

**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 September 30, 2021

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
(State or other jurisdiction of
incorporation or organization)

80-0943522
(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 \$.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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 November 8, 2021, there were 16,842,246 shares of the Registrant's common stock outstanding.

BIOCEPT, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED
September 30, 2021

INDEX

	<u>Page</u>
<u>IMPORTANT NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	3
PART I. <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements</u>	4
<u>Condensed Balance Sheets as of December 31, 2020 and September 30, 2021 (Unaudited)</u>	4
<u>Condensed Statements of Operations and Comprehensive (Loss)/Income for the three and nine months ended September 30, 2020 and 2021 (Unaudited)</u>	5
<u>Condensed Statements of Shareholders' Equity for the three and nine months ended September 30, 2020 and 2021 (unaudited)</u>	6
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2020 and 2021 (Unaudited)</u>	8
<u>Notes to Condensed Financial Statements (Unaudited)</u>	10
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	38
Item 4. <u>Controls and Procedures</u>	38
PART II. <u>OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	39
Item 1A. <u>Risk Factors</u>	39
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	69
Item 3. <u>Defaults Upon Senior Securities</u>	69
Item 4. <u>Mine Safety Disclosures</u>	69
Item 5. <u>Other Information</u>	69
Item 6. <u>Exhibits</u>	70

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” or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements.

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 our other filings with the Securities and Exchange Commission, or the SEC. 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

	December 31, 2020	September 30, 2021 (unaudited)
Current assets:		
Cash	\$ 14,367,942	\$ 27,698,334
Accounts receivable, net	14,144,911	15,972,256
Inventories, net	1,929,624	2,898,325
Prepaid expenses and other current assets	2,151,527	686,330
Total current assets	32,594,004	47,255,245
Fixed assets, net		
Lease right-of-use assets - operating	9,776,349	9,150,254
Lease right-of-use assets - finance	2,337,709	2,949,959
Other non-current assets	425,908	438,776
Total assets	\$ 47,451,586	\$ 61,946,040
Current liabilities:		
Accounts payable	\$ 8,364,858	\$ 6,087,085
Accrued liabilities	3,165,669	2,584,015
Current portion of lease liabilities - operating	—	404,466
Current portion of lease liabilities - finance	963,726	1,119,178
Supplier financings	—	209,164
Total current liabilities	12,494,253	10,403,908
Non-current portion of lease liabilities - operating	9,805,361	9,856,655
Non-current portion of lease liabilities - finance	1,459,550	1,629,793
Total liabilities	23,759,164	21,890,356
Commitments and contingencies (see Note 10)		
Shareholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 authorized; 2,111 shares issued and outstanding at December 31, 2020 and September 30, 2021.	—	—
Common stock, \$0.0001 par value, 150,000,000 authorized; 13,397,041 issued and outstanding at December 31, 2020; 16,668,937 issued and outstanding at September 30, 2021.	1,340	1,667
Additional paid-in capital	287,217,949	302,382,024
Accumulated deficit	(263,526,867)	(262,328,007)
Total shareholders' equity	23,692,422	40,055,684
Total liabilities and shareholders' equity	\$ 47,451,586	\$ 61,946,040

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

Biocept, Inc.

**Condensed Statements of Operations and Comprehensive (Loss)/Income
(Unaudited)**

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2021	2020	2021
Net revenues	\$ 6,586,144	\$ 17,469,502	\$ 8,950,160	\$ 47,272,859
Costs and expenses:				
Cost of revenues	5,859,370	10,292,299	11,323,668	26,759,975
Research and development expenses	1,087,741	1,302,893	3,989,133	3,483,232
General and administrative expenses	3,023,337	3,434,349	6,839,467	9,805,012
Sales and marketing expenses	1,434,481	1,938,415	4,232,867	5,806,348
Total costs and expenses	11,404,929	16,967,956	26,385,135	45,854,567
(Loss)/income from operations	(4,818,785)	501,546	(17,434,975)	1,418,292
Other expense:				
Interest expense	(59,549)	(74,499)	(171,891)	(219,432)
Warrant inducement expense	—	—	(2,102,109)	—
Total other expense	(59,549)	(74,499)	(2,274,000)	(219,432)
(Loss)/income before income taxes	(4,878,334)	427,047	(19,708,975)	1,198,860
Income tax expense	—	—	—	—
Net (loss)/income and comprehensive (loss)/income	\$ (4,878,334)	\$ 427,047	\$ (19,708,975)	\$ 1,198,860
Deemed dividend related to warrants down round provision	—	—	(2,774)	—
Net (loss)/income attributable to common shareholders	\$ (4,878,334)	\$ 427,047	\$ (19,711,749)	\$ 1,198,860
Weighted-average shares outstanding used in computing net (loss)/income per share attributable to common shareholders:				
Basic	13,333,427	15,384,469	11,324,289	14,089,537
Diluted	13,333,427	15,625,409	11,324,289	14,330,477
Net (loss)/income per common share:				
Basic	\$ (0.37)	\$ 0.03	\$ (1.74)	\$ 0.09
Diluted	\$ (0.37)	\$ 0.03	\$ (1.74)	\$ 0.08

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

Biocept, Inc.

**Condensed Statements of Shareholders' Equity
(Unaudited)**

	Common Stock		Series A Convertible Preferred Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	
Balance at December 31, 2019	5,473,848	\$ 547	2,133	\$ —	\$ 256,917,285	\$ (245,717,189)	\$ 11,200,643
Stock-based compensation expense	—	—	—	—	142,964	—	142,964
Shares issued upon exercise of common stock warrants	696,140	70	—	—	2,306,638	—	2,306,708
Shares issued upon cashless exercise of common stock warrants	608,000	61	—	—	(61)	—	—
Deemed dividends related to warrants downround provision	—	—	—	—	2,774	(2,774)	—
Shares issued for March 2, 2020 financing transaction, net of issuance costs	2,300,000	230	—	—	8,565,270	—	8,565,500
Shares issued for March 4, 2020 financing transaction, net of issuance costs	1,600,000	160	—	—	6,093,401	—	6,093,561
Shares issued for exercise of December 2019 overallotment warrants, net of issuance costs	192,750	19	—	—	659,939	—	659,958
Warrant inducement expense	—	—	—	—	2,102,109	—	2,102,109
Net loss	—	—	—	—	—	(8,341,338)	(8,341,338)
Balance at March 31, 2020	<u>10,870,738</u>	<u>\$ 1,087</u>	<u>2,133</u>	<u>\$ —</u>	<u>\$ 276,790,319</u>	<u>\$ (254,061,301)</u>	<u>\$ 22,730,105</u>
Stock-based compensation expense	—	—	—	—	194,236	—	194,236
Shares issued upon exercise of common stock warrants	20,584	2	—	—	72,606	—	72,608
Shares issued for April 2020 financing transaction, net of issuance costs	2,230,000	223	—	—	9,577,074	—	9,577,297
Net loss	—	—	—	—	—	(6,489,303)	(6,489,303)
Balance at June 30, 2020	<u>13,121,322</u>	<u>1,312</u>	<u>2,133</u>	<u>—</u>	<u>286,634,235</u>	<u>(260,550,604)</u>	<u>26,084,943</u>
Stock-based compensation expense	—	—	—	—	166,730	—	166,730
Shares issued upon exercise of common stock warrants	6,546	1	—	—	22,387	—	22,388
Shares issued upon cashless exercise of common stock warrants	268,772	27	—	—	(27)	—	—
Costs related to previous financings	—	—	—	—	(42,430)	—	(42,430)
Fractional shares adjustment upon one-for-ten reverse stock split	(70)	—	—	—	—	—	—
Net loss	—	—	—	—	—	(4,878,334)	(4,878,334)
Balance at September 30, 2020	<u>13,396,570</u>	<u>\$ 1,340</u>	<u>2,133</u>	<u>\$ —</u>	<u>\$ 286,780,895</u>	<u>\$ (265,428,938)</u>	<u>\$ 21,353,297</u>

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

Biocept, Inc.

**Condensed Statements of Shareholders' Equity
(Unaudited)**

	<u>Common Stock</u>		<u>Series A Convertible Preferred Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-in Capital</u>	<u>Deficit</u>	
Balance at December 31, 2020	13,397,041	\$ 1,340	2,111	\$ —	\$ 287,217,949	\$ (263,526,867)	\$ 23,692,422
Stock-based compensation expense	—	—	—	—	460,201	—	460,201
Shares issued upon exercise of common stock warrants	5,304	—	—	—	18,552	—	18,552
Shares issued upon conversion of preferred stock	23	—	—	—	—	—	—
Shares issued upon exercise of options	194	—	—	—	760	—	760
Net income	—	—	—	—	—	2,599,292	2,599,292
Balance at March 31, 2021	<u>13,402,562</u>	<u>\$ 1,340</u>	<u>2,111</u>	<u>\$ —</u>	<u>\$ 287,697,462</u>	<u>\$ (260,927,575)</u>	<u>\$ 26,771,227</u>
Stock-based compensation expense	—	—	—	—	494,330	—	494,330
Shares issued for ATM transaction, net of issuance costs	908,044	91	—	—	3,913,654	—	3,913,745
Net loss	—	—	—	—	—	(1,827,479)	(1,827,479)
Balance at June 30, 2021	<u>14,310,606</u>	<u>\$ 1,431</u>	<u>2,111</u>	<u>\$ —</u>	<u>\$ 292,105,446</u>	<u>\$ (262,755,054)</u>	<u>\$ 29,351,823</u>
Stock-based compensation expense	—	—	—	—	700,512	—	700,512
Shares issued for ATM transaction, net of issuance costs	2,357,988	236	—	—	9,575,140	—	9,575,376
Shares issued upon exercise of options	343	—	—	—	926	—	926
Net income	—	—	—	—	—	427,047	427,047
Balance at September 30, 2021	<u>16,668,937</u>	<u>\$ 1,667</u>	<u>2,111</u>	<u>\$ —</u>	<u>\$ 302,382,024</u>	<u>\$ (262,328,007)</u>	<u>\$ 40,055,684</u>

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

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

	For the nine months ended September 30,	
	2020	2021
Cash Flows from Operating Activities		
Net (loss)/income	\$ (19,708,975)	\$ 1,198,860
Adjustments to reconcile net income/(loss) to net cash provided by/(used in) operating activities:		
Depreciation and amortization	839,794	1,081,854
Amortization of right-of-use assets	(105,534)	1,110,469
Change in inventory reserve	57,350	(132,721)
Stock-based compensation	503,930	1,655,043
Warrant inducement expense	2,102,109	—
(Gain)/loss on disposal of fixed assets	(1,680)	3,941
Increase/(decrease) in cash resulting from changes in:		
Accounts receivable, net	(4,427,547)	(1,827,345)
Inventory	(2,605,153)	(835,980)
Prepaid expenses and other current assets	165,353	2,087,137
Accounts payable	3,853,736	(1,619,763)
Accrued liabilities	642,516	(581,654)
Other non-current assets	—	(12,868)
Net cash (used in)/provided by operating activities	(18,684,101)	2,126,973
Cash Flows from Investing Activities:		
Purchases of fixed assets	(64,331)	(981,927)
Net cash used in investing activities	(64,331)	(981,927)
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock	24,193,930	13,489,121
Proceeds from exercise of common stock warrants	2,401,704	18,552
Proceeds from exercise of stock options	—	1,686
Proceeds from exercise of overallotment warrants	659,958	—
Payments on finance leases	(518,190)	(911,237)
Payments on supplier and other third-party financings	(432,435)	(412,776)
Net cash provided by financing activities	26,304,967	12,185,346
Net increase in Cash	7,556,535	13,330,392
Cash at Beginning of Period	9,301,406	14,367,942
Cash at End of Period	<u>\$ 16,857,941</u>	<u>\$ 27,698,334</u>
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	<u>\$ 171,891</u>	<u>\$ 219,432</u>
Income taxes	<u>\$ —</u>	<u>\$ —</u>

Non-cash Investing and Financing Activities:

During the nine months ended September 30, 2020 and 2021, Biocept, Inc., or the Company, financed insurance premiums of approximately \$567,000 and \$622,000, respectively, through third-party financings.

Fixed assets purchased totaling approximately \$1,073,000 and \$1,237,000 during the nine months ended September 30, 2020 and 2021, respectively, were recorded as finance lease obligations and were excluded from cash purchases in the Company's statements of cash flows (see Note 6).

The amount of unpaid fixed assets excluded from cash purchases in the Company's statements of cash flows were approximately \$173,000 at September 30, 2020 and \$147,000 at September 30, 2021.

In January 2020, the Company issued an aggregate of 692,725 shares of its common stock pursuant to the exercise of certain warrants issued by the Company in February 2019 and March 2019, as part of a warrant repricing and exchange transaction. As part of the warrant repricing and exchange transaction, the Company issued an aggregate of 692,725 new warrants in exchange for the exercise of the February 2019 and March 2019 warrants and received net proceeds of approximately \$2.3 million. As a result of the warrant repricing, the exercise price of warrants to purchase an aggregate of 89,657 shares of common stock issued by the Company in January 2018 was adjusted from \$4.05 to \$3.495 per share.

In June 2020, the Company entered into an amendment of its facility lease relating to its current facility in San Diego, California to extend the term of the lease originally set to expire in July 2020 to November 2020. Pursuant to the extension of the lease term, the Company recorded an additional lease right-of-use asset and lease liability of \$482,000 (see Note 6).

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

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. The Company, Business Activities and Basis of Presentation**The Company and Business Activities**

The Company was founded in California in May 1997 and is a molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, 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 in order 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 blood, have the potential to provide more contemporaneous information on the characteristics of a patient's disease when compared with tissue biopsy and radiographic imaging. Additionally, commencing in October 2017, the Company's pathology partnership program, branded as Empower TC™, provides the unique ability for pathologists to participate in the interpretation of liquid biopsy results and is available to pathology practices and hospital systems throughout the United States. Further, sales to laboratory supply distributors of the Company's proprietary blood collection tubes commenced in June 2018, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world.

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 may perform 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 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.

The COVID-19 pandemic continues to evolve, and the extent to which COVID-19 may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, the emergence and impact of variants, vaccinations, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. While the Company experienced increased revenue levels in 2020 and the first three quarters of 2021 related to its COVID-19 testing business and attained net income for the first time in its operating history in the fourth quarter in 2020, and again in the first and third quarters of 2021, these results are not expected to be indicative of future results.

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 GAAP, and 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 condensed financial statements are unaudited and 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, 2020 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, 2020, filed with the U.S. Securities and Exchange Commission, or SEC, with our Annual Report on Form 10-K on March 31, 2021 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 September 3, 2020, pursuant to the approval of the Company's board of directors, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's outstanding common stock using a ratio of one-for-ten. As such, all references to share and per share amounts in these financial statements and accompanying notes have

been retroactively restated to reflect the one-for-ten reverse stock split, except for the authorized number of shares of the Company's common stock of 150,000,000 shares, which was not affected by the one-for-ten reverse stock split.

A novel strain of coronavirus, or COVID-19, continues to spread and severely impact the economy of the United States and other countries around the world. Since March 2020, federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers closing or severely curtailing their operations (voluntarily or in response to government orders), and the adoption of work-from-home policies, all of which have had, and the Company believes will continue to have, an impact on the Company's results of operations, financial position, and cash flows. Additionally, beginning during the second quarter of 2020, the Company experienced growing demand for COVID-19 molecular and antibody testing services and has expanded its capacity in order to satisfy such demand. As a result, operating results for the three and nine months ended September 30, 2021 may not be indicative of the results that may be expected for the full year or in the future.

Significant Accounting Policies

During the three and nine months ended September 30, 2021, 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, 2020.

Revenue Recognition and Accounts Receivable

The Company's commercial revenues are generated from diagnostic services provided to patient's physicians and billed to third-party insurance payers 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 payer 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 payers, 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 payer 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, 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, are subject to estimated deductions for such allowances and reserves 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 implied variability is due to several factors, such as the payment history or lack thereof for third-party payers, reimbursement rate changes for contracted and non-contracted payers, any patient co-payments, deductibles or compliance incentives, the existence of secondary payers and claim denials. The Company estimates the amount of variable consideration using the most likely amount approach to estimating variable consideration for third-party payers, including direct patient bills, whereby the estimated reimbursement for services are established by payment histories on CPT codes for each payer, or similar payer types. When no payment history is available, the value of the account is estimated at Medicare rates, with additional other payer-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 payer, among other variables. The estimates of amounts that will ultimately be realized from commercial diagnostic services for non-contracted payers 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 variable consideration 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, provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized. Further, although the Company believes that its estimate for contractual allowances and other reserves is appropriate, it is possible that the Company will experience an impact on cash collections as a result of the impact of the COVID-19 pandemic.

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, which are recorded within sales and marketing expenses.

The Company incurs certain other costs that are incurred 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 nine months ended September 30, 2020 and 2021, disaggregated by source and nature, are as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2021	2020	2021
Net revenues from contracted payers*	\$ 3,219,233	\$ 11,280,152	\$ 3,981,041	\$ 24,514,351
Net revenues from non-contracted payers	3,166,101	6,084,183	4,562,909	22,484,286
Development services revenues	46,500	34,091	145,282	106,806
Kits and Blood Collection Tubes (BCT) and other revenues	154,310	71,076	260,928	167,416
Total net revenues	\$ 6,586,144	\$ 17,469,502	\$ 8,950,160	\$ 47,272,859

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

Revenues for the three and nine months ended September 30, 2021 included \$17.5 million and \$47.2 million, respectively, in commercial test revenues, including \$16.5 million and \$45.5 million of revenues attributable to RT-PCR COVID-19 testing. In addition, during the nine months ended September 30, 2021, the Company recorded approximately \$1.1 million in additional reserves related to aged account receivable balances, which is reflected as a reduction to net revenues.

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2021	2020	2021
Net commercial revenues recognized upon delivery	\$ 6,385,334	\$ 17,364,335	\$ 8,543,950	\$ 46,998,637
Development services revenues recognized upon delivery	46,500	34,091	145,282	106,806
Kits and Blood Collection Tubes (BCT) and other revenues	154,310	71,076	260,928	167,416
Total net revenues	\$ 6,586,144	\$ 17,469,502	\$ 8,950,160	\$ 47,272,859

At December 31, 2020 and September 30, 2021, unbilled account receivables total approximately \$4.5 million and \$4.6 million, respectively.

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 payers of the Company's services such as Medicare, insurance companies, and other third-party payers. The Company's client base consists of many geographically dispersed clients diversified across various customer types.

The Company's third-party payers that represent more than 10% of total net revenues in any period presented, as well as their related net revenue amount as a percentage of total net revenues, during the three and nine months ended September 30, 2020 and 2021 were as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2021	2020	2021
Medicare and Medicare Advantage/CARES Act	32%	62%	32%	51%
Blue Cross Blue Shield	42%	10%	38%	21%

The Company's third-party payers that represent more than 10% of total net accounts receivable, and their related net accounts receivable balance as a percentage of total net accounts receivable, at December 31, 2020 and September 30, 2021 were as follows:

	December 31, 2020	September 30, 2021
Medicare and Medicare Advantage/CARES Act	35%	28%
Blue Cross Blue Shield	24%	20%

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, "Credit Losses (Topic 326)." ASU 2016-13 requires that financial assets measured at amortized cost, such as trade receivables and investments, be represented net of expected credit losses, which may be estimated based on

relevant information such as historical experience, current conditions, and future expectation for each pool of similar financial asset. The new guidance requires enhanced disclosures related to trade receivables and associated credit losses. In May 2019, the FASB issued ASU No. 2019-05, "Financial Instruments—Credit Losses (Topic 326) Targeted Transition Relief," which allows for a transition election on certain instruments. The guidance is effective for Small Reporting Companies for fiscal years beginning after December 15, 2022 and interim periods in those fiscal years. In November 2019, the FASB issued ASU No. 2019-11 which amends certain aspects of ASU No. 2016-13, including transition relief for trouble debt restructuring, among other topics. The Company is currently evaluating the impact of this pronouncement on its financial statements.

2. Liquidity

As of September 30, 2021, cash totaled \$27.7 million and the Company had an accumulated deficit of \$262.3 million. For the year ended December 31, 2020 and the nine months ended September 30, 2021, the Company incurred a net loss and net income of \$17.8 million and \$1.2 million, respectively, and had negative cash flows and cash generated from operations of \$19.8 million and \$2.1 million, respectively. At September 30, 2021, the Company had aggregate net interest-bearing indebtedness of \$3.0 million, of which \$1.3 million was due within one year, in addition to \$2.6 million of other non-interest-bearing current liabilities. The Company has historically funded its operations through sales of its equity securities.

The COVID-19 testing revenue during 2020 and through the third quarter of 2021, has provided the Company with increased levels of cash inflows from operations, and it is expected to continue, albeit at lower and declining levels, throughout at least the next twelve months. As a result, the Company believes that based on its current and planned cash usage, along with current COVID-19 testing revenues, its cash balances will support operations through the fourth quarter of 2022. As such, the Company determined that it is not probable based on projected cash flows that substantial doubt about the Company's ability to continue as a going concern exists for the one-year period following the date that the financial statements for the three and nine months ended September 30, 2021 were issued. The Company's determination was based on estimates regarding expected COVID-19 testing volumes, which are uncertain and subject to change as more individuals are expected to be vaccinated and as the pandemic subsides. The Company used all information currently available to make this determination.

Historically, the Company's principal sources of cash have included proceeds from the issuance of common and preferred stock, proceeds from the exercise of warrants to purchase common stock, proceeds from the issuance of debt, and revenues from laboratory services. The Company's principal uses of cash have included cash used in operations, payments relating to purchases of property and equipment and repayments of borrowings. The Company expects that the principal uses of cash in the future will be for continuing operations, hiring of sales and marketing personnel and increased sales and marketing activities, funding of research and development, capital expenditures, and general working capital requirements. The Company expects that, as revenues grow, sales and marketing and research and development expenses will continue to grow, albeit at a slower rate and, as a result, the Company will need to generate significant growth in net revenues to achieve and sustain income from operations.

In order to meet its long-term operating requirements beyond the next twelve months, the Company will need, among other things, additional capital resources. Until the Company can generate significant cash from operations, including assay revenues, management's plans to obtain such resources for the Company include proceeds from offerings of the Company's equity securities or debt, cash received from the exercise of outstanding common stock warrants, or transactions involving product development, technology licensing or collaboration. The Company cannot provide any assurances that such additional funds will be available on reasonable terms, or at all.

During the nine months ended September 30, 2021, the Company received net cash proceeds of approximately \$13.5 million from the sales of 3,266,032 shares of common stock at a weighted average sale price of \$4.32 per share, using the Company's at-the-market equity facility initiated in May 2021.

3. Sales of Equity Securities

In January 2020, the Company issued an aggregate of 692,725 shares of its common stock pursuant to the exercise of certain warrants issued by the Company in February 2019 and March 2019, as part of a warrant repricing and exchange transaction. As part of the warrant repricing and exchange transaction, the Company issued an aggregate of 692,725 new warrants in exchange for the exercise of the February 2019 and March 2019 warrants and received net proceeds of approximately \$2.3 million. As a result of the warrant repricing, the exercise price of warrants to purchase an aggregate of 89,657 shares of common stock issued by the Company in January 2018 was adjusted from \$4.05 to \$3.495 per share. In January 2020, the Company issued 192,750 shares of common stock pursuant to the partial exercise of the underwriters' overallotment option from the Company's December 2019 public offering. The net proceeds to the Company from the overallotment closing, was approximately \$700,000. The warrants issued in connection with the warrant repricing and exchange transaction were considered inducement warrants and are classified in equity. In addition, the modification expense associated with the change in fair value due to the repricing of February and March 2019 warrants is recorded as inducement expense, which was approximately \$191,000. The fair value of the warrants issued was approximately \$1.9 million. The fair value of the inducement warrants and warrant modification of \$2.1 million was expensed as warrant inducement expense in the accompanying condensed statements of operations for the nine months ended September 30, 2020.

On March 2, 2020, the Company sold and issued 2,300,000 shares of its common stock at a negotiated purchase price of \$4.00 per share in a registered direct offering and received net cash proceeds of approximately \$8.6 million after deducting placement agent fees and other expenses.

On March 4, 2020, the Company sold and issued 1,600,000 shares of its common stock at a negotiated purchase price of \$4.10 per share in a registered direct offering and received net cash proceeds of approximately \$6.1 million after deducting placement agent fees and other expenses.

On April 16, 2020, the Company sold and issued 2,230,000 shares of its common stock at a negotiated purchase price of \$4.60 per share in a registered direct offering and received net cash proceeds of approximately \$9.6 million after deducting placement agent fees and other expenses.

On May 12, 2021, the Company entered into a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Sales Agent"), under which the Company may issue and sell from time to time up to \$25,000,000 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 the Company's shelf registration statement on Form S-3, filed with the Securities and Exchange Commission on April 24, 2020. 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" 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 the Company at any time upon ten days' notice. The Sales Agent may terminate the Sales Agreement 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 nine months ended September 30, 2021, the Company sold and issued 3,266,032 shares of its common stock at a weighted average purchase price of \$4.32 under the Sales Agreement and received net cash proceeds of approximately \$13.5 million after deducting sales agent commissions and other offering costs.

4. Fair Value Measurement

The estimated nonrecurring fair value measurements associated with fixed asset purchases recorded as right-of-use asset finance lease obligations totaling approximately \$1,237,000 during the nine months ended September 30, 2021 were calculated as the present value of the lease payments based on contractual payment amounts and estimated market rates. Upon adoption of guidance in ASC Topic 842 Leases, the estimated fair value of the right-of-use operating lease asset was recorded based on the present value of future lease payments based on contractual payment amounts and estimated market rates in effect.

Other Fair Value Measurements

As of the closing of the Company's January 2020 warrant repricing and exchange transaction, the estimated grant date fair value of approximately \$2.80 per share associated with the warrants to purchase up to 692,725 shares of common stock issued in the transaction, or a total of approximately \$1.9 million, was recorded as a warrant inducement expense with an offset to additional paid-in capital. All warrants issued in this warrant inducement transaction have an exercise price of \$3.495 per share, became exercisable beginning 6 months from issuance and expire 5.5 years from the date of issuance. The fair value of the warrants was estimated using a Black-Scholes model with the following assumptions:

Beginning stock price	\$	3.00
Exercise price	\$	3.495
Expected dividend yield		0.00%
Discount rate-bond equivalent yield		1.66%
Expected life (in years)		5.50
Expected volatility		150.33%

In addition to the inducement warrants issued in the Company's January 2020 warrant repricing and exchange transaction, the Company adjusted the exercise prices of the February 2019 and March 2019 warrants from \$12.00 and \$12.50, respectively, to \$3.495 to induce exercise of these warrants. This price modification triggered the requirement for modification accounting of these warrants. Based on the applicable guidance, the modification required the Company to value the modified February 2019 and March 2019 warrants immediately prior to the modification of the exercise price and immediately following the modification and record the difference between the resulting two values as warrant inducement expense.

The estimated fair value prior to modification of the February 2019 and March 2019 warrants was approximately \$2.70 per share, whereas the estimated fair value of the February 2019 warrants increased to \$2.90 due to the adjustment of the exercise price, and the estimated fair value of the March 2019 warrants increased to \$3.00 per share. There were 216,725 February 2019 warrants and 476,000 March 2019 warrants eligible for this price modification and the resulting modification expense recorded as warrant inducement expenses were \$60,000 and \$130,000, respectively.

5. Balance Sheet Details

The following provides certain balance sheet details:

	December 31, 2020	September 30, 2021
Inventories		
Raw materials	1,235,620	2,102,132
Subassemblies	691,126	769,302
Finished goods	2,878	26,891
	<u>\$ 1,929,624</u>	<u>\$ 2,898,325</u>
Fixed Assets		
Machinery and equipment	\$ 2,974,320	\$ 3,051,018
Furniture and office equipment	156,987	160,542
Computer equipment and software	2,428,211	2,806,961
Leasehold improvements	570,173	543,987
Construction in process	761,221	38,229
Total fixed assets, gross	6,890,912	6,600,737
Less accumulated depreciation and amortization	(4,573,296)	(4,448,931)
Total fixed assets, net	<u>\$ 2,317,616</u>	<u>\$ 2,151,806</u>
Accrued Liabilities		
Accrued payroll	452,118	267,610
Accrued vacation	868,557	972,817
Accrued bonuses	1,022,421	900,902
Accrued sales commissions	456,526	170,000
Accrued other	366,047	272,686
Total accrued liabilities	<u>\$ 3,165,669</u>	<u>\$ 2,584,015</u>

6. Leases

Effective January 1, 2019, the Company adopted US GAAP accounting rules in ASC Topic 842, Leases (ASC 842), using the modified retrospective method. The Company elected to follow the package of practical expedients provided under the transition guidance within ASC 842, and accordingly, did not reassess whether any expired or existing contracts are or contain leases, did not reassess expired or existing leases, and did not reassess initial direct costs for any existing leases. Upon adoption, the Company recorded an operating lease right-of-use asset and an operating lease liability on the balance sheet. In addition, assets under equipment leases previously classified as capital leases within Fixed Assets on the Company's balance sheet were reclassified to finance lease right-of-use assets upon adoption of the guidance. Right-of-use assets and obligations were recognized based on the present value of remaining lease payments over the lease term. As the Company's operating lease does not provide an implicit rate, an estimated incremental borrowing rate was used based on the information available at the adoption date in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term. Variable lease costs such as common area costs and other operating costs are expensed as incurred. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

Finance Leases

The Company leases certain laboratory equipment under arrangements previously accounted for as capital leases, classified on the Company's balance sheet as fixed assets and related lease liabilities and depreciated on a straight-line basis over the lease term. Upon adoption of ASC 842, leased equipment previously classified as fixed assets totaling \$1.4 million in net book value were reclassified to lease right-of-use assets in accordance with the guidance. The equipment under finance leases is depreciated on a straight-line basis over periods ranging from approximately 3 to 7 years. The total gross value of equipment capitalized under such lease arrangements was approximately \$4,639,000 and \$5,876,000 at December 31, 2020 and September 30, 2021, respectively. Total accumulated depreciation related to equipment under finance leases was approximately \$2,302,000 and \$2,927,000 at December 31, 2020 and September 30, 2021, respectively. Total depreciation expense related to equipment under finance leases during the three months ended September 30, 2020 and 2021 was approximately \$267,000 and \$243,000, respectively, and during the nine months ended September 30, 2020 and 2021 was approximately \$541,000 and \$625,000, respectively.

During the nine months ended September 30, 2020, the Company entered into finance leases for a total capitalized amount of \$1,072,000 for laboratory equipment and software. Under the terms of the financing agreements, which were accounted for as finance lease transactions, the principal balance plus interest for the equipment are to be paid in installments ranging from 12 to 60 monthly installments of approximately \$36,322 totaling approximately \$1,360,000 through July 2025.

During the nine months ended September 30, 2021, the Company entered into finance leases for a total capitalized amount of \$1,237,000 for seven pieces of equipment. Under the terms of the financing agreements, which were accounted for as finance lease transactions, the principal balance plus interest for the equipment are to be paid in installments ranging from 36 to 60 monthly installments of \$31,544 totaling approximately \$1,453,000 through March 2026.

Operating Lease

The Company leases its primary laboratory and office facilities in San Diego, California. In accordance with the ASC 842 guidance, the facility lease is classified as an operating lease. From its inception until December 2020, the Company's primary facilities were located at 5810 Nancy Ridge Road in San Diego, California (Nancy Ridge Facility) and subject to a lease agreement dated March 31, 2004. The average monthly cash payment for the operating lease was approximately \$120,000 per month, and the lease term expired on July 31, 2020, but was extended as stated below. The Company recorded a lease right-of-use asset and lease liability of \$1,930,000 and \$2,201,000, respectively, as of January 1, 2019, based on present value of payments and an incremental borrowing rate of 4.5%.

On June 5, 2020, the Company entered into a fifth amendment (the "Amendment") to its lease agreement relating to the Nancy Ridge Facility. Pursuant to the Amendment, the expiration date of the lease was extended from July 31, 2020 to November 30, 2020. The monthly base rent during the extended term was the then-current monthly rate paid by the Company. The Company agreed to pay additional rent and all other charges as set forth in the lease through the expiration date. Pursuant to the extension of the expiration date of the lease, the Company recorded an additional lease right-of-use asset and lease liability of \$482,000. In order to allow the Company adequate time to move its operations to its new facility, the Company entered into an additional extension related to the facility extending the lease until December 11, 2020 at the prorated amount of the then-current rent.

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 lease includes a rent abatement period of seven months, from January 2021 through July of 2021, during which period the Company is exempted from paying the amount of base rent of \$111,000. In addition, the lease stipulates an additional two months of lease abatement period in the event that the property is sold within the first six months of the initial lease period. In March 2021, the Company was notified that the original landlord has sold the building, hence the Company is eligible for an additional two months of rent abatement period. In addition, the landlord agreed to pay for certain preapproved leasehold improvement costs through a one-time leasehold improvement allowance of approximately \$1,586,000, and an additional leasehold improvement allowance of approximately \$1,586,000. The amount of additional leasehold improvement allowance of approximately \$1,586,000 is to be paid back to the landlord during the term of the lease by the Company, amortized at an agreed upon annual rate of 7% as an additional rent payment of approximately \$18,000 per month. The average monthly cash payment including payment for the additional leasehold improvement allowance for the lease is approximately \$140,000 per month with initial monthly lease payments of \$128,000 per month. The Company recorded a lease right-of-use asset and lease liability of \$9,776,000 and \$9,805,000, respectively, as of December 31, 2020, based on the present value of payments and an incremental borrowing rate of 12%. As the Company's lease did not provide an implicit rate, the Company estimated the incremental borrowing rate based on the credit quality of the Company and by comparing interest rates available in the market for similar borrowings. The Company recorded \$1,631,000 in other current assets related to reimbursable leasehold improvement costs incurred as of December 31, 2020. All reimbursable leasehold improvement costs were reimbursed by the landlord as of September 30, 2021.

In addition, the Company reviews agreements at inception to determine if they include a lease, and when they do, uses its incremental borrowing rate or implicit interest rate to determine the present value of the future lease payments.

The following schedule sets forth the components of right-of-use lease assets as of December 31, 2020 and September 30, 2021 as follows:

	December 31, 2020	September 30, 2021
Lease right-of-use assets:		
Operating	\$ 9,776,349	\$ 9,150,254
Finance	2,337,709	2,949,959
Total	<u>\$ 12,114,058</u>	<u>\$ 12,100,213</u>

The following schedule sets forth the current portion of operating and finance lease liabilities as of December 31, 2020 and September 30, 2021:

	December 31, 2020	September 30, 2021
Current portion of lease liability:		
Operating	\$ —	404,466
Finance	963,726	1,119,178
Total	<u>\$ 963,726</u>	<u>\$ 1,523,644</u>

The following schedule sets forth the long-term portion of operating and finance lease liabilities as of December 31, 2020 and September 30, 2021:

	December 31, 2020	September 30, 2021
Long-term portion of lease liability:		
Operating	\$ 9,805,361	\$ 9,856,655
Finance	1,459,550	1,629,793
Total	<u>\$ 11,264,911</u>	<u>\$ 11,486,448</u>

The following schedule represents the components of lease expense for the three and nine months ended September 30, 2020 and 2021:

	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2021	2020	2021
Lease cost				
Finance lease cost				
Amortization of right-of-use assets	\$ 266,747	\$ 243,176	\$ 540,853	\$ 624,682
Interest on lease liabilities	56,372	71,397	164,044	211,389
Operating lease cost	357,914	414,384	993,924	1,243,570
Total	<u>\$ 681,033</u>	<u>\$ 728,957</u>	<u>\$ 1,698,821</u>	<u>\$ 2,079,641</u>

The following schedule sets forth the remaining future minimum lease payments outstanding under finance and operating leases, as well as corresponding remaining sales tax and maintenance obligation payments that are expensed as incurred and due within each respective year ending December 31, as well as the present value of the total amount of the remaining minimum lease payments, as of September 30, 2021:

	Finance		Operating
	Minimum Lease Payments	Maintenance and Sales Tax Obligation Payments	Minimum Lease Payments
2021 (remaining)	\$ 307,921	29,477	389,317
2022	1,143,530	111,077	1,586,210
2023	996,396	94,926	1,629,025
2024	538,635	61,564	1,671,841
Thereafter	209,368	16,184	11,995,434
Total payments	3,195,850	313,228	17,271,827
Less amount representing interest	(446,879)	—	(7,010,706)
Present value of payments	<u>\$ 2,748,971</u>	<u>\$ 313,228</u>	<u>\$ 10,261,121</u>

The following schedule sets forth supplemental cash flow information related to operating and finance leases as of September 30, 2021:

	2020	2021
Other information		
Operating cash flows from financing leases	\$ 164,044	\$ 211,389
Operating cash flows from operating leases	\$ 1,099,460	\$ 159,409
Financing cash flows from finance leases	\$ 518,190	\$ 911,237

The aggregate weighted average remaining lease term was 2.91 years on finance leases and 9.67 years on operating leases as of September 30, 2021. The aggregate weighted average discount rate was 18.21% on finance leases and 12.0% on operating leases as of September 30, 2021. During the nine months ended September 30, 2021, the Company added \$1,237,000 of right of use assets in exchange for finance lease liabilities.

7. Stock-Based Compensation

Equity Incentive Plans

The Company maintains the Biocept, Inc. Amended and Restated 2013 Equity Incentive Plan, which is a successor to the 2007 Equity Incentive Plan, or 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. As of September 30, 2021, 762,421 shares of the Company's common stock were authorized exclusively for the issuance of stock awards to employees who have not previously been an employee or director of the Company, except following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company, as defined under applicable Nasdaq Listing Rules.

As of September 30, 2021, under all plans, a total of 2,336,409 non-inducement shares were authorized for issuance, 1,903,706 shares had been issued with 1,935,820 non-inducement stock options and restricted stock units, or RSUs, underlying outstanding awards, and 354,090 non-inducement shares were available for grant. As of September 30, 2021, 761,836 inducement shares were authorized for issuance, 634,262 inducement shares had been issued under the 2013 Plan, with 597,342 inducement stock options and RSUs underlying outstanding awards and 164,410 inducement shares available for grant under the 2013 Plan.

Stock Options

A summary of stock option activity for the nine months ended September 30, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term in Years
Outstanding at December 31, 2020	1,078,704	\$ 11.64	9.36
Granted	1,558,510	\$ 3.96	
Exercised	(537)	\$ 3.14	
Cancelled/forfeited/expired	(103,515)	\$ 12.46	
Outstanding at September 30, 2021	<u>2,533,162</u>	\$ 6.90	9.39
Vested and unvested expected to vest at September 30, 2021	<u>2,466,880</u>	\$ 6.98	9.39

The intrinsic values of options outstanding, options exercisable, and options vested and unvested expected to vest at December 31, 2020 and September 30, 2021 were each \$4,714 and \$11,074, respectively.

The assumptions used in the Black-Scholes pricing model for stock options granted during the nine months ended September 30, 2021 were as follows:

Stock and exercise prices	\$3.62 - \$6.03
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	0.52% - 1.15%
Expected life (in years)	5.00 - 5.98
Expected volatility	163.1% - 173.9%

Restricted Stock

A summary of RSU activity for the nine months ended September 30, 2021 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	36	\$ 4,158
Granted	—	—
Vested and issued	—	—
Forfeited	—	—
Outstanding at September 30, 2021	36	\$ 4,158
Vested and unvested expected to vest at September 30, 2021	36	\$ 4,158

At September 30, 2021, the intrinsic values of RSUs outstanding and RSUs unvested and expected to vest were each approximately \$144. Of the 36 RSUs outstanding at September 30, 2021, all were fully vested.

Stock-based Compensation Expense

The following table presents the effects of stock-based compensation related to equity awards to employees and nonemployees on the unaudited condensed statements of operations and comprehensive loss during the periods presented:

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2020	2021	2020	2021
<u>Stock Options</u>				
Cost of revenues	\$ 25,352	\$ 184,469	\$ 78,917	\$ 391,324
Research and development expenses	25,397	67,539	78,914	161,626
General and administrative expenses	92,472	343,940	290,231	865,753
Sales and marketing expenses	23,509	104,564	55,868	236,340
Total expenses related to stock options	\$ 166,730	\$ 700,512	\$ 503,930	\$ 1,655,043

As of September 30, 2021, total unrecognized share-based compensation expense related to unvested stock options and RSUs, adjusted for estimated forfeitures, was \$8,368,879 and is expected to be recognized over a weighted-average period of approximately 2.71 years.

8. Common Stock Warrants Outstanding

A summary of equity-classified common stock warrant activity for the nine months ended September 30, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2020	997,167	\$ 35.48	3.3
Issued	—	—	
Exercised	(5,304)	3.50	
Expired	(3,877)	1,170.00	
Outstanding at September 30, 2021	987,986	\$ 31.20	2.6

All warrants outstanding at December 31, 2020 and September 30, 2021 are exercisable.

Warrants issued in the February 2019 financing transaction have an expiration date of February 12, 2024, warrants issued in the March 2019 transaction have an expiration date of September 19, 2024, warrants issued in the May 2019 inducement offering have an expiration date of December 2, 2024, warrants issued in December 2019 have an expiration date of December 11, 2024, and warrants issued in the January 2020 inducement offering have an expiration date of July 10, 2025.

During the nine months ended September 30, 2020, holders exercised their warrants in cashless exercise transactions for 876,772 shares of the Company's common stock. The intrinsic value of equity-classified common stock warrants outstanding at December 31, 2020 and September 30, 2021 was \$243,000 and \$128,000, respectively.

9. Net Loss per Common Share

Basic and diluted net income (loss) per common share is determined by dividing net loss applicable to common shareholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common shareholders for the three and nine months ended September 30, 2020, 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. For the three and nine months ended September 30, 2021, there is net income attributable to common shareholders and, as a result, 247,761 warrants and 27,762 options in the money were included in the calculation of dilutive weighted average shares. As these shares were in the money at September 30, 2021, an additional 240,940 shares were included in the calculation of diluted net income per share.

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 three and nine months ended	
	September 30,	
	2020	2021
Common warrants outstanding	997,171	987,986
RSUs outstanding	36	36
Convertible preferred stock outstanding (number of common stock equivalents)	47,139	46,651
Common options outstanding	254,356	2,533,162
Total anti-dilutive common share equivalents	<u>1,298,702</u>	<u>3,567,835</u>

10. 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 that are expected to have a material adverse effect on its financial condition, results of operations or liquidity.

We are currently in discussions with a former employee and certain current employees regarding disputed claims for certain sales commissions. We are not in agreement with their interpretations or claims and are unable to predict the outcome of this matter. In addition, at this time we cannot reasonably estimate any amount or range of potential expense associated with this matter.

During the three months ended September 30, 2020 and 2021, total expense recorded in the Company's unaudited condensed statements of operations and comprehensive income/loss for sales tax and maintenance obligations associated with equipment financing arrangements was approximately \$29,000 and \$41,000, respectively, with approximately \$111,000 and \$127,000 recorded during the nine months ended September 30, 2020 and 2021, respectively. At December 31, 2020 and September 30, 2021, approximately \$75,000 and \$80,000, respectively, of such sales tax and maintenance obligations incurred but not paid were recorded in accrued other liabilities in the Company's balance sheet (see Note 5). Future amounts totaling \$313,228 for sales tax and maintenance obligations associated with financed equipment were due under equipment financing arrangements at September 30, 2021, which will be expensed as incurred (see Note 6).

11. Related Party Transactions

A 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. The Company received payments totaling approximately \$26,000 and \$36,000 during the years ended December 31, 2019 and 2020, respectively, from Aegea as reimbursements for shared patent costs under the Cross-License Agreement. 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. 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 December 31, 2020 and September 30, 2021, the Company has accrued approximately \$2,900 and \$2,900 for royalty expenses, respectively, related to this arrangement. On June 3, 2020, the Company entered into a development agreement with Aegea focused on the co-development by Biocept and Aegea of a highly sensitive PCR-based assay designed by Aegea for detecting the COVID-19 virus. Pursuant to the agreement, the Company will receive compensation for development services performed based on time and materials expended. During the three and nine months ended September 30, 2021, the Company recorded development service revenues of approximately \$7,500 and \$67,000, respectively, and had approximately \$7,500 accounts receivable due from Aegea as of September 30, 2021, related to this

agreement. In February 2021, the Company entered into a supply agreement with Aegea for a new PCR-based COVID-19 assay kit designed by Aegea and co-developed by Aegea and the Company. Under the agreement, Aegea will supply the COVID-19 assay kit to the Company for validation in its CLIA-certified, CAP-accredited high-complexity molecular lab and subsequent commercialization of a laboratory developed test (LDT). In August 2021, the Company entered into a manufacturing agreement with Aegea. Under the agreement, the Company will manufacture PCR-based molecular assay reagent kits designed by Aegea for detecting the COVID-19 virus. In the three and nine months ended September 30, 2021, there has been no amounts exchanged under either the supply or manufacturing agreements.

12. Subsequent Events

From September 30, 2021 through the issuance of the financial statements, the Company sold 155,000 shares of its common stock at a weighted average purchase price of \$4.08 under the Sales Agreement and received net cash proceeds of approximately \$615,000 after deducting sales agent commissions.

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, 2020 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, 2020, filed with the Securities and Exchange Commission on March 31, 2021. 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 either blood or cerebrospinal fluid (CSF). The identification of circulating tumor cells, or CTCs, and circulating tumor nucleic acid including circulating tumor DNA, or ctDNA, and circulating tumor RNA, or ctRNA, deriving from solid tumors such as breast cancer or lung cancer using a standard blood sample has been described as a “liquid biopsy.”

Effective January 2020, we also adapted and validated this technology for commercial use in cerebrospinal fluid, or CSF, to identify tumor cells that have metastasized to the central nervous system, or CNS, in patients with advanced lung cancer or breast cancer. In April 2021, we rebranded our CSF version of the cell-based Target Selector™ assay as CNSide™. As the blood and CSF compartments are distinct and separate, to distinguish tumor cells derived from these sample types we often refer to tumor cells in CSF as CSF-TCs rather than CTCs.

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.

In June 2020, we entered into a development agreement with Aegea Biotechnologies, Inc., or Aegea, focused on the co-development by us and Aegea of a highly sensitive PCR-based assay designed by Aegea for detecting the COVID-19 virus. Pursuant to the development agreement, we receive compensation for development services performed based on time and materials expended. In February 2021, we entered into a supply agreement with Aegea for the PCR-based COVID-19 assay kit. Under the supply agreement, Aegea will supply the COVID-19 assay kit to us for validation in our high-complexity molecular clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and licensed by the California Department of Public Health, and accredited by the College of American Pathologists, or CAP, and subsequent commercialization of a laboratory developed test, or LDT.

Our current and planned blood and CSF assays are intended to provide information to aid healthcare providers by identifying tumor cells associated with progression or metastasis, and identifying specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy. These assays may also be used for monitoring response to treatment or to identify specific resistance mechanisms.

“Liquid biopsies” are intended to supplement or replace the need for additional invasive surgical tissue biopsies or repeated lumbar punctures to find tumor material (intact cells or tumor derived nucleic acid known as ctDNA and ctRNA) in blood or CSF. Our molecular assays are also designed to help find molecular alterations in situations where tumor tissue or CSF cytology samples are insufficient and/or unable to provide the molecular subtype information necessary for clinical decisions.

Our assays have the potential to provide faster, more contemporaneous information regarding therapy response or the characteristics of a patient’s disease when compared with surgical tissue biopsies which must be scheduled or radiographic imaging which may take a month or more to illustrate progression.

Our current assays and our planned future assays focus on key solid tumor indications utilizing our Target-Selector™ liquid biopsy technology platform for the biomarker analysis of CTCs and ctDNA from a standard blood sample or CSF-TCs and cell-free tumor DNA and RNA from a CSF sample. Our patented Target-Selector™ tumor cell platform assays are based on an internally developed microfluidics-based cell capture and analysis platform, with features that enable quantitative tumor cell counts and molecular assays related to these tumor cells, informing clinicians of changes in response to treatment and biomarkers in tumor cells that can inform physician treatment decisions, particularly as the tumor characteristics may change over time with clinical progression or metastasis.

In addition, our patented Target-Selector™ molecular technology enables detection of mutations and genome alterations with enhanced sensitivity and specificity, and is applicable to a broad range of diagnostic applications including detection of tumor-derived cell-free nucleic acid (ctDNA/RNA), and could potentially be validated for other sample types such as bone marrow, or tissue (surgical resections and/or biopsies).

In January 2019, we began offering research use only, or RUO, liquid biopsy kits containing our patented and proprietary ctDNA Target Selector™ molecular (PCR-based) testing for certain specific cancer genes to laboratories and researchers worldwide. In March 2020 we released an update for our RUO EGFR Target Selector™ Kit which expanded the sample types validated to include both blood and

formalin-fixed paraffin-embedded, or FFPE. In March 2020 we also released a RUO BRAF Target Selector™ validated for both ctDNA and FFPE.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under CLIA, licensed by the California Department of Public Health, and accredited by CAP. At this facility we perform our current assays, and we continue to perform research and development for our planned future assays. In addition, we currently manufacture our microfluidic channels and various chemistries used in our testing process, however, we have identified and have been working with a manufacturer to outsource certain manufacturing activities in the near term 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.

Our primary sales strategy is to engage medical oncologists and other physicians in the United States at private and group practices, hospitals, laboratories and cancer centers. In addition, we market our clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations. We also market and sell molecular assay kits which enable laboratories other than Biocept to perform our testing in house. Sales of these kits began in the first quarter of 2019. Further, sales to laboratory supply distributors of our proprietary blood collection tubes, or BCTs, commenced in June 2018, which allow for the intact transport of liquid biopsy samples for research use only from regions around the world.

Our revenue generating efforts are focused in three areas:

- providing laboratory services to medical oncologists, neuro-oncologists, and other physicians or healthcare providers treating patients with cancer or COVID-19 who use the biomarker information we provide in order to determine the best treatment plan for their patients;
- providing laboratory services using both our CTC and ctDNA and ctRNA assays in order to help pharmaceutical and biopharmaceutical companies run clinical studies establishing the use of novel drug therapies used to treat cancer; and
- licensing our proprietary technology and selling our distributed products, including our BCTs and assay kits, to partners in the United States and abroad.

We plan to grow our business by directly offering our CNSide™ and Target-Selector™ liquid biopsy CTC and molecular assays to medical oncologists, neuro-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.

Following the full commercial launch of our CSF assay, CNSide™, we submitted an initial application for Breakthrough Device Designation to the U.S. Food and Drug Administration (“FDA”). While the initial submission in early 2021 was denied, we continue to pursue options related to a future Breakthrough Device Designation for CNSide™, including pursuit of larger clinical trials that would provide more clinically detailed data to support an FDA filing. The test is currently marketed as a Lab Developed Test in the Company’s CLIA certified and CAP accredited lab. CNSide™ is designed to improve the clinical management of patients with suspected metastatic cancer involving the central nervous system. By comparison, the current “standard of care” diagnostic triad of cytology, radiology and clinical examination has significant limitations of both sensitivity and specificity for identifying brain metastasis and response to therapy.

Furthermore, using our CNSide and Target-Selector assays, cells in CSF or blood can be further interrogated to find various molecular alterations or “biomarkers” that can deliver important, actionable information used for better treatment decisions. These molecular alterations, such as *HER2* amplification, are not readily provided by other clinical tools unless patients undergo a surgical brain biopsy or biopsy of other metastatic tumor sites, while other competing “liquid biopsy” techniques are also limited. For example, the now historic FDA approved CellSearch® test which provides CTC enumeration in blood, is not approved for use in CSF or to perform biomarker analysis in blood or CSF. Other ctDNA based methods may not reliably capture certain molecular alterations such as copy number variations, including for example *HER2* amplification, found in rare tumor cells.

We believe our ability to rapidly translate insights about the utility of cytogenetic, immunocytochemical and molecular biomarkers to provide information to medical oncologists, neuro-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.

We currently offer and conduct our commercialized diagnostic assays and offer our clinical trial services at our CLIA-certified, CAP-accredited and state-licensed laboratory. We have commercialized our Target-Selector™ assays for a number of solid tumor indications such as: breast cancer, NSCLC, gastric cancer, colorectal cancer, prostate cancer, pancreaticobiliary cancer, and ovarian cancer. These assays utilize our dual CTC and ctDNA technology platforms and provide biomarker analysis from a patient's blood sample. In addition, to assist with the United States' urgent need for widespread COVID-19 testing, we launched our RT-PCR COVID-19 testing at our laboratory during the second quarter of 2020.

Our current assays and clinical trial services include:

- *CTC and ctDNA and ctRNA Testing.* Our current assays and our other planned cancer diagnostic assays are based on our Target-Selector™ technologies. After completing testing, we or our partners provide our customers with an easy to understand report that describes the results of the analyses performed, which is designed to help medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians make better decisions about the treatment of their patients.
- *Clinical Trial Services.* We plan to utilize our clinical laboratory and translational research capabilities to provide clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations to improve the efficiency and economic viability of their clinical studies. Our clinical studies and translational research services could leverage our knowledge of CTCs and ctDNA and ctRNA and our ability to develop and implement new cytogenetic, immunocytochemical and molecular diagnostic assays. Our current assays can, and our other planned cancer diagnostic assays and biomarker assays are anticipated to be able to, help optimize clinical trial patient selection and/or monitor cancer drivers during the course of treatment or disease progression. Demonstration of clinical utility of our assays would more easily enable these tests to be adopted in standard clinical practice, helping physicians select the most appropriate therapy for their patients.
- *RT-PCR COVID-19 Testing.* We are currently performing RT-PCR testing for COVID-19 and have received more than 640,000 samples for processing to date. We believe that our RT-PCR COVID-19 testing will be an important aspect of our business until the COVID-19 pandemic subsides.

In the case of our breast and gastric cancer offerings, biomarker analysis involves fluorescence *in situ* hybridization, or FISH, for the detection and quantitation of the human epidermal growth factor receptor 2, or *HER2*, gene copy number as well as immunocytochemical, or ICC, analysis of estrogen receptor, or ER, protein, progesterone receptor, or PR, protein, in breast cancer and androgen receptor, or AR, protein in prostate cancer; all of these tests are currently available commercially. We have also validated and offer a Next Generation sequencing assay for use in breast cancer. A patient's *HER2* status provides the physician with information about the appropriateness of therapies such as Herceptin® or Tykerb®. ER and PR status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

Our lung cancer biomarker analysis offering currently includes FISH testing for *ALK*, *ROS1*, *RET*, *MET* and *FGFR1* gene rearrangements, as well as analysis for the T790M, Deletion 19, and L858R mutations of the epidermal growth factor receptor, or *EGFR* gene, as well as *BRAF* and *KRAS*. The L858R mutation of the *EGFR* gene and Exon 19 deletions as activators of *EGFR* kinase activity. For lung cancer, we also offer a resistance profile assay consisting of the biomarkers *MET*, *HER2* (both of which we perform using our technology for CTCs), *KRAS*, and T790M (both of which are performed using ctDNA in plasma). These assays can be used by physicians to identify the mechanism causing disease progression for patients with NSCLC who are being treated with tyrosine kinase inhibitor, or TKI, therapy and therefore may qualify patients for inclusion in a clinical trial. We have also validated and offer a Next Generation sequencing assay for use in NSCLC.

Fibroblast growth receptor 1, or *FGFR1*, amplification is offered using our CTC technology. *FGFR1* is present in several tumor types, including both NSCLC and small cell lung cancer, or SCLC, and has been shown to be a prognostic indicator of progression. *FGFR1* is also a key target for several drugs undergoing clinical development.

We analytically validated PD-L1 testing utilizing our CTC technology in 2016. PD-L1 is a biomarker that is informative for immuno-oncology therapies currently marketed for lung cancer and melanoma, as well as therapies in development for other tumor types. We collaborated with David Rimm, M.D., Ph.D., a pathologist at Yale Medical School and a scientific advisor to us, on the analytical development of this assay.

In August 2017, we announced that we had executed a distribution agreement for our proprietary blood collection tubes with VWR International, LLC which can preserve intact cells (such as CTCs) for up to 96 hours and ctDNA for up to 8 days, allowing for the intact transport of RUO liquid biopsy samples from regions around the world.

We intend to continue to commercialize cancer diagnostic assays in the United States as LDTs performed in our CLIA-certified, CAP-accredited, and state-licensed laboratory. We plan to evaluate potential opportunities for the commercialization of our products in other countries. We believe the Target-Selector™ technology can be used for molecular biomarker screening, marked as RUO test kits.

We launched the first of our RUO Target Selector kit products, ctDNA *EGFR*, in January 2019. Additionally, we plan to evaluate opportunities for licensing of our products and proprietary technologies to partners in the United States and abroad.

In December 2018, we entered into a Software License and Laboratory Data Supply Agreement with Prognos, Inc., an innovator in predicting disease by applying artificial intelligence, or AI, to clinical laboratory diagnostics. Under the agreement, we will supply de-identified data from its liquid biopsy testing to Prognos, which will leverage its AI capabilities to help its pharmaceutical clients ensure that the right patients receive the right therapies. This agreement could provide revenue sharing opportunities in future periods.

In May 2019, we announced the launch of the Target-Selector™ NGS lung cancer panel. We are working to gain payment for our assay with Palmetto MolDx, who is contracted by CMS to vet new technologies and assays. This means that they must determine that our test is reasonable and necessary for the care of patients diagnosed with late-stage Non-Small Cell Lung Cancer. This is the first step in gaining reimbursement for a proprietary test, and we are in the process of negotiating coding and pricing. Once that is finalized, Noridian (the Medicare carrier for our region) must review and accept the recommendation for payment from Palmetto. If they agree with the recommendation from Palmetto MolDx, then Noridian will adopt the payment and reimbursement recommendation or develop their own, and we can then receive payment from Medicare for our lung cancer panel.

In June 2019, we announced launch of the Target-Selector™ NGS breast cancer panel, a multi-gene liquid biopsy panel specifically developed for breast cancer. This panel is being marketed to physicians and cancer researchers for the detection and monitoring of actionable genomic biomarkers associated with breast cancer.

In November 2019, we announced launch of our liquid biopsy test to detect TRK biomarkers in the blood of patients diagnosed with cancer. Identification of TRK protein enables physicians to rapidly and cost-effectively identify the potential presence of NTRK fusions used to inform on treatment options.

In April 2020, we announced the availability of RUO kits that can allow molecular laboratories around the world to utilize Biocept's Target-Selector™ molecular assay kits to detect key oncogene mutations through the analysis of both Formalin-Fixed Paraffin-Embedded (FFPE) tissue gained from surgical biopsies as well as circulating tumor DNA (ctDNA) gained from blood-based liquid biopsies. In addition, we announced the award of CE (Conformité Européenne)-IVD Mark for our Target-Selector™ molecular assay EGFR kit.

In May 2020, we announced the availability of a Target-Selector™ molecular assay RUO kit for the detection of BRAF mutations in ctDNA and FFPE samples.

We launched our RT-PCR COVID-19 testing business during the second quarter of 2020. We have received more than 640,000 samples for processing through our RT-PCR technology at our laboratory through the date of filing and we believe that performing highly accurate RT-PCR testing for COVID-19 will be an important aspect of our business until the COVID-19 pandemic subsides.

We also expanded our prostate panel offerings as a key element for growing the demand for our testing among urologists, including the AR-V7 assay which helps physicians determine if a patient should stay on hormone therapy or switch to chemotherapy, as well as *PTEN*, *MET*, *MYC*, and *EGFR* FISH assays which provide valuable prognostic information as to the aggressiveness of a patient's prostate cancer.

In April 2021, we announced full commercial launch of our CNSide™ cerebrospinal fluid assay to address unmet needs of patients with metastatic brain cancer. The CNSide™ cerebrospinal fluid assay is designed to better detect and manage treatment of metastatic cancers involving the central nervous system (CNS).

In June 2021, we announced a collaboration with Quest Diagnostics to provide laboratory testing services to Quest patients using our Target Selector™ NGS-based liquid biopsy targeted lung cancer panel. Quest Diagnostics is the leading provider of diagnostic information services, including advanced diagnostics.

In July 2021, we received a positive final Local Coverage Determination (LCD) that expands Medicare coverage for use of our Target Selector™ assay to identify the HER2 biomarker from circulating tumor cells (CTCs). This coverage determination from the Centers for Medicare & Medicaid Services (CMS) Molecular Diagnostics Program (MolDx) was effective July 4, 2021.

Pharmaceutical, Research and Health Economic Collaborations

We continue to execute on our strategies intended to expand our business globally, as well as to engage with pharmaceutical companies on clinical trials and assay development. We have preferred provider agreements in place in Mexico with Quest Diagnostics to support testing for Astra Zeneca.

As a follow up to the CTC findings published in *Cancer Medicine*, we were involved in a clinical study led by investigators at the Dana-Farber Cancer Institute. Study enrollment was completed. During the screening phase of this study, our CLIA-certified, CAP accredited laboratory tested blood samples from a cohort of patients with *HER2* negative tissue status, with the aim to identify individuals with *HER2* amplified CTCs. These patients were then assigned to chemotherapy plus Herceptin®. Additional CTC testing with *HER2* FISH biomarker analyses were performed at subsequent time points. At the December 2014 San Antonio Breast Cancer Symposium, we presented findings of 311 patients tested with *HER2* negative tissue status, where 22% had CTCs with *HER2* gene amplification at disease progression. *HER2* gene amplification subsequently categorized these patients as potential candidates for anti-*HER2* therapy as the cancer evolved. Moreover, our multi-antibody CTC capture method identified a substantial subset of patients who would not likely have had detectable CTCs with commonly used CTC capture technologies. This added 10% (included in the 22%) to the number of women who were candidates for this highly specific targeted therapy.

With our cooperation, researchers at Columbia University published a study in the journal *Clinical and Translational Oncology* in January 2015. The study demonstrated the high correlation (79%) of circulating tumor cells, primary tumor tissue biopsy and metastatic tumor tissue biopsy in the determination of hormone receptor status, or ER/PR, of breast cancer patients. The investigators also found that this high correlation was strongest when comparing metastatic tissue biopsy to CTCs (83%). The conclusion of the study was that determining ER/PR status in CTCs using our platform is feasible, with high concordance in ER/PR between tumor tissue (as determined with immunohistochemistry, or IHC) and CTCs (as determined with immunocytochemistry, or ICC). The authors suggest a larger trial to determine the prognostic significance of these findings.

In September 2015, we presented the clinical validation data of our ctDNA assay in collaboration with the University of California, San Diego. The results demonstrated a very high level of concordance to tissue results (88%), together with >95% analytical sensitivity and 99% analytical specificity, supporting our offering of a validated, robust non-invasive solution for mutation identification and monitoring in patients with lung cancer. Subsequent FDA approval of Tagrisso®, a third-generation tyrosine kinase inhibitor, presented an opportunity for patients to be monitored using a ctDNA and ctRNA assay.

In April 2016, we announced a study collaboration with Dr. Giuseppe Giaccone at the MedStar Georgetown University Hospital to assess resistance biomarkers in non-small cell lung cancer, or NSCLC, patients treated with *EGFR* inhibitors or chemotherapy. Later in 2016, we announced another collaboration involving a study presented at the European Society for Medical Oncology, or ESMO, Annual Congress in October 2016, evaluating the detection of *EGFR* alterations (del19, L858R and T790M) by our Target-Selector™ liquid biopsy. Subsequent to this study, we have earned business in both Mexico and Columbia for *EGFR* gene mutation testing in blood to qualify patients for a pharmaceutical company's targeted therapy. The relationship also resulted in a study initiated during the following year that includes peripheral blood CTC assessment of PD-L1 protein expression in patients undergoing chemotherapy as a monotherapy or in combination with a checkpoint inhibitor.

In December 2016, we announced a clinical study agreement with Columbia University Medical Center to evaluate the clinical utility of our Target-Selector™ platform to diagnose leptomeningeal metastases, or LM, in breast cancer patients. This work was expanded in the fourth quarter of 2018 to include patients with other primary solid tumor types. Dr. Kevin Kalinsky leads this study to test CTCs in cerebrospinal fluid and blood, where CTC analysis will be compared to standard methods for confirming LM diagnosis. In September 2020, Dr. Kalinsky moved to Emory University in Atlanta, but his work with Columbia University on this project continues.

In May 2017, we entered into a clinical study agreement with the University of Texas Southwestern Medical Center. Led by recognized oncologist and *ALK* alteration researcher, Dr. Saad Khan, the study is designed to evaluate the clinical utility of our Target-Selector™ platform for patients diagnosed with *ALK*-positive NSCLC and treated with *ALK*-inhibitor therapy. A second arm of the study evaluated patients with rare cancers such as anaplastic thyroid cancer to determine if genetic drivers such as *ALK* gene rearrangements can be identified and treated with targeted therapy to improve patient outcomes.

Two complementary posters on the highly sensitive Target Selector ctDNA assays were presented in 2018. The first poster entitled "Biocept Study Shows Incorporation of Thermo Fisher QuantStudio 5 PCR Instrument into Target Selector Platform Improves Sensitivity and Specificity in Detection of Lung Cancer Biomarkers" was presented in January 2018 at the Fifth AACR-IASLC International Joint Conference: Lung Cancer Translational Science from the Bench to the Clinic. The related poster, entitled "Validation of highly sensitive TargetSelector™ ctDNA assays for *EGFR*, *BRAF*, and *KRAS* mutations" was presented at the April 2018 American Association for Cancer Research annual meeting. Together, these posters highlight improvements to the Target Selector ctDNA platform, enabling more sensitive mutation detection down to a single copy, thereby increasing the likelihood of identifying actionable molecular drivers towards guiding targeted therapy decisions and better management of a patient's cancer.

In collaboration with Dr. Shilpa Gupta from the Masonic Cancer Center at the University of Minnesota, a poster was presented at the April 2018 American Association for Cancer Research annual meeting. The results demonstrated proof-of-concept use of our Target-Selector™ CTC platform, correlating CTC count with clinical responses in refractory testicular cancer patients undergoing therapy. This work is part of a Phase 2 clinical trial of brentuximab vedotin (an anti-CD-30 antibody) with bevacizumab in refractory CD-30 + germ cell tumors. The capability for our Target-Selector™ CTC platform to monitor this rare cancer type presents the potential for a precision medicine-based approach to guide treatment decisions for these patients.

During the first half of 2018, three key case studies were published in peer-reviewed journals. In April, the 2018 Spring issue of *Oncology & Hematology Review* featured a case report demonstrating the clinical utility of our CTC platform whereby identification of an *ALK* rearrangement enabled sequential targeted therapy and improved quality of life in a patient with NSCLC. This case illustrated the use of our technology to monitor therapeutic response and early detection of drug resistance to manage patient disease through the course of treatment with various *ALK* inhibitors. A Letter to the Editor in the May 2018 issue of *Journal of Thoracic Oncology* described the identification of a *ROS1* rearrangement by Biocept CTC analysis using FISH (fluorescent in situ hybridization). The *ROS1* translocation was concordant with tissue biopsy. In contrast, next-generation sequencing analysis of plasma by another vendor failed to detect the genetic alteration in the patient with lung cancer. Also, in May 2018, a case report describing the application of our CTC technology in the management of metastatic breast cancer was published in *Clinics in Oncology*. This work described a patient with recurrent breast cancer where numerous tissue-based evaluations of the individual's bone-only metastases had repeated challenges or inclusive results. *HER2* amplification detected in CTCs from blood provided crucial information towards changing treatment strategies to include anti-HER therapy, consequently extending and improving the patient's quality of life. Each of the three published cases provide real-life examples in lung and breast cancer towards establishing the importance of liquid biopsy to identify and monitor clinically actionable biomarkers to improve outcomes of patients with cancer.

In July 2018, we announced a collaboration involving two studies with the University of California, San Diego. Each of the two studies will enroll 100 patients with solid tumors, for a total of 200 patients. One study will assess the feasibility of using our CTC and ctDNA methodologies to predict post-resection disease recurrence in patients with Stage II or III cancer, and the other study will use our technology to predict response to therapy in patients with metastatic disease. Dr. Rebecca Shatsky and Dr. Razelle Kurzrock are the investigators key to both studies.

In August 2018, we announced a Quality Improvement Initiative with Highmark Health to help improve molecular testing rates of NCCN Category I Guidelines for NSCLC. The Initiative aims to improve health outcomes by using liquid biopsy to more rapidly assess a patient's actionable biomarker status towards selecting appropriate therapy, while reducing the overall cost of care. The project will evaluate at least 100 patients in the Highmark Health-affiliated Allegheny Health Network, or AHN, Cancer Institute. Patients will receive our CTC and ctDNA testing in addition to tissue biopsy with the goal of obtaining biomarker status results for a higher percentage of patients compared to standard testing.

Two scientific posters featuring the Target Selector™ CTC and ctDNA platforms were presented in September 2018 at the International Association for the Study of Lung Cancer, or IASLC, 19th World Conference on Lung Cancer. Data from these clinical studies demonstrate the ability of our technology to detect and monitor CTC counts and actionable biomarkers in both blood and cerebrospinal fluid, or CSF, of patients with advanced NSCLC. The first poster described interim results of a collaboration with Dr. Janakiraman Subramanian at the Saint Luke's Cancer Institute in Kansas City, Missouri. This study evaluates CTC enumeration in advanced stage NSCLC patients before and during the course of chemotherapy. Interim data suggest that CTC counts may have prognostic and predictive potential to assess therapeutic benefit. The second poster was in collaboration with Kadmon Corporation, featuring CTC and ctDNA analyses and monitoring in the CSF of NSCLC patients with LM who were treated with tsevatib in Kadmon's clinical trial KD019-206. In this study, alterations detected in the CSF of patients were concordant with original tissue biopsies, and serial monitoring of CTCs and ctDNA biomarkers in CSF were consistent with the overall clinical.

A case series was published in the January 2019 issue of the peer reviewed journal, *Clinics in Oncology*. The work highlights the clinical utility of liquid biopsy to stratify patients who may benefit from targeted therapy, describing three patients with metastatic NSCLC for whom tissue biopsy was insufficient for molecular profiling. In all three cases, our ctDNA liquid biopsy analyses detected an activating *EGFR* mutation. *EGFR* tyrosine kinase inhibitor therapy subsequently was initiated. Complete response lasting approximately two years was observed in one patient. For two patients, our ctDNA testing was performed at signs of clinical progression and Osimertinib was administered upon our liquid biopsy identification of the *EGFR* T790M resistance marker. In sum, patient survival was dramatically extended in all cases presented where targeted therapies were prescribed based on liquid biopsy results.

In April 2019, we presented a poster at the annual meeting of the American Association for Cancer Research. The work describes analytical validation of Target Selector *ESR1* Next Generation Sequencing, or NGS, ctDNA assays with single copy mutant detection. The assays have a limit of detection, or LOD, 0.03% or better, with >99% sensitivity for mutant allele fractions, or MAF, ranging from greater than 5% down to 0.03%. *ESR1* gene mutations are associated with acquired drug resistance in up to 55% of patients with estrogen receptor, or ER, positive metastatic breast cancer, or mBC, who received anti-estrogen treatment. Detection of *ESR1* mutations may enable the prediction of treatment failure and disease progression in these patients. As new therapies are developed that antagonize ER activity by mechanisms that differ from current drug treatments, *ESR1* mutation testing can be a helpful tool to identify patients who may benefit from these alternative agents.

In October 2019, we announced the publication of a peer-reviewed journal article featuring the analytical validation results demonstrating the high sensitivity of our Target Selector™ testing for *EGFR*, *BRAF*, and *KRAS* mutation in plasma circulating tumor DNA (ctDNA). The article was published in the journal, *PLOS ONE*, Volume 14, October 2019, and will also be included as part of a special collection of topical articles, entitled *Targeted Anticancer Therapies and Precision Medicine In Cancer*.

In November 2019, we presented clinical data highlighting performance of our Target Selector™ tests and kits for detecting actionable oncology biomarkers at the 2019 Association for Molecular Pathology, or AMP, Annual Meeting held at the Baltimore Convention Center, in Baltimore, MD. The content of our posters will be published in *The Journal of Molecular Diagnostics*.

In December 2019, we presented clinical data supporting the use of our Target Selector™ CTC platform as an aid in the monitoring and treatment of breast cancer in a poster session at the 2019 San Antonio Breast Cancer Symposium, or SABS. The data demonstrated the Target Selector™ platform's ability to accurately detect, enumerate, and interrogate CTCs in a cohort of over 1,500 patients, representing various clinical and treatment stages of breast cancer.

In March 2020, we announced publication of clinical data in the peer-reviewed *Journal of Clinical Pathology* that further validates the Company's Target Selector™ qPCR Assay using "Switch Blocker" technology to identify cancer-related mutations in liquid biopsy samples. The study examined 127 clinical assays for mutations commonly associated with cancer found in the EGFR, BRAF and KRAS genes. Each Target Selector™ assay in the study demonstrated extremely high accuracy, sensitivity and specificity when compared to results obtained from tissue samples, showing a 93%-96% concordance to blinded tissue samples across all assays.

In October 2020, we announced results from a prospective study comparing our Target Selector™ CSF testing to conventional cytology in patients with non-small cell lung cancer, or NSCLS, and LM showing that our Target Selector™ CSF testing may provide a more robust method for detecting lung cancer metastasis in CSF than the current standard of cytology analysis.

In November 2020, we announced results of a study analyzing CSF samples in patients with primary lung or breast cancer with either brain or LM disease. The findings indicate that Target Selector™ CSF assays are a viable and sensitive platform for CTC detection and molecular analysis compared to the current standard of care, CSF cytology, which is typically used to establish or confirm LM disease when cytology imaging findings are suspicious or equivocal.

In December 2020, we announced results from a prospective study showing Target Selector™ was highly accurate in monitoring HER2 alterations in patients with metastatic breast cancer. The results were featured in a poster presentation at the virtual 2020 San Antonio Breast Cancer Symposium.

In February 2021, we presented data at the Molecular Med Tri-Con Virtual Conference, showing that our Target Selector™ molecular assay kit detects mutations in up to 50% of tissue biopsy specimens, from patients diagnosed with non-small cell lung cancer, that were deemed quantity not sufficient (QNS) by conventional methods.

In February 2021, we announced establishing a research collaboration with Protean BioDiagnostics, Inc. to research the ability of our Target Selector™ molecular assay to determine EGFR status in non-small lung cancer (NSCLC) patients.

In August 2021, we presented data at the Society of NeuroOncology (SNO) Brain Metastasis conference related to our CNSide experience on several non-small cell lung cancer (NSCLC) cases from one institution, the University of Utah. Recently, we had other abstracts accepted for poster presentation at the upcoming annual November meeting of the Society of Neuro-Oncology (SNO) in Boston and the annual San Antonio Breast Cancer Symposium in December.

Provider Agreements

In January 2017, we announced that we had secured an in-network provider agreement with Blue Cross Blue Shield of Texas, the largest provider of health benefits in Texas. In addition, we entered into a national master business agreement with the Blue Cross Blue Shield Association, a not-for-profit trade association that provides multiple services for its 38-member Blue Cross and Blue Shield health plan companies across the U.S., including forming national strategic vendor partnerships. We were selected by the Blue Cross Blue Shield Association based on a rigorous request-for-proposal process. This agreement establishes pricing for our Target-Selector™ liquid biopsy testing service through the Blue Cross Blue Shield Association's group purchasing organization, CareSourcing Workgroup. The pricing offered by the CareSourcing Workgroup group purchasing organization is available to those Blue Cross and Blue Shield member health plans that have, or may seek, in-network agreements with us.

In June 2017, we entered into a participating provider agreement with MediNcrease Health Plans, LLC and a preferred provider agreement with Scripps Health Plan Services, Inc., both establishing pricing for our Target-Selector™ liquid biopsy testing service.

In December 2017, we signed an agreement with Wellmark, Inc., the largest health insurer in Iowa and South Dakota. The agreement marks our third Blue Cross Blue Shield contract and enables patients diagnosed with cancer the ability to access our proprietary testing services in-network under their Wellmark health plan.

In August 2018, we entered into a quality initiative program with Highmark and Alleghany Health Network as a result of the CareSourcing Workgroup. The focus is to improve access to molecular testing to members with a diagnosis of lung cancer. Enrollment began in August 2018 and has been steadily increasing.

In July 2019, we announced that we entered into a Laboratory Services Provider Agreement with Beacon Laboratory Benefit Solutions, Inc., a nationally recognized premier provider of laboratory benefit management technology solutions to health and managed care companies in the United States.

In February 2020, we announced that we entered into an agreement with a California-based independent physician association, or IPA, to provide our liquid biopsy testing services to physicians and patients in their network. Our Target Selector™ offering includes the choice of individual biomarker tests or a larger liquid biopsy panel, enabling physicians to select the best approach for each patient.

In June 2020, we announced that we entered into a managed care provider agreement with Medical Cost Containment Professional LLC (MCCP), to process out-of-network claims for Biocept's Target Selector™ liquid biopsy testing. MCCP is a reference-based pricing insurance network that includes more than 150,000 providers nationwide.

In August 2020, we announced the expansion of our agreement with MultiPlan, Inc. to include COVID-19 testing services at a pre-negotiated price per test. MultiPlan is a healthcare cost management company offering payment integrity, network-based and analytics-based services. With the expanded agreement, our RT-PCR COVID-19 testing, in addition to our liquid biopsy oncology testing services, are now accessible to consumers who have access to the PHCS and MultiPlan Networks, MultiPlan's national primary and complementary networks. More than 1 million healthcare providers participate in MultiPlan's networks and 60 million health plan members have access to the company's services.

In addition, in August 2020, we entered into an agreement with a healthcare group to provide RT-PCR COVID-19 testing to skilled nursing facilities. The group operates and supports more than 50 facilities in multiple states, with most located in California, the state with one of the most stringent COVID-19 testing regulations in the United States.

In September 2020, we announced that Highmark, America's fourth largest Blue Cross Blue Shield affiliate, has made a positive coverage determination that our Target Selector™ liquid biopsy assay has been accepted for medical coverage for use in the diagnosis and treatment of patients with NSCLC. In addition, we announced that we entered into an agreement with Health Net Federal Services LLC to be an in-network provider for Target Selector™ liquid biopsy oncology platform testing for cancer patients in the TRICARE West (TriWest) region network. TriWest provides healthcare services to approximately three million members of the U.S. military and their families.

In December 2020, we announced entering into laboratory services agreements with two Southern California regional independent physician associations (IPAs) providing physicians and patients in-network access to our full array of Target Selector™ liquid biopsy assays and services. Both IPAs are headquartered in San Diego and combined they serve more than 70,000 covered lives in the Southern California region.

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 to be considered as an "in-network" provider with additional plans.

Patents and Technology

The proprietary nature of, and protection for, our products, services, processes, and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our products, services, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our products, services and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business.

We also rely on trade secrets, know-how, and continuing innovation to develop and maintain our competitive position. We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

Our success depends on an intellectual property portfolio that supports our future revenue streams and erects barriers to our competitors. We are maintaining and building our patent portfolio through filing new patent applications, prosecuting existing applications, and licensing and acquiring new patents and patent applications.

We have issued patents with broad claims covering our blood collection tube, antibody cocktail approach, microchannel, CTC detection methodologies, and ctDNA analysis. In addition to issued patents in the U.S., we have patents for our proprietary microchannel in China, South Korea, Europe, Hong Kong, Canada and Japan, and for our antibody cocktail in Australia, Europe, Canada, China, Hong Kong and Japan. Our patent estate continues to evolve, and in addition to the broad patent estate around our CTC platform, we also have issued patents in the U.S., Australia, Brazil, Europe, Hong Kong, Japan, China and South Korea for our novel switch blocker technology, solidifying our proprietary enrichment methodology for detecting ctDNA with very high sensitivity. We also have recently issued patents in the U.S. Australia, Japan, and Korea for a unique primer switch technology which can be used for detecting rare genetic alterations, and for improving the performance of PCR based amplification assays. Our CTC platform patents were filed from 2005 through 2012, and we expect to have patent protection into the 2030s. Our CTC patents and applications cover not only cancer as a target, but also prenatal and other rare cells of interest. Recently granted patents in the U.S. cover the capture of any target of interest on any solid surface using our

antibody capture approach. The patent for our proprietary specimen collection tubes expires in 2031, and the patents for our ctDNA technology expire in the early 2030s.

As of September 30, 2021, we owned 53 issued patents and have nine patent applications pending related to our core business. Of these, 13 were issued U.S. patents and three were pending patent applications in the U.S., while 40 were issued patents in non-U.S. territories and six were pending patent applications in non-U.S. territories.

Coronavirus (COVID-19) Pandemic

The COVID-19 pandemic continues to evolve, and the extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, the emergence and impact of variants, vaccinations, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We estimate that the COVID-19 pandemic led to an approximate 15 to 25% decline in commercial volume from current customers for the year ended December 31, 2020, and has also impacted opportunities for us to gain new customers with the closing of many physician offices and labs. We are continuing to vigilantly monitor the situation with our primary focus on the health and safety of our employees and clients.

In April 2020, we announced that we verified a COVID-19 molecular diagnostic test and that we would begin accepting physician-ordered testing requests. The testing volume was initially limited by the national shortage of specimen collection kits. On June 22, 2020, we announced the availability of 10,000 specimen collection kits for COVID-19 testing for physician ordering. Collected specimens are shipped to our high-complexity, CLIA-certified, CAP-accredited and BSL-2 safety level laboratory in San Diego with results returned to ordering physicians in an estimated 24 to 48 hours. We have received more than 640,000 samples for processing through our RT-PCR technology at our laboratory to date and we believe that performing highly accurate RT-PCR testing for COVID-19 will be an important aspect of our business until the COVID-19 pandemic subsides.

On June 3, 2020, we entered into a development agreement with Aegea focused on the co-development by us and Aegea of a highly sensitive PCR-based assay designed by Aegea for detecting the COVID-19 virus. In February 2021, we entered into a supply agreement with Aegea for a new PCR-based COVID-19 assay kit designed by Aegea and co-developed by Aegea and us. Under the supply agreement, Aegea will supply the COVID-19 assay kit to us for validation in our CLIA-certified, CAP-accredited high-complexity molecular lab and subsequent commercialization of a laboratory developed test (LDT).

In January 2021, we signed an agreement with the Foundation for California Community Colleges to make COVID-19 testing available to the 116 California community colleges and their more than 2.1 million students. Through the Foundation's CollegeBuys program, our PCR-based COVID-19 test is now available for community colleges to purchase for students, faculty and staff.

In June 2021, we announced a collaboration with CLEARED4, a market leader in pandemic health and safety solutions, to develop a system for tracking and managing COVID-19 testing requirements and test results for our customers.

Results of Operations

Three Months Ended September 30, 2020 and 2021

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

	Three months ended September 30,		Change	
	2020	2021	\$	%
Net revenues	\$ 6,586	\$ 17,470	\$ 10,884	165%
Cost of revenues	5,859	10,292	4,433	76%
Research and development expenses	1,088	1,303	215	20%
General and administrative expenses	3,023	3,434	411	14%
Sales and marketing expenses	1,434	1,938	504	35%
(Loss)/income from operations	(4,818)	503	5,321	(110%)
Interest expense	(60)	(74)	(14)	23%
(Loss)/income before income taxes	(4,878)	429	5,307	(109%)
Income tax expense	—	—	—	0%
Net (loss)/income	\$ (4,878)	\$ 429	\$ 5,307	(109%)

Net Revenues

Net revenues were approximately \$17.5 million for the three months ended September 30, 2021, compared with approximately \$6.6 million for the same period in 2020, with the increase attributable primarily to RT-PCR COVID-19 testing. Revenues for the three months ended September 30, 2021 included \$17.4 million in commercial revenues, with \$16.5 million attributable to RT-PCR COVID-19 testing, \$34,000 in development services test revenue and \$71,000 in revenue for distributed products, Target Selector™ RUO kits, CEE-Sure® blood collection tubes and payments from Aegea for services associated with the development of a COVID-19 assay. Revenues for the three months ended September 30, 2020 included \$6.4 million in commercial test revenue, which includes \$5.7 million attributable to RT-PCR COVID-19 testing, \$47,000 in development services test revenue and \$154,000 in revenue for distributed products, Target Selector™ RUO kits, CEE-Sure® blood collection tubes and payments from Aegea Bioscience for services associated with the development of a COVID-19 assay. The increase in net revenues is due to an increase in overall accession volumes, which is attributable to the COVID-19 testing business, which was launched during the second quarter of 2020, resulting in approximately 47,000 and 152,000 delivered accessions during the quarter ended September 30, 2020 and 2021, respectively.

The net estimated revenue per commercial accession delivered during the three months ended September 30, 2021 was \$114, based on 152,796 commercial accessions delivered, while during the three months ended September 30, 2020 it was approximately \$133, based on 48,109 commercial accessions delivered. The decrease in net revenue per commercial accessions delivered was primarily due to lower payor reimbursement rates recorded on our COVID-19 testing business.

The following table sets forth certain information regarding commercial accessions received during the three months ended September 30, 2020 and 2021:

	Three months ended September 30,		Change	
	2020	2021	# / \$	%
# Commercial accessions delivered	48,109	152,796	104,687	218%
\$ Value estimated per commercial accession delivered	\$ 133	\$ 114	\$ (19)	(14%)

Additionally, overall development revenues stayed relatively flat as compared to the same period in the prior year. The net revenue per accession decreased primarily due to the lower average number of biomarkers ordered per test during period as compared to the same period in the prior year as follows:

	Three months ended September 30,		Change	
	2020	2021	# / \$	%
# Development services accessions delivered	113	120	7	6%
\$ Value per development services accession delivered	\$ 412	\$ 284	\$ (128)	(31%)

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately \$10,292,000 for the three months ended September 30, 2021, compared with approximately \$5,859,000 for the same period in 2020, representing an increase of \$4,433,000, or 76% primarily resulting from increased revenues related to our RT-PCR COVID-19 testing business. As we continue to leverage the fixed components of our costs, our cost of revenues as a percentage of net revenues decreased by approximately 30% for the three months ended September 30, 2021 as compared to the same period in the prior year. Cost of revenues are comprised of, but not limited to, expenses related to personnel costs, materials, shipping and other direct costs, as well as equipment depreciation and software amortization expenses.

Research and Development Expenses. Research and development expenses were approximately \$1,303,000 for the three months ended September 30, 2021, compared with approximately \$1,088,000 for the same period in 2020, an increase of \$215,000, or 20%. The increase is primarily due to higher material and supply costs in the three months ended September 30, 2021 related to materials used in our laboratory to advance our research programs costs as compared to the same period in the prior year. Research and development expenses are comprised of, but not limited to, personnel costs, material, shipping and other direct costs, computer and laboratory equipment maintenance and facility related costs.

General and Administrative Expenses. General and administrative expenses were approximately \$3,434,000 for the three months ended September 30, 2021, compared with approximately \$3,023,000 during the same period in 2020, an increase of \$411,000, or 14%. The increase was primarily due to headcount additions and other costs related to COVID-19 testing. General and administrative expenses are comprised of, but not limited to, personnel costs, facilities, depreciation, repairs and maintenance costs, stock-based compensation expenses, patent and legal costs, accounting and audit fees, as well as insurance, office and other expenses.

Sales and Marketing Expenses. Sales and marketing expenses were approximately \$1,938,000 for the three months ended September 30, 2021, compared with approximately \$1,434,000 for the same period in 2020, an increase of \$504,000, or 35%. The increase was primarily attributable to higher sales commissions due to higher revenues during the current period. Sales and marketing expenses are comprised of, but not limited to, personnel costs, which include commissions, trade show and other marketing related expenses, as well as office and other costs.

Interest Expenses. Interest expenses were approximately \$74,000 for the three months ended September 30, 2021 compared with approximately \$60,000 for the same period in 2020, an increase of \$14,000 or 23% reflecting interest recognized on leases initiated since the same period in the prior year.

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.

Results of Operations

Nine Months Ended September 30, 2020 and 2021

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

	Nine months ended September 30,		Change	
	2020	2021	\$	%
Net revenues	\$ 8,950	\$ 47,273	\$ 38,323	428%
Cost of revenues	11,324	26,760	15,436	136%
Research and development expenses	3,989	3,483	(506)	(13%)
General and administrative expenses	6,839	9,805	2,966	43%
Sales and marketing expenses	4,233	5,806	1,573	37%
(Loss)/income from operations	(17,435)	1,419	18,854	(108%)
Interest expense	(172)	(219)	(47)	27%
Warrant inducement and other expenses	(2,102)	—	2,102	(100%)
(Loss)/income before income taxes	(19,709)	1,200	20,909	(106%)
Income tax expense	—	—	—	0%
Net (loss)/income	\$ (19,709)	\$ 1,200	\$ 20,909	(106%)

Net Revenues

Net revenues were approximately \$47.3 million for the nine months ended September 30, 2021 compared with approximately \$9.0 million for the same period in 2020, with the increase being attributable to significant RT-PCR COVID-19 testing volumes during the nine months ended September 30, 2021.

Revenues for the nine months ended September 30, 2021 included \$47.0 million in commercial test revenue, which includes \$45.5 million attributable to RT-PCR COVID-19 testing, \$107,000 in development services test revenue and \$167,000 in revenue for Target Selector™ RUO kits, CEE-Sure blood collection tubes and payments from Aegea Bioscience for services associated with the development of a COVID-19 assay. Commercial revenues for the nine months ended September 30, 2021 were reduced by \$1.1 million as a result of an increase in reserves for aged accounts receivable balances. Revenues for the nine months ended September 30, 2020 included \$8.5 million in commercial test revenue, which included \$5.7 million attributable to RT-PCR COVID-19 testing, \$145,000 in development services test revenue and \$261,000 in revenue for Target Selector™ RUO kits, CEE-Sure blood collection tubes and payments from Aegea Bioscience for services associated with the development of a COVID-19 assay. The increase in net revenues is due to an increase in overall accession volumes, which is attributable to the COVID-19 testing business which was launched by the Company during the second quarter of 2020, which resulted in 47,000 and 395,000 billed accessions from RT-PCR COVID-19 testing during the nine months ended September 30, 2020 and 2021, respectively.

The net estimated revenue per commercial accession delivered during the nine months ended September 30, 2021 was \$118, based on 398,197 commercial accessions delivered, while during the nine months ended September 30, 2020 it was approximately \$170, based on 50,140 commercial accessions delivered.

The following table sets forth certain information regarding commercial accessions delivered during the nine months ended September 30, 2020 and 2021:

	Nine months ended September 30,		Change	
	2020	2021	# / \$	%
# Commercial accessions delivered	50,140	398,197	348,057	694%
\$ Value estimated per commercial accession delivered	\$ 170	\$ 118	\$ (52)	(31%)

Additionally, overall development revenues stayed relatively flat as compared to the same period in the prior year. The net revenue per development services accession decreased primarily due to the lower average number of biomarkers ordered per test during period as compared to the same period in the prior year as follows:

	Nine months ended September 30,		Change	
	2020	2021	# / \$	%
# Development services cases delivered	353	355	2	1%
\$ Value per development services accession delivered	\$ 412	\$ 301	\$ (111)	(27%)

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately \$26,760,000 for the nine months ended September 30, 2021, compared with approximately \$11,324,000 for the same period in 2020, representing an increase of \$15,436,000, or 136%, primarily resulting from increased revenues related to our RT-PCR COVID-19 testing business. As we continue to leverage the fixed components of our costs, our cost of revenues as a percentage of net revenues decreased by approximately 70% for the nine months ended September 30, 2021 as compared to the same period in the prior year. Cost of revenues are comprised of, but not limited to, expenses related to personnel costs, materials, shipping and other direct costs, as well as equipment depreciation and software amortization expenses.

Research and Development Expenses. Research and development expenses were approximately \$3,483,000 for the nine months ended September 30, 2021, compared with approximately \$3,989,000 for the same period in 2020, a decrease of \$506,000, or 13%. The decrease was primarily attributable to lower facilities and cost of revenue allocations to research of development during the nine months ended September 30, 2021. Research and development expenses are comprised of, but not limited to, personnel costs, material, shipping and other direct costs, computer and laboratory equipment maintenance and facility related costs.

General and Administrative Expenses. General and administrative expenses were approximately \$9,805,000 for the nine months ended September 30, 2021, compared with approximately \$6,839,000 during the same period in 2020, an increase of \$2,966,000, or 43%. The increase was primarily due to headcount additions and other costs related to COVID-19 testing. General and administrative expenses are comprised of, but not limited to, personnel costs, facilities, depreciation, repairs and maintenance costs, stock-based compensation expenses, patent and legal costs, accounting and audit fees, as well as insurance, office and other expenses.

Sales and Marketing Expenses. Sales and marketing expenses were approximately \$5,806,000 for the nine months ended September 30, 2021 compared with approximately \$4,233,000 for the same period in 2020, an increase of \$1,573,000, or 37%. The increase was primarily attributable to higher sales commissions due to higher revenues during the current period. Sales and marketing expenses are comprised of, but not limited to, personnel costs, which include commissions, trade show and other marketing related expenses, as well as office and other costs.

Interest Expenses. Interest expenses were approximately \$219,000 for the nine months ended September 30, 2021, compared with approximately \$172,000 for the same period in 2020, an increase of \$47,000, or 27%, primarily reflecting interest recognized on leases initiated since the same period in the prior year.

Warrant Inducement and Other Expenses. There was no warrant inducement expense recognized in the nine months ended September 30, 2021 compared to approximately \$2,102,000 for the same period in 2020. Warrant inducement expense was recognized in the first quarter of 2020 related to the fair value of the inducement warrants issued in January 2020 and warrant modification costs.

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 losses 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

Cash Flows

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

	Nine months ended September 30,	
	2020	2021
Cash provided by/ (used in):		
Operating activities	\$ (18,684)	\$ 2,127
Investing activities	(64)	(982)
Financing activities	26,305	12,185
Net increase in cash	<u>\$ 7,557</u>	<u>\$ 13,330</u>

Cash Used in Operating Activities. Net cash provided by operating activities was \$2.1 million for the nine months ended September 30, 2021, compared to net cash used in operating activities of \$18.7 million for the same period in 2020. The net decrease in cash used was primarily related to revenues generated from our COVID-19 testing business during the nine months ended September 30, 2021.

Cash Used in Investing Activities. Net cash used in investing activities of approximately \$982,000 and \$64,000 during the nine months ended September 30, 2021 and 2020, respectively, was related to purchases of fixed assets used in our laboratory operations.

Cash Provided by Financing Activities. Net cash provided by financing activities was \$12.2 million for the nine months ended September 30, 2021, compared to net cash provided by financing activities of \$26.3 million for the same period in 2020. Our primary sources of cash from financing activities during the nine months ended September 30, 2021 consisted of \$13.5 million in net proceeds from our sale of common stock through our at-the-market equity facility, partially offset by \$911,000 of payments related to finance leases for equipment used in our laboratory operations, and \$412,000 of payments related to supplier and other third-party financing transactions. Our primary sources of cash from financing activities during the nine months ended September 30, 2020 consisted of \$660,000 in net proceeds from exercise of overallotment warrants from the December 2019 warrants in January 2020, net proceeds of \$24.2 million from our sale of common stock in three equity financing transactions in March and April 2020, and \$2.4 million in proceeds from exercise of common stock warrants. Net proceeds from financing transactions were partially offset by \$0.5 million of principal payments made on finance leases and indebtedness.

Liquidity, Capital Resources and Expenditure 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.

During the nine months ended September 30, 2021, we received net cash proceeds of approximately \$13.5 million from the sales of 3,266,032 shares of our common stock at a weighted average sale price of \$4.32 per share, using the Company's at-the-market equity facility initiated in May 2021.

As of September 30, 2021, our cash totaled \$27.7 million. The COVID-19 testing revenue during 2020 and through the third quarter of 2021, has provided us with increased levels of cash inflows from operations, and it is expected to continue, albeit at lower and declining levels, throughout at least the next twelve months. As a result, we believe that based on our current and planned cash usage, along with current COVID-19 testing revenues, our cash balances will support our operations through the fourth quarter of 2022. As such, we determined that it is not probable based on projected cash flows that substantial doubt about our ability to continue as a going concern exists for the one-year period following the date that the financial statements for the three and nine months ended September 30, 2021 were issued. The COVID-19 pandemic continues to evolve, and the extent to which COVID-19 may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. While the Company experienced increased revenue levels in 2020 and 2021 related to its COVID-19 testing business and attained net income for the first time in its operating history in the fourth quarter in 2020, and then again in the first and third quarter in 2021, these results are not expected to be indicative of future results as the COVID-19 pandemic subsides.

In May 2020, the SEC declared effective a shelf registration statement filed by us. The shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$100.0 million.

In May 2021, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (the “Sales Agent”), under which we may issue and sell from time to time up to \$25,000,000 of our common stock through or to the Sales Agent, as sales agent or principal. Any sale of shares of our common stock under the Sales Agreement will be made under our shelf registration statement on Form S-3, which was declared effective by the SEC in May 2020. 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. Each time we wish to issue and sell common stock under the Sales Agreement, we notify 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 we have 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 our common stock are subject to a number of conditions that we must meet. The Sales Agent is entitled to compensation from us 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 nine months ended September 30, 2021, we sold and issued 3,266,032 shares of our common stock at a weighted average purchase price of \$4.32 under the Sales Agreement and received net cash proceeds of approximately \$13.5 million after deducting sales agent commissions. As of September 30, 2021, \$10.9 million of our common stock remained available for sale under the Sales Agreement.

We expect that we will need additional financing to execute on our current or future business strategies beyond the next twelve months. Until we can generate significant cash from operations, including assay revenues, we expect to continue to fund operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time until expiration in May 2023. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. 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 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:

- the impact of the COVID-19 pandemic on our business;
- 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 payers 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 our other filings with the SEC.

We may raise additional capital to fund our current operations and to fund expansion of our business to meet our long-term business objectives through public or private equity offerings, debt financings, 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, additional capital may not be available when needed on acceptable terms, or at all. If adequate funds are not available, we will need to curb our expansion plans or limit our research and development activities, which would have a material adverse impact on our business prospects and results of operations.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

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, 2020. 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, 2020.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. 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.

As of September 30, 2021, 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 effective at the reasonable assurance level as of September 30, 2021.

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 months ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 Securities and Exchange Commission before making investment decisions regarding our common stock.

- We are an early-stage 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.
- If we are unable to increase sales 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.
- Our business is subject to risks arising from pandemic and epidemic diseases, such as the COVID-19 pandemic.
- 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.
- Clinical utility studies are important in demonstrating to both customers and payers 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.
- The loss of key members of our executive management team could adversely affect our business.
- Our failure to continue 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 blood 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 BCTs, 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 payers, 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 payers for a significant portion of our revenues and if these or other payers 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 payers 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 payers, 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 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.

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, 2020 filed with the Securities and Exchange Commission on March 31, 2020.*

Risks Relating to Our Financial Condition and Capital Requirements

****We are an early-stage 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 \$17.8 million for the year ended December 31, 2020. While for the first time in our operating history we have generated net income in the fourth quarter of 2020 and also had net income in the first and third quarters of 2021, both from our revenues from COVID-19 testing, it is expected that once the COVID-19 pandemic subsides, that we will continue to incur net losses and negative cash flows from operations for the foreseeable future. At September 30, 2021, our accumulated deficit was approximately \$262.3 million. Before 2008, we were pursuing a business plan relating to fetal genetic disorders and other fields, all of which were unrelated to cancer diagnostics. The portion of our accumulated deficit that relates to the period from inception through December 31, 2007 is approximately \$66.5 million.

We expect our losses to continue as a result of costs relating to our laboratory operations as well as increased sales and marketing costs and ongoing 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. However, the COVID-19 testing revenue during 2020 and through the third quarter of 2021, has provided the Company with increased levels of cash inflows from operations, and it is expected to continue, albeit at lower and declining levels, throughout at least the next twelve months. 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 ongoing issues arising from the COVID-19 pandemic, 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 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.

Risks Relating to Our Business and Strategy

If we are unable to increase sales 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.

We currently derive substantially all of our revenues from sales of diagnostic assays. We began offering our assays through our Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified, College of American Pathologists, or CAP accredited,

and state-licensed laboratory in 2014. Additionally, the sale of our proprietary blood collection tubes, or BCTs commenced in June 2018, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world. 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 sales of 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 sales and marketing strategy for 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. To date, our revenue has been insufficient to fund operations.

Although we believe that our current assays and our planned future assays, our molecular kits as well as our blood and viral collection tube product, 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 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. The process of publication in leading medical journals is 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 market the products and diagnostic assays that we have developed, and may develop in the future, will depend on numerous factors, including:

- conducting clinical utility studies of such assays in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether our current or future partners, vigorously support our offerings;
- the success of our sales force;
- 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, BCTs, shipping kits and other products that we sell or consume in our manufacturing process that are of sufficient quality and supply;
- our ability to continue to fund planned sales and marketing activities; and
- whether private health insurers, government health programs and other third-party payers will adopt liquid biopsy-based assays in their guidelines, or cover such diagnostic assays and, if so, whether they will adequately reimburse us.

The COVID-19 pandemic may also increase the risk of certain of the events described above and delay our development timelines. 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 drugs have been approved, and a number of new 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 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. The COVID-19 pandemic may also increase the risk of certain of the events described above and delay our development timelines.

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. We completed the process of moving our operations and equipment to our new laboratory facility in San Diego in December 2020. Our new 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, such as the COVID-19 pandemic.***

A pandemic, including COVID-19 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 COVID-19 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 payers, delay ongoing and planned clinical trials involving our tests and have a material adverse effect on our business, financial condition and results of operations. We estimate that the COVID-19 pandemic led to an approximate 15 to 25% decline in oncology commercial volume from current customers for the year ended December 31, 2020, and also impacted opportunities for us to gain new customers due to the temporary closing of many physician offices and labs. Beginning the week of March 16, 2020, much of our workforce began working from home either all or substantially all of the time, except for staff in our clinical laboratory and manufacturing operations. The ongoing COVID-19 pandemic has 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. In some places, these orders have been lifted whereas other locations continue to be subject to restrictions. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of restrictions will be imposed in the future, notwithstanding vaccination efforts. The effects of state and local stay-at-home orders and our work-from-home policies may

negatively impact productivity, 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 the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic continues to have the potential for disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We are still in the midst of the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, commercialization efforts, healthcare systems or to the global economy as a whole. These effects could have a material impact on our financial condition and operations. We will continue to monitor the COVID-19 situation closely.

****The successful development of a vaccine for COVID-19 may harm our RT-PCR COVID-19 testing business.***

We launched our RT-PCR COVID-19 testing business during the second quarter of 2020. We have received more than 640,000 samples for processing through our RT-PCR technology at our laboratory to date and we believe that performing highly accurate RT-PCR testing for COVID-19 will be an important aspect of our business until the COVID-19 pandemic subsides. During the year ended December 31, 2020 and the first nine months of 2021, we saw a significant increase in our net revenues due to our substantial COVID-19 testing volumes during that time. In early 2021, the FDA approved multiple COVID-19 vaccines for administration to the public. As of the fourth quarter of 2021, children five and older are also eligible to receive a COVID-19 vaccine. The continued vaccination efforts and increase in immunization levels throughout the U.S. population will likely impact revenues generated by our RT-PCR COVID-19 testing business, and we will lose much of the revenue generated related to COVID-19 testing once demand for such testing declines. Our RT-PCR COVID-19 testing is done pursuant to an Emergency Use Authorization which will be revoked when the public health emergency is no longer in effect, and we will no longer be able to offer the test under the EUA after such revocation.

****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, urologists, 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 blood-based CTC and ctDNA assays, in their practices in conjunction with or instead of molecular diagnostic tests from tissue biopsies.

Blood or liquid biopsy molecular tests based on CTC 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, have achieved FDA clearance for their proprietary laboratory tests.

There are a number of 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. In June 2021, we announced a collaboration with Quest Diagnostics to provide laboratory testing services to Quest patients for our Target Selector NGS-based liquid biopsy targeted lung cancer panel. However, this collaboration does not prevent Quest from offering or providing testing services that are competitive with our panel.

Another new area of science and medicine is CTC and ctDNA assays performed from cerebrospinal fluid (CSF) samples for neuro-oncology applications and there is currently limited competition for our CSF-based CTC and ctDNA assays. There are no known specialty oncology diagnostic companies or large laboratory services companies that offer CSF-based CTC 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 purposes.

There are a number of companies which are focused on the oncology diagnostic market, who while not currently offering CTC or ctDNA assays are selling to the medical oncologists and pathologists and could develop or offer CTC or ctDNA assays. Large laboratory services companies such as Quest and LabCorp provide more generalized cancer diagnostic assays and testing but could also offer a CTC or ctDNA assay service. 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 BCTs, and in the future, companies like Covidien, Beckton Dickinson, Thermo Fisher, and other large medical device companies may develop BCTs 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 blood collection tubes. 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 developed 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 payers, 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.

****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 year ended December 31, 2020 and the nine months ended September 30, 2021, our research and development expenses were \$5.2 million and \$3.5 million, respectively, and our sales and marketing expenses were \$6.4 million and \$5.8 million, respectively. We expect our expenses to continue to increase for the foreseeable future as we conduct studies of our current products, assays and services and our planned future products, assays and services, continue to 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 need to generate significant revenues in order to achieve sustained profitability.

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 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 payers. We 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. Our ability to interface with physicians and other medical professionals has been impacted and will likely continue to be impacted by the ongoing COVID-19 pandemic.

Clinical utility studies are important in demonstrating to both customers and payers 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 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 payers 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 COVID-19 pandemic may also increase the risk of certain of the events described above and delay our development timelines.

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 continue 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 are able to develop, we must expand our sales force in the United States and/or internationally by recruiting additional 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 continue to build our 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 intend 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 current or 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 blood 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 blood 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 blood samples or other biological materials are impacted by the COVID-19 pandemic, our costs and availability of such supplies may be impacted.

We currently rely on third-party suppliers for our BCTs, 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 BCTs 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 BCTs, 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 BCTs and 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 BCTs, 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 the COVID-19 pandemic, 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.

Although we believe that our existing product and professional liability insurance is adequate, 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 BCTs, 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 payers, including Medicare, insurance companies and patients, all of which have different billing requirements. We generally bill third-party payers 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 payers;
- compliance with complex federal and state regulations related to billing Medicare;
- risk of government audits related to billing Medicare;
- disputes among payers as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payers, 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 payer. 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 payers 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. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payer 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 payers, 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 payers based on the specific payer 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 payers 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 payers, 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 due to the impact of the COVID-19 pandemic.

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.

Our business strategy is to pursue increased international expansion, including partnering with academic and commercial testing laboratories, and introducing our technology outside the United States as part of in vitro diagnostic (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 payer systems, multiple payer-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, 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.

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

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high

unemployment, precipitated an economic slowdown and recession. If the economic climate deteriorates, our business, including our access to patient samples and the addressable market for products or diagnostic assays that we may successfully develop, as well as the financial condition of our suppliers and our third-party payers, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

****If our security measures, or those maintained on our behalf, are compromised now, or in the future, or the security, confidentiality, integrity or availability of our information systems, software, services, networks, communications or data is compromised, limited or fails, our business could experience a material adverse impact, including, without limitation, a material interruption to our operations, harm to our reputation, significant fines, penalties, liability, breach or triggering of data protection laws, policies, or other data protection obligations, or a loss of customers or sales.***

In the ordinary course of our business, we may collect, process, store and transmit proprietary, confidential and sensitive information, personal data (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. Additionally, we depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing software provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including assay processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities.

Despite the implementation of security measures, however, our infrastructure, or the infrastructure of third parties upon whom we rely (including the Internet and related systems), may be vulnerable to cyberattacks, physical break-ins, fires, telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, and similar disruptive problems. Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. In addition to traditional computer “hackers,” threat actors, software bugs, malicious code (such as viruses and worms), personnel misconduct or error, employee theft or misuse, denial-of-service attacks (such as credential stuffing), and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). We may also be the subject of phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data or other computer assets, adware or other similar issues. Additionally, 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 data (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). 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. Additionally, due to the COVID-19 pandemic and our remote workforce, there is an increased risk to our information technology assets and data. 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 remediate actual and potential vulnerabilities.

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 data or our customers’ data, or disrupt our ability to provide our platform or our service providers’ ability to support our services or develop or deliver our products. For example, despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing assays; providing assay results to medical oncologists, neuro-oncologists, surgical oncologists, urologists, pulmonologists, pathologists, and other physicians; billing payers; processing reimbursement appeals; handling patient or physician inquiries; conducting research and development activities and managing the administrative aspects of our business. 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. 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; temporary or permanent bans on all or some processing of personal data (which could impact our ability to conduct tests or develop our products); or orders to destroy or not use personal data. Further, individuals or other relevant stakeholders could sue us for our actual or perceived failure to comply with our security obligations including, without limitation, in class action litigation. Security incidents could also result in indemnity obligations, negative publicity and financial loss. Security incidents and vulnerabilities may cause some of our customers and users to stop using our services and our failure, or perceived failure, to meet expectations with regard to the security, integrity, availability and confidentiality of our systems and sensitive data could damage our reputation and affect our ability to retain customers, attract new

customers and grow our business. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, contracts, policies or data other protection obligations related to information security or security incidents.

Applicable data protection laws, contracts, policies and other data protection obligations may require us to notify relevant stakeholders of security including affected individuals, customers, regulators, the media and others. For example, the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and subsequently by the Final Omnibus Rule adopted in 2013, imposes notification requirements on covered entities in the event that certain health information has been used, accessed or disclosed without authorization. Additionally, all fifty states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose additional data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Disclosures following a security incident may be costly, and the disclosure or the failure to comply with such requirements could lead to material adverse impacts such as negative publicity, loss of customer confidence in our services or security measures, regulatory investigations or actions, private or government claims, litigation and fines and penalties.

Regulatory 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, President Trump signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties effective January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and eliminating the implementation of certain ACA-mandated fees, including but not limited to the Medical Device Excise Tax. 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. Thus, the ACA will remain in effect in its current form. 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, which began on February 15, 2021 and remained open through August 15, 2021. 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. 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 payer (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 to our tests that were impacted did not materially affect our payments beginning in 2018; however, we cannot predict how this may change future payment in coming years. In January 2020, CMS announced that data reporting for clinical diagnostic laboratory tests was delayed by one year. Additionally, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law in March 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, further delayed the reporting period. The next data reporting period is now January 1, 2022 through March 31, 2022 and will be based on the data collection period of January 1, 2019 through June 30, 2019. CMS further clarified that reporting will resume on a three-year cycle thereafter (i.e. 2025, 2028, etcetera). In addition, CMS updated the statutory phase-in provisions such that, for 2020, the rates for clinical diagnostic laboratory tests may not be reduced by more than 10% of the

rates for 2019. Pursuant to the CARES Act, the statutory phase-in of payment reductions has been extended through 2024, with a 0% reduction cap for 2021, and a 15% reduction cap for each of 2022, 2023, and 2024. 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 2030 unless additional congressional action is taken. COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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 the budget reconciliation process.

In April 2020, the CMS announced that it would increase the reimbursement for certain COVID-19 molecular tests making use of high-throughput technologies developed by the private sector that allow for increased testing capacity, faster results, and more effective means of combating the spread of the virus to \$100 per test, effective April 14, 2020. However, beginning January 1, 2021, Medicare changed the base reimbursement rate for COVID-19 diagnostic tests run on high-throughput technologies to \$75 per test with an additional payment of \$25 per test if certain additional requirements are met. We are currently reviewing how this reimbursement policy will impact laboratories and the patients we serve.

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.

In addition, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, particularly in light of the new presidential administration, or how any future legislation or regulation may affect us. 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 payers 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 payers, 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 payers, such as managed care organizations and government payers (e.g., Medicare and Medicaid), pay a substantial portion of the assay price. Coverage and reimbursement by a third-party payer may depend on a number of factors, including a payer'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 payer 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 payers 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 payer generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic assays, seeking payer 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 payers 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 payers 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 payers 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 payers for a significant portion of our revenues and if these or other payers stop providing reimbursement or decrease the amount of reimbursement for our current assays and our planned future assays, our revenues could decline.***

Approximately 51% and 51% of total net revenues during the year ended December 31, 2020 and the nine months ended September 30, 2021, respectively, were associated with Medicare and CARES Act reimbursement. Approximately 20% and 21% of total net revenues during the year ended December 31, 2020 and the nine months ended September 30, 2021, 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 payer 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 payers 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. Payers 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 payers 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 payers 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 payers) 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 payer 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 payers 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 payers 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 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. Although approximately 86% and 90% of all billable cases received, excluding COVID-19 testing cases, during the year ended December 31, 2020 and the nine months ended September 30, 2021, respectively, relate to our Target-Selector™ biomarker assays, we continue to receive orders for traditional enumeration testing, which counts disease burden, and therefore the enumeration testing receives no payment from Medicare based upon the existing coverage decision. The CTC enumeration counts disease burden and is a prognostic assay, and although valuable, it does not meet many of the medical necessity requirements of Medicare and the payers. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing for some of our Target-Selector™ 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 payer 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.

****We may not receive breakthrough device designation by the FDA for our Target-Selector CSF Assay, and even if we do, such designation may not lead to a faster development, regulatory review or clearance process, and it may not increase the likelihood that the assay will receive marketing authorization from the FDA.***

Following the full commercial launch of our CSF assay, CNSide™, we submitted an initial application for Breakthrough Device Designation to the FDA in the second quarter of 2021. While that initial submission was denied, we intend to continue to pursue Breakthrough Device Designation for CNSide™ and are gathering data based on the feedback provided by the FDA to further support the submission. The FDA's breakthrough devices program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and healthcare providers with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket approval, 510(k) clearance and de novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

Even if received, breakthrough device designation may not result in a faster development process, review or clearance compared to conventional FDA procedures and does not assure ultimate marketing authorization by the FDA. In addition, even if a product qualifies as a breakthrough device, the FDA may later decide that the product no longer meets the conditions for qualification and revoke such designation.

Long payment cycles of Medicare, Medicaid and/or other third-party payers, 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 payers 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 payers 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 payers 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 payer can focus its review on clinical utility.

The container we provide for collection and transport of blood samples from a health care provider to our clinical laboratory, as well as our BCTs, 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.

Our BCTs and Target Selector kits are marketed for RUO and distributed and sold to end users, some of which will be researchers and institutions while other end users could be labs performing clinical testing that will create their own LDTs. Some end users may assert that our ROU products caused their assays to perform inadequately or give erroneous results. If that was the case, we could potentially incur additional liabilities.

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 1 of our 15 CLIA validated assays 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 payers, 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 may find it necessary to engage contract research organizations 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 payer” statute);
- HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing 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) and teaching hospitals, and certain physician ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives during the previous year; 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 payer, 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 privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security, including laws and regulations related to health information. We may expend significant resources to comply and any failure or perceived failure to comply with such obligations could result in enforcement or litigation (which could result in material criminal and civil penalties), a disruption of the development or delivery of our products and services, reputational harm or other adverse effects.***

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share 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.

For example, HIPAA, as amended by HITECH, and the respective implementing regulations, imposes limitations on the use and disclosure of an individual's healthcare information by certain healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services involving the creation, receipt, maintenance or transmission of individually identifiable health information for or on behalf of covered entities, collectively referred to as business associates as well as their covered subcontractors. HITECH also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general.

HHS has issued privacy regulations that regulate the use and disclosure of protected health information by covered entities engaging in certain electronic transactions or "standard transactions." They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information or to request restrictions on the use or disclosure of protected health information. The HIPAA security regulations establish administrative, physical and technical standards for maintaining the confidentiality, integrity and availability of protected health information in electronic form. These standards apply to covered entities and also to business associates or third parties providing services to covered entities involving the use or disclosure of protected health information. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information. As a result, we may be required to comply with both HIPAA privacy regulations and varying state privacy and security laws, as well as other obligations.

Moreover, HITECH, among other things, established certain health information security breach notification requirements, which were later further modified by the Final Omnibus Rule. In the event of a breach of unsecured protected health information, a covered entity must notify each individual whose protected health information is breached, federal regulators, and in some cases, the local or national media. Certain breaches may be publicized by federal regulators who publicly identify the breaching entity, the circumstances of the breach and the number of individuals affected.

These laws contain significant fines and other penalties for wrongful use or disclosure of protected health information, in addition to other consequences such as litigation, investigations, and enforcement actions.

Additionally, states within the United States have enacted data breach notification laws, personal data privacy laws, and consumer protection privacy laws. For example, the California Consumer Privacy Act of 2018 (“CCPA”) imposes several obligations on covered businesses, including requiring specific disclosures related to a business’s collection, use and sharing of personal data, new operational practices, and requirements to respond to requests from California residents related to their personal data (e.g. requests to understand what personal data is collected, to delete the consumer’s personal data, and to opt out of certain disclosures of personal data). The CCPA provides for significant civil penalties as well as a private right of action for data breaches and statutory damages, which are expected to increase data breach class action litigation and result in significant legal exposure. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, we may be or may become subject to the CCPA and other similar laws, which could impact our business activities. In addition, it is anticipated that the California Privacy Rights Act of 2020 (“CPRA”), effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on the retention of personal data, expand the types of data breaches subject to the CCPA’s private right of action, and establish 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 its Consumer Data Protection Act, and Colorado recently passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. Other data privacy and security laws have also been proposed and may be enacted.

Additionally, the privacy laws in the European Union have also been significantly reformed, to which we may be subject. For example, in May 2018, the European Union’s General Data Protection Regulation (“EU GDPR”), took effect in the European Economic Area (EEA). The GDPR governs the collection, use, disclosure, transfer or other 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 UK GDPR, which largely mirrors the EU GDPR in UK national law. The relationship between the UK GDPR and the EU GDPR in relation to certain aspects of data protection law remains unclear, and it is unclear how the UK’s data protection laws and regulations will develop in the medium to longer term.

The number and scope of obligations related to data privacy and security, including but not limited to the complex requirements of HIPAA, and HITECH, and GDPR, are rapidly evolving and are subject to change and potentially in conflict with each other. As a result, preparing for and complying with these obligations requires significant resources and potentially significant changes to our 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. Adding to the complexity is that our operations are evolving, and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services.

We may publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal data and/or other confidential information. Although we endeavor to comply with our published policies, other documentation, and all applicable privacy and security laws, regulations and guidance, 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 our published policies and documentation. If we fail, or are perceived to have failed, to address or comply with obligations related to data privacy and security, we could face foreign, federal, state, or local government enforcement actions that could include investigations, fines, penalties, audits and inspections; additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data; and orders to destroy or not use personal data. Individuals, data protection regulators or supervisory authorities or other relevant stakeholders could file claims against us for our actual or perceived failure to comply with our data privacy and security obligations, including, without limitation, in class action litigation. Any of these events could have a material adverse effect on our reputation, business, or financial condition, and could lead to a loss of actual or prospective customers, collaborators or partners; interrupt or stop clinical trials; result in an 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 result in diversion of management’s attention and 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. 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 United States Patent and Trademark Office, or 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. 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.

For example, in August 2016, we received a letter from MolecularMD Corp. offering a license to two U.S. Patents owned by the Memorial Sloan-Kettering Cancer Center, and licensed to MolecularMD Corp., that are relevant to one of the biomarkers we detect in our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector™ assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector™ assay. One of the two patents is expected to expire in 2026. The other patent is expected to expire in 2028. Although we believe that the claims of both patents relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector™ Assay and our Liquid Biopsy Lung

Cancer Resistance Profile Target-Selector™ Assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

In addition, we are aware of a U.S. Patent owned by Amgen, Inc. that is relevant to one of the biomarkers we detect in our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector™ assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector™ assay. The patent is expected to expire in 2028. Although we believe that the claims of the patent relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector™ assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector™ assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

We are also aware of a U.S. Patent owned by Genentech, Inc. that is relevant to one of the biomarkers we detect in our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector™ assay and our Liquid Biopsy Colon Cancer Profile Target-Selector™ assay. The patent is expected to expire in 2025. Although we believe that the claims of the patent relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector™ assay and our Liquid Biopsy Colon Cancer Profile Target-Selector™ assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

In addition, in July 2016, we received a communication from the Mayo Foundation for Medical Education and Research (“Mayo”) offering a license to a U.S. Patent owned by Mayo that is relevant to an antibody that we use in our Liquid Biopsy Immuno-Oncology PD-L1 assay. The patent is expected to expire in 2021. At present, we believe that we will need a license to this patent to continue commercializing our Liquid Biopsy Immuno-Oncology PD-L1 assay. We are currently in discussions with Mayo and believe a license can be obtained on commercially reasonable terms. However, if we are unable to secure such a license, we may be liable for past damages, and our business could be materially and adversely affected.

In addition, in December 2020, we received a communication from counsel for RavGen, Inc., or RavGen, offering to discuss licensing terms for certain patents owned by RavGen, which RavGen’s communication alleged are relevant to Biocept’s Target Selector™ Liquid Biopsy test kits and panels. If we are unable to secure a license on commercially reasonable terms, and if RavGen subsequently files suit and a court or jury makes a determination that our test kits and panels infringe any valid RavGen patent claims, then we may be liable for damages, and our business could be materially and adversely affected. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our products or services, the holders of any such patents may be able to block our ability to commercialize such products or services unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all.

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, through licenses from third parties and 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 payers;
- 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 man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- 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, 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 and September 2019, 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. Although we were able to regain compliance with the Nasdaq continued listing requirements discussed in the May 2016, June 2016, November 2016, January 2018 and September 2019 letter, there can be no assurance that we will be able to maintain compliance with the continued listing requirements of the Nasdaq Capital Market. If we fail to 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 of the ongoing COVID-19 pandemic on our core oncology business;
- the impact of a COVID-19 vaccine on our ability to generate revenues from our RT-PCR COVID-19 testing business;
- third-party payer 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. For example, in May 2020, the SEC declared effective a shelf registration statement filed by us. This shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$100 million. In May 2021, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (the “Sales Agent”), under which we may issue and sell from time to time up to \$25,000,000 of our common stock through or to the Sales Agent, as sales agent or principal. Any sale of shares of our common stock under the Sales Agreement will be made under our shelf registration statement on Form S-3. 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. As of September 30, 2021, \$10.9 million of our common stock remained available for sale under the Sales Agreement. Depending on a variety of factors, including market liquidity of our common stock, the sale of shares under this shelf registration statement may cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this shelf registration statement, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

We had outstanding 16,842,246 shares of common stock as of November 8, 2021, most of which are not subject to resale restrictions under Rule 144 of the Securities Act. In addition, as of November 8, 2021, we had outstanding preferred stock convertible into 46,585 shares of our common stock, options to purchase 2,533,162 shares of our common stock, 36 shares of common stock were issuable upon the settlement of outstanding restricted stock units, or RSUs, and 867,026 shares of our common stock were issuable upon the exercise of outstanding warrants. Shares issued upon the exercise of stock options or upon the settlement of outstanding RSUs 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 are unable to favorably assess the effectiveness of our internal control over financial reporting, investors may lose confidence in our financial reporting and our stock price could be materially adversely affected.

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. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as a “non-accelerated filer,” with less than \$100 million in annual revenues, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading 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 “smaller reporting company” with less than \$100 million in annual revenues, 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 financial statement restatements and require us to incur the expense of remediation.

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, the Tax Cuts and Jobs Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Cuts and Jobs Act or future 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 the Tax Cuts and Jobs Act as modified by the CARES Act, 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 in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act. 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, 2020, we had estimated federal and state net operating loss carryforwards of approximately \$75.4 million and \$44.2 million, respectively, and estimated federal and California research and development tax credits of approximately \$577,000 and \$3.9 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 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. For example, California imposed limits on the usability of California state net operating losses and certain state tax credits in tax years beginning after 2019 and before 2023. 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

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.

Use of Proceeds

Not applicable.

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.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
3.1	<u>Certificate of Amendment of Certificate of Incorporation (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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
3.4	<u>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).</u>
3.5	<u>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).</u>
3.6	<u>Certificate of Designation of Preference, 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).</u>
3.7	<u>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).</u>
4.1	Reference is made to Exhibits <u>3.1</u> , <u>3.2</u> , <u>3.3</u> , <u>3.4</u> , <u>3.5</u> , <u>3.6</u> and <u>3.7</u> .
4.2	<u>Specimen Common Stock certificate of Biocept, Inc. (incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 16, 2020).</u>
4.3	<u>Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of April 30, 2014, by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).</u>
4.4	<u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), as amended, filed with the SEC on February 6, 2015).</u>
4.5	<u>Form of Common Stock Purchase Warrant issued to the investors under the Securities Purchase Agreement, dated April 29, 2016, by and among Biocept, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 29, 2016).</u>
4.6	<u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.16 of the Registrant's Post-Effective Amendment to Registration Statement on Form S-1 (File No. 333-213111), filed with the SEC on October 14, 2016).</u>
4.7	<u>Form of Common Stock Purchase Warrant issued to the investors under the Securities Purchase Agreement, dated March 28, 2017, by and among Biocept, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2017).</u>
4.8	<u>Common Stock Purchase Warrant issued by the Registrant in favor of Ally Bridge LB Healthcare Master Fund Limited under the Common Stock and Warrant Purchase Agreement dated August 9, 2017 (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 10, 2017).</u>
4.9	<u>Common Stock Purchase Warrant issued in favor of Dawson James Securities, Inc. under the Securities Purchase Agreement dated December 5, 2017 (incorporated by reference to Exhibit 4.18 of the Registrant's Registration Statement on Form S-1 (File No. 333-221648), as amended, filed with the SEC on January 22, 2018).</u>
4.10	<u>Form of Warrant to Purchase Common Stock issued to the investors under the Securities Purchase Agreement, dated January 26, 2018 (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on January 30, 2018).</u>
4.11	<u>Warrant Agency Agreement dated August 13, 2018 by and between the Registrant and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 13, 2018).</u>
4.12	<u>Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 3.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-225147), as amended, filed with the SEC on July 11, 2018).</u>

4.13	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Registrant’s Current Report on Form 8-K, filed with the SEC on September 24, 2018).
4.14	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of the Registrant’s Current Report on Form 8-K, filed with the SEC on September 24, 2018).
4.15	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.24 of the Registrant’s Registration Statement on Form S-1 (File No. 333-228566), filed with the SEC on November 28, 2018).
4.16	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.25 of the Registrant’s Registration Statement on Form S-1 (File No. 333-228566), filed with the SEC on November 28, 2018).
4.17	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Registrant’s Current Report on Form 8-K, filed with the SEC on March 18, 2019).
4.18	Form of Series C Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Registrant’s Current Report on Form 8-K, filed with the SEC on May 29, 2019).
4.19	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.19 of the Registrant’s Registration Statement on Form S-1 (File No. 333-234459), as amended, filed with the SEC on December 6, 2019).
4.20	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.20 of the Registrant’s Registration Statement on Form S-1 (File No. 333-234459), as amended, filed with the SEC on November 8, 2019).
4.21	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 of the Registrant’s Current Report on Form 8-K, filed with the SEC on December 11, 2019).
4.22	Form of Warrant Amendment (incorporated by reference to Exhibit 4.1 of the Registrant’s Current Report on Form 8-K, filed with the SEC on January 9, 2020).
4.23	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of the Registrant’s Current Report on Form 8-K, filed with the SEC on January 9, 2020).
10.1+	Amended and Restated 2013 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant’s Quarterly Report on Form 10-Q, filed with the SEC on August 16, 2021).
31.1	Certification of Michael Nall, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Timothy Kennedy, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Michael Nall, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Timothy Kennedy, Chief 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)

+ Indicates management contract or compensatory plan.

* 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.

(Registrant)

Date: November 15, 2021

By: /s/ Michael W. Nall
Michael W. Nall
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 15, 2021

By: /s/ Timothy C. Kennedy
Timothy C. Kennedy
Chief Financial Officer, Chief Operating Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

I, Michael W. Nall, 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Michael W. Nall

Michael W. Nall

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, Timothy Kennedy, 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Timothy Kennedy

Timothy Kennedy

Chief Financial Officer, Chief Operating Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

I, Michael W. Nall, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 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 September 30, 2021 (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: November 15, 2021

/s/ Michael W. Nall

Michael W. Nall
President and Chief Executive Officer
(Principal Executive 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.

CERTIFICATION

I, Timothy Kennedy, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 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 September 30, 2021 (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: November 15, 2021

/s/ Timothy Kennedy

Timothy Kennedy

Chief Financial Officer, Chief Operating Officer

(Principal Financial and Accounting 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.