransomware attacks, supply chain attacks, malware installation (including as a result of advanced persistent threat intrusions), server malfunction, software or hardware failures, loss of data or other computer assets, adware, physical break-ins, fires, telecommunications or network failures, malicious human acts, natural disasters, or other similar issues. Ransomware attacks, including those from organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials, loss of sensitive information (including data related to clinical trials), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

In addition, we rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including without limitation, assay processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive information with or from third parties. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our platform, systems and networks or the systems and networks of third parties that support us and our services. Despite the security controls we have in place, such attacks are very difficult to avoid.

Any of the aforementioned threats and other similar attacks, disruptions or accidents could cause a security incident, which, in turn, could result in unauthorized access to, damage to, disablement or encryption of, use or misuse of, disclosure of, modification of, destruction of, or loss of our sensitive information, or disrupt our ability to provide our platform or our service providers' ability to support our services or develop or deliver our products. We may expend significant resources, fundamentally change our business

activities and practices, or modify our operations in an effort to protect against security incidents and to mitigate, detect and address actual and potential vulnerabilities. Certain data privacy and security obligations may require us to implement and maintain specific, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. Despite the precautionary measures we have taken to try to prevent a security incident, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. These vulnerabilities pose risk to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure of any security incident or the failure to comply with such requirements could lead to adverse consequences. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, such as preventing us from processing assays; providing assay results to medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, and other physicians; billing payors; processing reimbursement appeals; handling patient or physician inquiries; conducting research and development activities and managing the administrative aspects of our business.

Furthermore, if we or any third party upon whom we rely experience a security incident, or are perceived to have experienced a security incident, it could result in: government enforcement actions that could include investigations, fines, penalties, audits and inspections; additional reporting requirements and/or oversight; restrictions on processing personal data or sensitive information (which could impact our ability to conduct tests or develop our products); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Furthermore, there can be no assurance that our contracts contain limitations of liability, and even where they do, such limitations may not be enforceable, adequate or otherwise protect us from liabilities or damages if we fail to comply with obligations related to security incidents. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Regulatory and Reimbursement Risks Relating to Our Business

Healthcare policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations and cash flows.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, made a number of substantial changes in the way health care is financed by both governmental and private insurers.

Although some of these provisions may negatively impact payment rates for clinical laboratory tests, the ACA also extends coverage to over 30 million previously uninsured people, which resulted in an increase in the demand for our current assays and our planned future assays. There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA

will be subject to judicial or congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Protecting Access to Medicare Act of 2014, or PAMA, was signed to law, which, among other things, significantly altered the current payment methodology under the Medicare Clinical Laboratory Fee Schedule, or CLFS. Beginning in 2017 and every three years thereafter (or annually in the case of advanced diagnostic laboratory tests), applicable clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic laboratory test that it furnishes during the specified time period. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Effective January 1, 2018, the Medicare payment rate for each clinical diagnostic laboratory test is equal to the weighted median amount for the test from the most recent data collection period. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. The PAMA rate changes did not materially affect our payments beginning in 2018; however, we cannot predict how this may affect future payment in coming years. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. Based on current law, between January 1, 2024 and March 31, 2024, applicable laboratories will be required to report on data collected during January 1, 2019 and June 30, 2019. This data will be utilized to determine 2025 to 2026 CLFS rates. In addition, CMS updated the statutory phase-in provisions such that the rates for clinical diagnostic laboratory tests in 2020 could not be reduced by more than 10% of the rates for 2019. Pursuant to the CARES Act, the statutory phase-in of the payment reductions has been extended through 2024, with a 0% reduction cap for 2021-2022 and a 15% reduction cap for 2024 through 2026. It is unclear what impact new quality and payment programs or new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations, or cash flows.

Also, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS is required to publicly report payment for the tests. Further, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. We cannot determine at this time the full impact of PAMA, including its implementing regulations, on our business, financial condition and results of operations.

Additionally, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers and suppliers of up to 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The full impact on our business the sequester law is uncertain. In addition, the Middle-Class Tax Relief and Job Creation Act of 2012, or MCTRJCA, mandated an additional change in Medicare reimbursement for clinical laboratory tests. In addition, Congress is considering additional health reform measures as part of other reform initiatives.

Some of our laboratory assay business is subject to the Medicare Physician Fee Schedule and, under the current statutory formula, the rates for these services are updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenue and results of operations. If in future years Congress does not adopt interim legislation to block or offset, and/or CMS does not moderate, any substantial CMS-proposed reimbursement reductions, the resulting decrease in payments from Medicare could adversely impact our revenues and results of operations.

We cannot predict whether future health care initiatives will be implemented at the federal or state level. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. The expansion of government's role in the U.S. health care industry, and changes to the reimbursement amounts paid by Medicare and other payors for our current assays and our planned future assays, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance payment requirement on patients for clinical laboratory tests reimbursed under the CLFS, which would require us to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for our assays could often exceed the amount actually received from the patient.

Our commercial success could be compromised if hospitals or other clients do not pay our invoices or if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our current assays and our planned future assays.

Medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians may not order our current assays and our planned future assays unless third-party payors, such as managed care organizations and government payors (e.g., Medicare and Medicaid), pay a substantial portion of the assay price. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that assays using our technologies are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Uncertainty surrounds third-party payor coverage and adequate reimbursement of any test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic assays, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current assays and our planned future assays will be provided in the future by additional third-party payors or that existing agreements, policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and adequate reimbursement from private and governmental payors such as Medicare and Medicaid for our current assays, or new assays or assay enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we may experience delays and interruptions in the receipt of payments from third-party payors due to missing documentation and/or other issues, which could cause delay in collecting our revenue.

In addition, to the extent that our assays are ordered for Medicare inpatients and outpatients, only the hospital may receive payment from the Medicare program for the technical component of pathology services and any clinical laboratory services that we perform, unless the testing is ordered at least 14 days after discharge and certain other requirements are met. We therefore must look to the hospital for payment for these services under these circumstances. If hospitals refuse to pay for the services or fail to pay in a timely manner, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow.

We expect to depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our current assays and our planned future assays, our revenues could decline.*

Approximately 21% and 36% of total net revenues during the six months ended June 30, 2023 and 2022, respectively, were associated with Medicare and CARES Act reimbursement. Approximately 15% and 16% of total net revenues during the six months ended June 30, 2023 and 2022, respectively, were associated with Blue Cross Blue Shield reimbursement. We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare and Blue Cross Blue Shield covered portions of our current assays and our planned future assays would, without such contracted payor reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

Medicare and other third-party payors may change their coverage policies or cancel future contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our assays altogether, which would reduce our total revenues. Payors have increased their efforts to control the cost, utilization and delivery of health care services. In the past, measures have been undertaken to reduce payment rates for and decrease utilization of clinical laboratory testing generally. Because of the cost-trimming trends, third-party payors that currently cover and provide reimbursement for our current assays and our planned future assays may suspend, revoke or discontinue

coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we are currently considered a "non-contracted provider" by many private payors because we have not entered into a specific contract to provide diagnostic assays to their insured patients at specified rates of reimbursement. Additionally, a significant amount of our non-Medicare business (private payors) has historically not been contracted, and reimbursement for this business has historically not been at "in network" rates and has therefore been inconsistent. We first began to contract private payor networks in 2015, and since then our number of accessions treated as "in network" has increased as we continue to execute additional contracts, and reimbursement is improving. We are currently contracted with nine preferred provider organization networks, three large health plans, and five regional independent physician associations, and expect to continue to gain contracts in order to be considered as an "in-network" provider with additional plans. If we were to become a contracted provider with additional payors in the future, the amount of overall reimbursement we receive would likely decrease because we could be reimbursed less money per assay performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we typically are unable to collect payments from patients beyond that which is paid by their insurance and will continue to experience lost revenue as a result.

Because of certain Medicare billing policies, we may not receive complete reimbursement for assays provided to Medicare patients. Medicare reimbursement revenues are an important component of our business model, and private payors sometimes look to Medicare determinations when making their own payment determinations; therefore, incomplete or inadequate reimbursement from Medicare would negatively affect our business.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the CTC enumeration portion of our assays. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our assays. The previous MAC for California, Palmetto, which is contracted with CMS to administer the Molecular Diagnostic Services, or MolDX, program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto. Therefore, the enumeration portion of our assays is not currently covered, and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. Tumor cell enumeration counts disease burden and is a prognostic assay, and although valuable, it does not yet meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CNSide technology that allows us to run our diagnostic testing for some of our assays.

We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare, Blue Cross Blue Shield, and United Healthcare-covered portions of our current assays and our planned future assays would, without such contracted payor reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

The processing of Medicare claims is subject to change at CMS' discretion at any time. Cost containment initiatives may be a threat to Medicare reimbursement levels (including for the covered components of our current assays and our planned future assays, including FISH analysis and molecular assays) for the foreseeable future.

Long payment cycles of Medicare, Medicaid and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we must satisfy in order to receive payment, and the programs can be expected to carefully audit and monitor our compliance with these requirements. We must also comply with numerous other laws applicable to billing and payment for healthcare services, including, for example, privacy laws. Failure to comply with these requirements may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. In addition, failure by third-party payors to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under

CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform high complexity testing, and our laboratory is accredited by one of the CLIA-approved accreditation organizations. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA and CAP inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The failure to comply with CLIA or CAP requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA and/or CAP certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for assays provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition, our laboratory is located in California and is required by state law to have a California state license; as we expand our geographic focus, we may need to obtain laboratory licenses from additional states. California laws establish standards for operation of our clinical laboratory, including the training and skills required of personnel and quality control. In addition, we hold licenses from the states of Pennsylvania, Maryland and Rhode Island to test specimens from patients in those states or received from ordering physicians in those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our assays. We currently do not have the necessary New York license, but we are in the process of addressing the requirements for licensure in New York. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our assays outside the United States.

If we were to lose our CLIA certification or California or other state laboratory license, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our assays, which would limit our revenues and harm our business. If we were to lose, or fail to obtain, a license in any other state where we are required to hold a license, we would not be able to test specimens from those states. If we were to lose our CAP accreditation, our reputation for quality, as well as our business, financial condition and results of operations, could be significantly and adversely affected.

If the FDA were to begin requiring approval or clearance of our current products or assays and our planned future products or assays, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our assays.*

We provide our assays as LDTs. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. In January 2017, the FDA announced that final guidance on the oversight of LDTs would allow for further public discussion. On January 13, 2017 the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which states that the material in the document does not represent a final version of the LDT draft guidance documents that were published in 2014 or position of the FDA; rather, the document is a method to encourage additional dialogue. The timing of when, if at all, the draft guidance documents will be finalized is unclear, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

FDA review, if required and successfully accomplished, would be expected to have some advantages. Certain health insurance payors have paid higher amounts over LDT prices for FDA approved or cleared tests, recognizing the additional costs of bringing a test through regulatory review. Some payors also accept FDA approval or clearance as a presumptive evidence of an assay's analytic validity and clinical validity, which can reduce the barriers to coverage since the payor can focus its review on clinical utility.

The container we provide for transport of CSF samples from a health care provider to our clinical laboratory, as well as our STTs, may be medical devices subject to the FDA regulation but are currently exempt from pre-market review by the FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition.

Some of the materials we use for our current products, assays and services and may use in our planned future products, assays and services are labeled for RUO. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research or investigational use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational use only, the device would be misbranded and adulterated within the meaning of the Federal Food, Drug and Cosmetic Act. Some of the materials and reagents obtained by us from suppliers for use in our current products, assays and services and our planned future products, assays and services are currently labeled as research or investigational use only products. If the FDA were to undertake enforcement actions, some of our suppliers might cease selling research or investigational use products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, including increasing the cost of materials or reagents used in our current products, assays and services or planned future products, assays and services or delaying, limiting or prohibiting the purchase of materials or reagents necessary to sell our current products or planned future products or to perform our current assays or our planned future assays.

Further, the Department of Health and Human Services, or HHS, requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report's recommendations for increased oversight of genetic testing were to result in further regulatory burdens, they could negatively affect our business and delay the commercialization of assays in development.

Additionally, on March 16, 2018, CMS issued a final determination decision memo for Next-Generation Sequencing, or NGS, tests for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). Under this final determination, NGS tests that gain FDA approval or clearance as a companion diagnostic will receive coverage, and the final determination of coverage for NGS tests that are LDTs will be left up to the local MAC. Currently, only 2 of our 17 CLIA validated assays utilized in CNSide is NGS-based; however, we plan to offer additional NGS assays in the future. To gain coverage for those assays, we will need to apply to Palmetto, which is the MAC that evaluates and recommends payment coverage or denial for molecular testing in our jurisdiction. Historically, Palmetto has offered a path to reimbursement by providing coverage while data is being gathered known as Coverage with Data Development, or CDD. Going forward, the extent to which CDD will be continued, if at all, or to the extent that a process will be available in its place, if any, are unclear.

The requirement of pre-market review could negatively affect our business until such review is completed and clearance to market or approval is obtained. The FDA could require that we stop selling our products or diagnostic assays pending pre-market clearance or approval. If the FDA allows our products or assays to remain on the market but there is uncertainty about our products or assays, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from laboratory supply distributors and physicians, or reimbursement from third-party payors, may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission or filing a pre-market approval application with the FDA. If the FDA requires pre-market review, our products or assays may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our products or assays if we determine that doing so would be appropriate.

If we were required to conduct additional clinical studies or trials before continuing to offer assays that we have developed or may develop as LDTs, those studies or trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.

If the FDA decides to require that we obtain clearance or approvals to commercialize our current assays or our planned future assays, we may be required to conduct additional pre-market clinical testing before submitting a regulatory notification or application for commercial sales. In addition, as part of our long-term strategy we may plan to seek FDA clearance or approval, so we can sell our assays outside our CLIA laboratory; however, we would need to conduct additional clinical validation activities on our assays before we can submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or the FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our assays. It may take two years or more to conduct the clinical studies and trials necessary to obtain approval from the FDA to commercially launch our current assays and our planned future assays outside of our clinical laboratory. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our assay claims or that the FDA or foreign authorities will agree with our conclusions regarding our assay results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our assay development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that our current assays and our planned future assays are effective for the proposed indicated uses, which could cause us to abandon an assay candidate and may delay development of other assays.

We have engaged a contract research organization to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our current assays and our planned future assays. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our assays or to achieve sustained profitability.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of “designated health services” with whom the physician or a member of the physician’s immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal health care programs to include private insurance (i.e., it is an “all payor” statute);
- HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
- HIPAA, as amended by HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on “covered entities,” including certain healthcare

providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose or otherwise process individually identifiable health information;

- federal false claims and civil monetary penalties laws, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government;
- the federal Physician Payments Sunshine Act requirements under the ACA, which require certain manufacturers of drugs, devices, biologics and medical supplies to report to CMS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, and certain physician ownership and investment interests held by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal health care fraud statutes. Where the intent requirement has been lowered, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may now 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 false claims statutes. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages and fines, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government funded healthcare programs such as Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal-the California Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We are or may become subject to stringent and changing U.S. and foreign laws, regulations, rules, standards, policies, contractual obligations and other obligations related to data privacy and security, including laws and regulations related to health information. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, enforcement or litigation, fines and penalties), a disruption of the development or delivery of our products and services, reputational harm, loss of revenue or profits, or other adverse business consequences.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) personal data and other sensitive information, including but not limited to proprietary and confidential business information, trade secrets, intellectual property, health information and sensitive third-party information. Accordingly, we are, or may become, subject to numerous federal, state, local and foreign data privacy and security laws, regulations, guidance and industry standards, including laws that specifically regulate health information, as well as external and internal privacy and security policies, contracts and other obligations that apply to the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, and the respective implementing regulations, imposes limitations on certain entities' processing of individual health information, and also grants individuals rights with respect to their health information. HITECH also made significant increases in the penalties for improper processing of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. For more information regarding risks associated with HIPAA, please refer to the section above titled *Confidentiality and Security of Personal Health Information*.

As another example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal information of consumers, business representatives, and employees, and requires covered businesses to provide specific disclosures related to a business's processing of personal data, new operational practices, and requirements to respond to certain requests from California residents related to their personal data. The CCPA provides for significant civil penalties of up to $7,500 per violation as well as a private right of action for data breaches and statutory damages. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, the CCPA and other similar laws may impact our business activities and increase our compliance costs. In addition the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, expanded the CCPA's rights, including by, among other things, giving California residents the ability to correct their personal data and limit use of certain sensitive personal data, establishing restrictions on the retention of personal data, expanding the types of data breaches subject to the CCPA's private right of action, and establishing a new

California Privacy Protection Agency to implement and enforce the new law. In addition, other states have enacted or proposed data privacy laws, which could further complicate the legal landscape. For example, Virginia recently passed the Consumer Data Protection Act which became effective on January 1, 2023, and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in July 2023. Other data privacy and security laws have also been proposed at the federal, state, and local levels, and may be enacted.

Additionally, outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, governs the processing of personal data of European persons, and sets out extensive compliance requirements. The EU GDPR provides for fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. Additionally, we may be subject to the United Kingdom's GDPR or UK GDPR, which largely mirrors the EU GDPR in UK national law. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we may be legally or contractually bound to comply.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

The number and scope of obligations related to data privacy and security, including but not limited to the complex requirements of HIPAA, GDPR and US state data privacy law requirements, are rapidly evolving, subject to change and potentially in conflict with each other. As a result, preparing for and complying with these obligations requires significant resources and may necessitate changes to our services, information technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors, consultants or other third parties that process personal data on our behalf, any of which could have a negative impact on our operations. Our business model materially depends on our ability to process personal data, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. Adding to the complexity is that our operations are evolving, and these laws will apply differently depending on our operations, for example whether we electronically bill for our services.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, partners, third-party collaborators, service providers, contractors or consultants fail to comply with such obligations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to foreign, federal, state, or local government enforcement actions that could include investigations, fines, penalties, audits and inspections; litigation (including class-action claims); additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data (including in relation to clinical trials); and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to loss of actual or prospective customers, collaborators or partners; interruption or stoppage in clinical trials; inability to process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; or require us to revise or restructure our operations. Moreover, such claims, even if we are not found liable, could be expensive and time-consuming to defend and could divert management's attention and cause adverse publicity that could harm our business or have other material adverse effects.

Clinical research is heavily regulated and failure to comply with human subject protection regulations may disrupt our research program leading to significant expense, regulatory enforcement, private lawsuits and reputational damage.

Clinical research is subject to federal, state and, for studies conducted outside of the United States, foreign regulation. At the federal level, the FDA imposes regulations for the protection of human subjects and requirements such as initial and ongoing institutional review board review; informed consent requirements, adverse event reporting and other protections to minimize the risk and maximize the benefit to research participants. Many states impose human subject protection laws that mirror or in some cases exceed federal requirements. HIPAA also regulates the use and disclosure of protected health information in connection with research activities. Research conducted overseas is subject to a variety of national protections such as mandatory ethics committee review, as well as laws regulating the use, disclosure and cross-border transfer of personal data. For example, if we obtain certain personal information regarding residents in the European Union, we may be subject to the GDPR. The costs of compliance with these laws may be significant and compliance with regulatory requirements may result in delay of our clinical research and other business operations. Noncompliance may disrupt our research and result in data that is unacceptable to regulatory authorities, data lock or other sanctions that may significantly disrupt our operations.

Violation of a state's prohibition on the corporate practice of medicine could result in a material adverse effect on our business.

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in significant civil, criminal and administrative penalties imposed against us and/or the professional through licensure proceedings, and exclusion from state and federal health care programs.

Intellectual Property Risks Related to Our Business

If we are unable to obtain and maintain effective patent rights for our products or services, we may not be able to compete effectively in our markets.*

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies, products and services. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The possibility exists that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of diagnostic companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own, or in-license, may fail to result in issued patents with claims that cover our products or services in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products and services, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and services, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our products and services. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. For example, our U.S. patent related to our STTs was recently under a reexamination procedure in the U.S. Patent and Trademark Office, or USPTO, and was issued a Reexamination Certificate. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any products and services that we may offer. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or service under patent protection could be reduced.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific

patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our products or services, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have conducted commercially reasonable due diligence on these individuals, organizations and systems, our agreements with such partners or our or their security measures may nevertheless be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.*

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and services. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. For example, a third party has notified us that it believes our prior commercial use of certain blood collection tubes has infringed patients owned by the third party, and on that basis has suggested that we in-license the patent rights from the third party. This third party has succeeded in a patent infringement jury trial against another party relating to the same patents. We are currently in discussion with the third party and cannot guarantee an outcome that is favorable to us.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products and services. We have conducted freedom to operate analyses with respect to only certain of our products and services, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these products and services. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or services may infringe.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to our products or services through acquisitions and in-licenses.*

We currently have rights to the intellectual property, under patents that we own, to develop our products and services. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our products or services. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We sometimes collaborate with U.S. and foreign institutions to accelerate our research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our products or services, the defendant could counterclaim that the patent covering our product or service is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise sufficient capital to continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help commercialize our products or services.

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

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

We employ certain individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our products or services. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Our collaborators may assert ownership or commercial rights to inventions we develop from our use of the biological materials which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, physicians and researchers in scientific matters. We do not have written agreements with certain of such collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with blood samples and biological materials that we use to develop assays. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Risks Relating to Our Common Stock

The price of our common stock may be volatile.*

Market prices for our common stock have historically been volatile. The factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- progress, or lack of progress, in performing, developing and commercializing our current assays and our planned future assays;
- favorable or unfavorable decisions about our assays from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- disruptions caused by geopolitical conflicts (such as the current Russia-Ukraine conflict) man-made or natural disasters or public health pandemics or epidemics or other business interruptions;
- changes in the structure of healthcare payment systems;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described herein; and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.*

If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum stockholders' equity requirement, Nasdaq may take steps to de-list our common stock. For example, in May 2016 and May 2023, we received a letter from Nasdaq indicating that we are not in compliance with the minimum stockholders' equity requirement of Nasdaq Listing Rule 5550(b)(1), and in each of June 2016, November 2016, January 2018, September 2019 and October 2022, we received letters from Nasdaq indicating that we were not in compliance with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2), which requires that companies listed on The Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share. We were able to regain compliance with the Nasdaq continued listing requirements discussed in the May 2016, June 2016, November 2016, January 2018, September 2019, and October 2022 letters. With respect to the May 2023 letter, we submitted a plan to regain compliance and were granted an extension until November 13, 2023 to regain compliance with the minimum stockholders' equity requirement. There can be no assurance that we will be able to regain and maintain compliance with the stockholders' equity requirement. In addition, we were unable to timely file our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which resulted in us not being in compliance with Nasdaq Listing Rule 5250(c)(1). We subsequently filed such Quarterly Report on Form 10-Q within the additional period granted by Nasdaq. However, it is possible that we will be unable to timely file future periodic reports in a timely manner. If we fail to regain and maintain compliance with Nasdaq's continued listing requirements, Nasdaq may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with Nasdaq's listing requirements.

Our quarterly operating results may fluctuate significantly.*

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

- the rate of adoption and/or continued use of our current assays and our planned future assays by healthcare practitioners;
- variations in the level of expenses related to our development programs;
- addition or reduction of resources for sales and marketing;
- addition or termination of clinical utility studies;
- any intellectual property infringement lawsuit in which we may become involved;
- the impact that a health epidemic or pandemic may have on our core oncology business;
- third-party payor coverage and reimbursement determinations affecting our assays; and
- regulatory developments affecting our assays.

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

Future sales of our common stock or other securities, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.*

Sales of substantial amounts of our common stock or other securities, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

We had outstanding 2,407,381 shares of common stock as of June 30, 2023, most of which are not subject to resale restrictions under Rule 144 of the Securities Act. In addition, as of June 30, 2023, we had outstanding preferred stock convertible into 1,519 shares of our common stock, options to purchase 40,023 shares of our common stock and 1,103,192 shares of our common stock were issuable upon the exercise of outstanding warrants. Shares issued upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.*

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. In connection with the restatement of our unaudited condensed financial statements as of, and for the three and nine months ended, September 30, 2021, we determined that we had a material weakness as of September 30, 2021, namely that our review control over the completeness and accuracy of our accounts payable did not operate effectively, resulting in a material error in the unaudited condensed financial statements. Subsequently, in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2021, management determined that a deficiency existed related to the methods used to develop certain estimates and the timely review of such estimates. Additionally, in connection with the preparation and review of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, as well as in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2022, management determined that a material weakness existed related to our controls to review and approve certain revenue-related manual journal entries, including the review of the completeness and the accuracy of the information used. In addition, in connection with the preparation and review of our Annual Report on Form 10-K for the year ended December 31, 2022, management determined that a material weakness existed related to our review control over the completeness and accuracy of information used when calculating stock-based compensation expense, which resulted in a material error in the unaudited condensed financial statements included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. A material weakness means a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

We have implemented certain aspects of a plan to remediate the material weaknesses in our internal control over financial reporting, including steps to design and implement new controls and expand the review of any potential unrecorded liabilities. We will also need to design and implement additional controls related to the material weaknesses identified above. However, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all, or that we will be able to maintain effective controls and procedures even if we remediate our material weaknesses. If we are unable to successfully remediate our material weaknesses, implement and maintain effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a "non-accelerated filer", our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to future financial statement restatements and require us to incur additional expenses of remediation.

Warrants to purchase common stock issued in our December 2019 and May 2023 public offerings include a right to receive the Black-Scholes value of the unexercised portion of the warrants in the event of a fundamental transaction, which payment could be significant.*

The warrants to purchase shares of common stock issued by us in connection with our December 2019 and May 2023 public offerings provide that, in the event of a "fundamental transaction" that is approved by our board of directors, including, among other things, a merger or consolidation of our company or sale of all or substantially all of our assets, the holders of such warrants have the option to require us to pay to such holders an amount of cash equal to the Black-Scholes value of the warrants. Such amount could be significantly more than the warrant holders would otherwise receive if they were to exercise their warrants and receive the same consideration as the other holders of common stock, which in turn could reduce the consideration that holders of common stock would be concurrently entitled to receive in such fundamental transaction. Any future equity financing we conduct may require us to issue warrants that have a similar feature.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. For example, Delaware law provides that if a corporation has a classified board of directors, stockholders cannot remove any director during his or her term without cause. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- classify our Board of Directors into three classes of equal (or roughly equal) size, with all directors serving for a three-year term and the directors of only one class being elected at each annual meeting of stockholders, so that the terms of the classes of directors are "staggered";
- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- authorize our Board of Directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the Board of Directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our Board of Directors does not approve;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholders meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Because we do not expect to pay cash dividends for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation known as the Tax Cuts and Jobs Act of 2017, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act of 2022 enacted many significant changes to the U.S. tax laws. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

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

Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a cumulative change in its equity ownership by "5-percent shareholders" of greater than 50 percentage points (by value) over a three-year period, the corporation's ability to use its estimated pre-change net operating loss carryforwards and certain other tax attributes (such as research tax credits) to offset its post-change taxable income and taxes, as applicable, may be limited. As of December 31, 2022, we had estimated federal and state net operating loss carryforwards of approximately $91.3 million and $66.8 million, respectively, and estimated federal and California research and development tax credits of approximately $1.0 million and $4.0 million, respectively, which could be limited if we have experienced or do experience any "ownership changes." We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future. We believe, however, that multiple ownership changes have likely occurred. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We have estimated that the use of our net operating loss is limited and the amounts above remain fully offset by a valuation allowance.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because early-stage life sciences companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

General economic or business conditions may have a negative impact on our business.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in increased unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the ongoing Russia-Ukraine conflict, high interest rights, inflation and recent bank failures have created extreme volatility in the global capital markets and may have further global economic consequences. Continuing concerns over United States health care reform legislation have also contributed to increased volatility. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The Nasdaq Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations includes significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly, and increases demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in

continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed below are hereby filed with the SEC as part of this Quarterly Report on Form 10-Q.

Exhibit No.	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation, as amended by a Certificate of Amendment thereto (incorporated by reference to Exhibit 3.1.4 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 14, 2014).
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2016).
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on July 6, 2018).
3.4	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 4, 2020).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 13, 2018).
3.6	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 16, 2023).
3.7	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
3.8	Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2017).
3.9	Second Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2022).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8 and 3.9.
4.2	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.13 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-271355), filed with the SEC on May 19, 2023).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.14 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-271355), filed with the SEC on May 15, 2023).
10.1	Purchase Agreement, dated April 10, 2023, by and between Biocept, Inc. and the purchaser named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 10, 2023).
31.1	Certification of Principal Executive and Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive and Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
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 (formatted as inline XBRL and contained in Exhibit 101)

* This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

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.

BIOCEPT, INC.

Date: August 14, 2023

By: /s/ Antonino Morales
Antonino Morales
President and Chief Executive Officer
(Principal Executive and Financial Officer)

Date: August 14, 2023

By: /s/ Robert Walsh
Robert Walsh
Vice President and Controller
(Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Antonino Morales, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biocept, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my 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 my 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. I have disclosed, based on my 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: August 14, 2023

/s/ Antonino Morales

Antonino Morales
President and Chief Executive Officer
(Principal Executive and Financial Officer)

EXHIBIT 32.1

CERTIFICATION

I, Antonino Morales, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that, to my knowledge, the Quarterly Report on Form 10-Q of Biocept, Inc. for the period ended June 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: August 14, 2023

/s/ Antonino Morales

Antonino Morales
President and Chief Executive Officer
(Principal Executive and Financial Officer)

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.