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 March 31, 2020

OR

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

For the transition period from _____ to _____.

Commission file number: 001-36284

Biocept, Inc.

(Exact name of registrant as specified in its charter)

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

5810 Nancy Ridge Drive, 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of May 8, 2020, there were 131,100,876 shares of the Registrant’s common stock outstanding.

BIOCEPT, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED
March 31, 2020

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IMPORTANT NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements included or incorporated by reference in this Quarterly Report other than statements of historical fact, are forward-looking statements. You can identify these and other forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" 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.

Item 1. Financial Statements

Biocept, Inc.

Condensed Balance Sheets

	December 31, 2019	March 31, 2020 (unaudited)
Current assets:		
Cash	$ 9,301,406	$ 21,493,192
Accounts receivable, net	3,527,078	3,418,897
Inventories, net	767,986	918,698
Prepaid expenses and other current assets	296,127	429,131
Total current assets	13,892,597	26,259,918
Fixed assets, net	1,504,330	1,463,128
Lease right-of-use assets - operating	729,330	419,461
Lease right-of-use assets - finance	1,606,387	1,669,823
Total assets	$ 17,732,644	$ 29,812,330
Current liabilities:		
Accounts payable	$ 2,011,827	$ 2,407,158
Accrued liabilities	1,980,204	2,365,988
Current portion of lease liabilities - operating	842,452	484,102
Current portion of lease liabilities - finance	724,329	718,480
Supplier financing	—	56,068
Total current liabilities	5,558,812	6,031,796
Non-current portion of lease liabilities - finance	973,189	1,050,429
Total liabilities	6,532,001	7,082,225
Commitments and contingencies (see Note 10)		
Shareholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 authorized; 2,133 shares issued and outstanding at December 31, 2019 and March 31, 2020.	—	—
Common stock, $0.0001 par value, 150,000,000 authorized; 54,738,485 issued and outstanding at December 31, 2019; 108,707,392 issued and outstanding at March 31, 2020.	5,474	10,871
Additional paid-in capital	256,912,358	276,780,535
Accumulated deficit	(245,717,189)	(254,061,301)
Total shareholders' equity	11,200,643	22,730,105
Total liabilities and shareholders' equity	$ 17,732,644	$ 29,812,330

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

Biocept, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

	For the three months ended March 31,	
	2019	**2020**
Net revenues	$ 1,024,239	$ 1,446,549
Costs and expenses:		
Cost of revenues	2,599,364	2,946,858
Research and development expenses	1,223,291	1,312,676
General and administrative expenses	1,681,837	1,904,433
Sales and marketing expenses	1,374,560	1,465,115
Total costs and expenses	6,879,052	7,629,082
Loss from operations	(5,854,813)	(6,182,533)
Other expense:		
Interest expense	(61,974)	(56,696)
Warrant inducement expense	—	(2,102,109)
Total other expense	(61,974)	(2,158,805)
Loss before income taxes	(5,916,787)	(8,341,338)
Income tax expense	—	—
Net loss and comprehensive loss	$ (5,916,787)	$ (8,341,338)
Deemed dividend related to warrants down round provision	(99,743)	(2,774)
Net loss attributable to common shareholders	$ (6,016,530)	$ (8,344,112)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:		
Basic	9,792,093	78,999,924
Diluted	9,792,093	78,999,924
Net loss per common share:		
Basic	$ (0.61)	$ (0.11)
Diluted	$ (0.61)	$ (0.11)

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

Biocept, Inc.

Statement of Shareholders' Equity
(Unaudited)

For the three months ended March 31, 2019	Common Stock		Series A Convertible Preferred Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Total
Balance at December 31, 2018	4,629,174	$ 463	4,417	$ —	$ 223,499,634	$ (220,457,578)	$ 3,042,519
Stock-based compensation expense	—	—	—	—	102,459	—	102,459
Shares issued upon exercise of common stock warrants	5,985	1	—	—	4,747	—	4,748
Deemed dividends related to warrants downround provision	—	—	—	—	99,743	(99,743)	—
Shares and warrants issued for January 2019 financing transaction, net of issuance costs	990,000	99	—	—	2,032,212	—	2,032,311
Shares and warrants issued for February 2019 financing transaction, net of issuance costs	6,250,000	625	—	—	6,602,110	—	6,602,735
Shares issued for January 2019 financing transaction overallotment, net of issuance costs	538,867	54	—	—	592,252	—	592,306
Shares and warrants issued for March 2019 financing transaction, net of issuance costs	5,950,000	595	—	—	7,553,198	—	7,553,793
Shares issued upon conversion of preferred stock	503,438	50	(2,278)	—	(50)	—	—
Net loss	—	—	—	—	—	(5,916,787)	(5,916,787)
Balance at March 31, 2019	18,867,464	$ 1,887	2,139	$ —	$ 240,486,305	$ (226,474,108)	$ 14,014,084

For the three months ended March 31, 2020	Common Stock		Series A Convertible Preferred Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Total
Balance at December 31, 2019	54,738,485	$ 5,474	2,133	$ —	$ 256,912,358	$ (245,717,189)	$ 11,200,643
Stock-based compensation expense	—	—	—	—	142,964	—	142,964
Shares issued upon exercise of common stock warrants	6,961,407	696	—	—	2,306,012	—	2,306,708
Shares issued upon cashless exercise of common stock warrants	6,080,000	608	—	—	(608)	—	—
Deemed dividends related to warrants downround provision	-	—	—	—	2,774	(2,774)	—
Shares issued for March 2, 2020 financing transaction, net of issuance costs	23,000,000	2,300	—	—	8,563,200	—	8,565,500
Shares issued for March 4, 2020 financing transaction, net of issuance costs	16,000,000	1,600	—	—	6,091,961	—	6,093,561
Shares issued for exercise of December 2019 overallotment warrants, net of issuance costs	1,927,500	193	—	—	659,765	—	659,958
Warrant inducement expense	—	—	—	—	2,102,109	—	2,102,109
Net loss	—	—	—	—	—	(8,341,338)	(8,341,338)
Balance at March 31, 2020	108,707,392	$ 10,871	2,133	$ —	$ 276,780,535	$ (254,061,301)	$ 22,730,105

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

Biocept, Inc.

Condensed Statements of Cash Flows

(Unaudited)

	For the three months ended March 31,	
	2019	2020
Cash Flows from Operating Activities		
Net loss	$ (5,916,787)	$ (8,341,338)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	222,128	242,758
Amortization of right-of-use assets	(37,806)	(48,481)
Inventory reserve	531	25,240
Stock-based compensation	102,459	142,964
Warrant inducement expense	—	2,102,109
Increase/(decrease) in cash resulting from changes in:		
Accounts receivable, net	(303,536)	108,181
Inventory	9,407	(175,952)
Prepaid expenses and other current assets	155,713	(133,004)
Accounts payable	152,635	412,879
Accrued liabilities	367,744	385,784
Net cash used in operating activities	(5,247,512)	(5,278,860)
Cash Flows from Investing Activities:		
Purchases of fixed assets	(32,898)	(18,507)
Net cash used in investing activities	(32,898)	(18,507)
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock and warrants	16,781,145	14,659,061
Proceeds from exercise of common stock warrants	4,748	2,306,708
Payments on finance leases	(166,658)	(136,574)
Proceeds from exercise of overallotment warrants	—	659,958
Net cash provided by financing activities	16,619,235	17,489,153
Net increase in Cash	11,338,825	12,191,786
Cash at Beginning of Period	3,423,373	9,301,406
Cash at End of Period	$ 14,762,198	$ 21,493,192
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 61,974	$ 56,696

Non-cash Investing and Financing Activities:

Fixed assets purchased totaling approximately $149,000 and $208,000 during the three months ended March 31, 2019 and 2020, respectively, were recorded as finance leases and were excluded from cash purchases in the Company's statements of cash flows (see Note 6).

The amount of unpaid fixed asset purchases excluded from cash purchases in the Company's statements of cash flows increased from approximately $25,000 at December 31, 2018 to approximately $86,000 at March 31, 2019 and decreased from approximately $32,000 at December 31, 2019 to approximately $17,000 at March 31, 2020.

On January 1, 2019, the Company adopted the accounting rules in ASC Topic 842, Leases (ASC 842), and as a result, recorded net lease right-of-use assets of $1.9 million related to its operating lease, and recorded operating lease liabilities of $2.2 million. In addition, in accordance with the guidance, $1.4 million of assets under capital leases previously classified in the property, plant, and equipment section of the balance sheet were reclassified to lease right-of-use assets.

On January 18, 2019, the Company completed an offering of 990,000 shares of the Company's common stock. The shares were sold at a purchase price of $2.25 per share and the net proceeds to the Company from this offering were approximately $2.0 million, after deducting expenses related to the offering including dealer-manager fees and expenses.

On February 12, 2019, the Company received net cash proceeds of approximately $6.6 million as a result of the closing of a follow-on public offering of 6,250,000 shares of its common stock and warrants to purchase up to an aggregate of 6,250,000 shares of its common stock at a combined offering price of $1.20 per unit. All warrants sold in this offering have an exercise price of $1.20 per share, are exercisable immediately and expire five years from the date of issuance. In addition, the Company sold warrants to purchase up to an aggregate of 937,500 shares of the Company's common stock in connection with the partial exercise of the over-allotment option granted to the underwriters. Upon closing of the transaction, warrants to purchase 915,000 shares were issued pursuant to the placement agents' partial exercise of their overallotment. The estimated aggregate grant date fair value on a relative fair value basis of approximately $6.8 million associated with these warrants was recorded as an offset to additional paid-in capital (see Note 4).

Pursuant to the down round adjustment feature of the January 2018 warrants, the exercise price of these warrants was adjusted to the $1.20 offering price per share in the February 2019 financing transaction and it resulted in recording a deemed dividend of $99,000.

On March 19, 2019, the Company received net cash proceeds of approximately $7.6 million as a result of completing a registered direct offering of 5,950,000 shares at a negotiated purchase price of $1.37 per share. In addition, in a concurrent private placement, the Company issued to purchasers a warrant to purchase one share of the Company's common stock for each share purchased for cash in the offering. All warrants issued in this offering have an exercise price of $1.25 per share, are exercisable immediately upon issuance and expire 5.5 years following the date of issuance. The estimated aggregate grant date fair value on a relative fair value basis of approximately $6.0 million associated with these warrants was recorded as an offset to additional paid-in capital (see Note 4).

In January 2020, the Company issued an aggregate of 6,927,258 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 6,927,258 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 896,578 shares of common stock issued by the Company in January 2018 was adjusted from $0.405 to $0.3495 per share.

In January 2020, the Company issued 1,927,500 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.

On March 2, 2020, the Company received net cash proceeds of approximately $8.6 million from a registered direct offering to certain institutional investors of 23,000,000 shares of common stock at a negotiated purchase price of $0.40 per share.

On March 4, 2020, the Company received net cash proceeds of approximately $6.1 million from a registered direct offering to certain institutional investors of 16,000,000 shares of common stock at a negotiated purchase price of $0.41 per share.

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

1. The Company, Business Activities and Basis of Presentation

The Company and Business Activities

The Company was founded in California in May 1997 and is an early stage 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.

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, 2019 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, 2019, filed with the U.S. Securities and Exchange Commission, or SEC, with our Annual Report on Form 10-K on March 27, 2020 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.

Significant Accounting Policies

During the three months ended March 31, 2020, 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, 2019, except as described in Recent Accounting Pronouncements below.

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. Commencing on January 1, 2018, the Company recognizes revenue in accordance with ASC 606,

Revenue from Contracts with Customers, or ASC 606, which requires that an entity recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted the provisions of ASC 606 using the modified retrospective application method applied to all contracts, which did not impact amounts previously reported by the Company, nor did it require a cumulative effect adjustment upon adoption, as the Company's method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for the Company to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

Contracts

For its commercial revenues, while the Company markets directly to physicians, its customer is the patient. Patients do not 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 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, 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. 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. Revenue recognized from changes in transaction prices was not significant during the three months ended March 31, 2019 and 2020.

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 months ended March 31, 2019 and 2020 disaggregated by source and nature are as follows:

	For the three months ended March 31,	
	2019	2020
Net revenues from contracted payers*	$ 481,420	$ 500,188
Net revenues from non-contracted payers	495,009	817,413
Development services revenues	42,498	60,329
Kits and Blood Collection Tubes (BCT)	5,312	68,619
Total net revenues	$ 1,024,239	$ 1,446,549

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

	For the three months ended March 31,	
	2019	2020
Net commercial revenues recognized upon delivery	$ 976,429	$ 1,317,601
Development services revenues recognized upon delivery	42,498	60,329
Kits and Blood Collection Tubes (BCT)	5,312	68,619
Total net revenues	$ 1,024,239	$ 1,446,549

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 months ended March 31, 2019 and 2020 were as follows:

	For the three months ended March 31,	
	2019	2020
Medicare and Medicare Advantage	45%	37%
Blue Cross Blue Shield	14%	29%
United Healthcare	12%	6%

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, 2019 and March 31, 2020 were as follows:

	December 31, 2019	March 31, 2020
Blue Cross Blue Shield	26%	27%
Medicare and Medicare Advantage	17%	13%
United Healthcare	12%	10%
Aetna	7%	10%

Recent Accounting Pronouncements

In November 2018, the FASB issued authoritative guidance clarifying the interaction between Collaborative Arrangements (Topic 808) and Revenue from Contracts with Customers (Topic 606) to address diversity in practice related to how companies account for collaborative arrangements. For public companies, this guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Revenue from Contracts with Customers (Topic 606). The Company adopted this guidance for the fiscal year beginning on January 1, 2020, and determined that the adoption of this guidance does not have a material impact on its financial statements or disclosures.

2. Liquidity and Going Concern Uncertainty

As of March 31, 2020, cash totaled $21.5 million and the Company had an accumulated deficit of $254.1 million. For the year ended December 31, 2019 and the three months ended March 31, 2020, the Company incurred net losses of $25.1 million and $8.3 million, respectively, and had negative cash flows from operations of $5.2 million and $5.3 million, respectively. At March 31, 2020, the Company had aggregate net interest-bearing indebtedness of $1.8 million, of which $718,000 was due within one year, in addition to $2.9 million of other non-interest-bearing current liabilities. While Management believes that, absent the COVID-19 pandemic, based on historical and planned cash usage the Company's current cash would have supported its operations through most of 2021, due to the uncertainty introduced by the impact of COVID-19 on revenues and cash usage, there is uncertainty as to the period of time for which existing cash can support the Company's ongoing operations. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these financial statements were issued. The accompanying financial statements and notes have been prepared assuming that the Company will continue as a going concern. The accompanying 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.

While the Company is currently in the commercialization stage of operations, the Company has not yet achieved profitability and anticipates that it will continue to incur net losses and negative cash flows from operations for the foreseeable future. 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. These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these financial statements were

issued. The accompanying financial statements and notes have been prepared assuming that the Company will continue as a going concern. The accompanying 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.

On March 11, 2020 the World Health Organization declared the disease caused by the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. In addition, as we are located in California, we are currently under a shelter in place mandate and many of our clients worldwide are similarly impacted. As a healthcare provider, we are allowed to remain open in compliance with the shelter in place mandate and continue to provide critical information for patients diagnosed with cancer. However, the global outbreak of the COVID-19 coronavirus continues to rapidly evolve, and the extent to which the COVID-19 coronavirus 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 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. We estimate that the COVID-19 pandemic led to an approximate 15 to 25% decline in commercial volume from current customers, and 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 January 2020, the Company issued an aggregate of 6,927,258 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 6,927,258 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 896,578 shares of common stock issued by the Company in January 2018 was adjusted from $0.405 to $0.3495 per share.

In January 2020, the Company issued 1,927,500 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.

On March 2, 2020, the Company received net cash proceeds of approximately $8.6 million from a registered direct offering to certain institutional investors of 23,000,000 shares of common stock at a negotiated purchase price of $0.40 per share.

On March 4, 2020, the Company received net cash proceeds of approximately $6.1 million from a registered direct offering to certain institutional investors of 16,000,000 shares of common stock at a negotiated purchase price of $0.41 per share.

On April 16, 2020, the Company received net cash proceeds of approximately $9.6 million from a registered direct offering to certain institutional investors of 22,300,000 shares of common stock at a negotiated purchase price of $0.46 per share.

Management's Plan to Continue as a Going Concern

In order to continue as a going concern, 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. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. Based on the above, the Company's management concluded that the going concern uncertainty has not been alleviated and as such , there is substantial doubt about the Company's ability to continue as a going concern as of March 31, 2020.

3. Sales of Equity Securities

On January 18, 2019, the Company completed an offering of 990,000 shares of the Company's common stock. The shares were sold at a purchase price of $2.25 per share and the net proceeds to the Company from this offering were approximately $2.0 million, after deducting expenses related to the offering including dealer-manager fees and expenses.

On February 12, 2019, the Company received net cash proceeds of approximately $6.6 million as a result of the closing of a follow-on public offering of 6,250,000 shares of its common stock and warrants to purchase up to an aggregate of 6,250,000 shares of its common stock at a combined offering price of $1.20 per unit. All warrants sold in this offering have an exercise price of $1.20 per share, are exercisable immediately and expire five years from the date of issuance. In addition, the Company sold warrants to purchase up to an aggregate of 937,500 shares of the Company's common stock in connection with the partial exercise of the over-allotment option granted to the underwriters. Upon closing of the transaction, warrants to purchase 915,000 shares were issued pursuant to the placement agents' partial exercise of their overallotment. Subsequent to the closing of this offering, no additional cash proceeds have been received from the exercise of warrants sold in this offering. On March 11, 2019, the underwriters exercised their overallotment

option for 538,867 shares of the Company's common stock related to the February 12, 2019 follow-on offering, purchasing shares at $1.20 per share for net cash proceeds of approximately $592,000.

Pursuant to the down round adjustment feature of the January 2018 warrants, the exercise price of these warrants was adjusted to the $1.20 price per share offering price in the February 2019 financing transaction.

On March 19, 2019, the Company received net cash proceeds of approximately $7.6 million as a result of completing a registered direct offering of 5,950,000 shares at a negotiated purchase price of $1.37 per share. In addition, in a concurrent private placement, the Company issued to purchasers a warrant to purchase one share of the Company's common stock for each share purchased for cash in the offering. All warrants issued in this offering have an exercise price of $1.25 per share, are exercisable immediately upon issuance and expire 5.5 years following the date of issuance.

In January 2020, the Company issued an aggregate of 6,927,258 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 6,927,258 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 896,578 shares of common stock issued by the Company in January 2018 was adjusted from $0.405 to $0.3495 per share. In January 2020, the Company issued 1,927,500 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 consolidated statements of operations for the three months ended March 31, 2020.

On March 2, 2020, the Company received net cash proceeds of approximately $8.6 million from a registered direct offering to certain institutional investors of 23,000,000 shares of common stock at a negotiated purchase price of $0.40 per share.

On March 4, 2020, the Company received net cash proceeds of approximately $6.1 million from a registered direct offering to certain institutional investors of 16,000,000 shares of common stock at a negotiated purchase price of $0.41 per share.

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 $208,000 during the three months ended March 31, 2020 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 present value of future lease payments based contractual payment amounts and estimated market rates in effect.

Other Fair Value Measurements

As of the closing of the Company's February 12, 2019 offering, the estimated grant date fair value of approximately $0.95 per share associated with the warrants to purchase up to 7,165,000 shares of common stock issued in this offering, or a total of approximately $6.8 million, was recorded as an offset to additional paid-in capital on a relative fair value basis. All warrants sold in this offering have an exercise price of $1.20 per share, are exercisable immediately and expire five 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	$	1.05
Exercise price	$	1.20
Expected dividend yield		0.00%
Discount rate-bond equivalent yield		2.49%
Expected life (in years)		5.00
Expected volatility		147.7%

As of the closing of the Company's March 19, 2019 offering, the estimated grant date fair value of approximately $1.01 per share associated with the warrants to purchase up to 5,950,000 shares of common stock issued in this offering, or a total of approximately $6.0 million, was recorded as an offset to additional paid-in capital on a relative fair value basis. All warrants sold in this offering have an exercise price of $1.25 per share, are exercisable immediately 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	$	1.12
Exercise price	$	1.25
Expected dividend yield		0.00%
Discount rate-bond equivalent yield		2.44%
Expected life (in years)		5.50
Expected volatility		140.0%

As of the closing of the Company's January 2020 warrant repricing and exchange transaction, the estimated grant date fair value of approximately $0.28 per share associated with the warrants to purchase up to 6,927,258 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 $0.3495 per share, are 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	$	0.30
Exercise price	$	0.3495
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 $1.20 and $1.25, respectively, to $0.3495 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 $0.27 per share, whereas the estimated fair value of the February 2019 warrants increased to $0.29 due to the adjustment of the exercise price, and the estimated fair value of the March 2019 warrants increased to $0.30 per share. There were 2,167,258 February 2019 warrants and 4,760,000 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, 2019	March 31, 2020
Fixed Assets		
Machinery and equipment	$ 2,857,538	$ 2,932,112
Furniture and office equipment	156,987	156,987
Computer equipment and software	1,552,891	1,552,891
Leasehold improvements	570,173	570,173
Construction in process	625,038	607,490
Total fixed assets, gross	5,762,627	5,819,653
Less accumulated depreciation and amortization	(4,258,297)	(4,356,525)
Total fixed assets, net	$ 1,504,330	$ 1,463,128
Accrued Liabilities		
Accrued payroll	$ 298,855	$ 523,552
Accrued vacation	622,792	693,389
Accrued bonuses	748,742	970,159
Accrued sales commissions	89,562	75,150
Accrued other	220,253	103,738
Total accrued liabilities	$ 1,980,204	$ 2,365,988

During the three months ended March 31, 2020, there were no disposals and $283,000 of fixed assets were acquired.

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 Property, Plant and Equipment 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 $3,125,000 and $3,422,000 at December 31, 2019 and March 31, 2020, respectively. Total accumulated depreciation related to financed equipment was approximately $1,606,000 and $1,752,000 at December 31, 2019 and March 31, 2020, respectively, and total depreciation expense related to financed equipment during the three months ended March 31, 2019 and 2020 was approximately $110,000 and $146,000, respectively.

On January 31, 2019, the Company executed an equipment financing commitment with a third-party lender for total proceeds of approximately $149,000, which was funded by the lender on February 1, 2019. Under the terms of the equipment financing agreement, which was accounted for as a finance lease transaction, the principal balance plus interest for the equipment are to be repaid in full after 36 monthly installments of $5,013 totaling approximately $180,000 through February 2022.

In February 2020, the Company entered into finance leases for a total capitalized amount of $197,000 for three pieces of equipment. Under the terms of the equipment financing agreement, which was accounted for as a finance lease transaction, the principal balance plus interest for the equipment are to be repaid in full in installments ranging from 48 to 60 monthly installments of $4,532 totaling approximately $265,000 through January 2025. In addition, in March 2020, the Company entered into a finance lease for a capitalized amount of $11,000 for an additional piece of equipment. Under the term of the equipment financing agreement, the principal amount plus interest are to be repaid in 48 monthly installments of $288 totaling approximately $14,000 through February 2024.

Operating Lease

The Company leases its primary laboratory and office facilities in San Diego, California. This lease is classified as an operating lease in accordance with the ASC 842 guidance. The average monthly cash payment for the operating lease is approximately $120,000 per month, and the lease term ends on July 31, 2020. 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%.

The Company is in good standing with its landlord and is negotiating terms associated with extending its lease for its current facility until a new facility becomes available to move into. Such terms have not yet been finalized.

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, 2019 and March 31, 2020 as follows:

	December 31, 2019	March 31, 2020
Lease right-of-use assets:		
Operating	$ 729,330	$ 419,461
Finance	1,606,387	1,669,823
Total	$ 2,335,717	$ 2,089,284

The following schedule sets forth the current portion of operating and finance lease liabilities as of December 31, 2019 and March 31, 2020:

	December 31, 2019	March 31, 2020
Current portion of lease liabilities:		
Operating	$ 842,452	$ 484,102
Finance	724,329	718,480
Total	$ 1,566,781	$ 1,202,582

The following schedule sets forth the long-term portion of operating and finance lease liabilities as of December 31, 2019 and March 31, 2020:

	December 31, 2019	March 31, 2020
Long-term portion of lease liability:		
Operating	$ —	$ —
Finance	973,189	1,050,429
Total	$ 973,189	$ 1,050,429

The following schedule represents the components of lease expense for the three months ended March 31, 2019 and March 31, 2020:

	For the three months ended	
	March 31, 2019	March 31, 2020
Lease cost		
Finance lease cost		
Amortization of right-of-use assets	$ 110,330	$ 144,530
Interest on lease liabilities	61,974	56,701
Operating lease cost	318,005	318,005
Total	$ 490,309	$ 519,236

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 March 31, 2020:

	Finance		Operating
	Minimum Lease Payments	Maintenance and Sales Tax Obligation Payments	Minimum Lease Payments
2020	$ 610,882	$ 67,647	$ 488,649
2021	593,225	72,933	—
2022	469,775	61,379	—
2023	345,759	61,978	—
Thereafter	120,050	12,656	—
Total payments	2,139,691	276,593	488,649
Less amount representing interest	(370,782)	—	(4,547)
Present value of payments	$ 1,768,909	$ 276,593	$ 484,102

The following schedule sets forth supplemental cash flow information related to operating and finance leases as of March 31, 2019 and March 31, 2020:

	For the three months ended	
	March 31, 2019	March 31, 2020
Other information		
Operating cash flows from finance leases	$ 61,974	$ 56,701
Operating cash flows from operating leases	$ 355,812	$ 366,487
Financing cash flows from finance leases	$ 166,658	$ 136,574

The aggregate weighted average remaining lease term was 3.18 years on finance leases and 0.34 years on operating leases as of March 31, 2020. The aggregate weighted average discount rate was 20.98% on finance leases and 4.5% on operating leases as of March 31, 2020. During the three months ended March 31, 2020, the Company added $208,000 of right of use assets in exchange for finance lease liabilities. In the three months ended March 31, 2019, upon adoption of the accounting guidance in ASC 842, $1.4 million of net machinery and equipment was reclassified to lease right-of-use assets related to assets under finance leases and $1.9 million of right-of-use facility lease was recorded under operating lease.

7. Stock-Based Compensation

Equity Incentive Plans

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

At the Company's annual meeting of stockholders held on June 28, 2018, 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 146,666 shares. At the Company's annual meeting of stockholders held on June 17, 2019, the Company's stockholders approved additional amendments to the 2013 Plan including the increase in the number of non-inducement shares of common stock authorized for issuance under the 2013 Plan by 2,800,000 shares. As of March 31, 2020, 124,211 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 March 31, 2020, under all plans, a total of 3,064,098 non-inducement shares were authorized for issuance, 2,569,437 shares had been issued with 2,451,332 non-inducement stock options and restricted stock units, or RSUs, underlying outstanding awards, and 636,655 non-inducement shares were available for grant. As of March 31, 2020, a total of 118,368 inducement shares were authorized for issuance, 118,368 inducement shares had been issued with 117,534 inducement stock options and RSUs underlying outstanding awards, and no inducement shares were available for grant under the 2013 Plan.

Stock Options

A summary of stock option activity for the three months ended March 31, 2020 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term in Years
Outstanding at December 31, 2019	2,732,023	$ 3.66	9.25
Granted	58,739	$ 0.30	
Exercised	—	—	
Cancelled/forfeited/expired	(221,325)	$ 1.33	
Outstanding at March 31, 2020	2,569,437	$ 3.79	9.0
Vested and unvested expected to vest at March 31, 2020	2,500,632	$ 3.86	9.0

The intrinsic values of options outstanding, options exercisable, and options vested and unvested expected to vest at December 31, 2019 and March 31, 2020 were each zero.

Restricted Stock

A summary of RSU activity for the three months ended March 31, 2020 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2019	360	$ 415.80
Granted	—	—
Vested and issued	—	—
Forfeited	—	—
Outstanding at March 31, 2020	360	$ 415.80
Vested at March 31, 2020	360	$ 415.80

At March 31, 2020, the intrinsic values of RSUs outstanding and RSUs vested were each approximately $100. Of the 360 RSUs outstanding at March 31, 2020, all were fully vested.

The assumptions used in the Black-Scholes pricing model for stock options granted during the three months ended March 31, 2020 were as follows:

Stock and exercise prices	$0.27 - $0.31
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	0.50% – 1.37%
Expected life (in years)	5.95 – 5.96
Expected volatility	146.1% - 164.6%

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 March 31,	
	2019	2020
Stock Options		
Cost of revenues	$ 8,147	$ 22,813
Research and development expenses	28,194	24,435
General and administrative expenses	47,581	94,414
Sales and marketing expenses	18,537	1,302
Total expenses related to stock options	102,459	142,964

Stock-based compensation expense was recorded net of estimated forfeitures of 0% - 8% per annum during each of the three months ended March 31, 2019 and 2020. As of March 31, 2020, total unrecognized share-based compensation expense related to unvested stock options and RSUs, adjusted for estimated forfeitures, was approximately $1,731,000 and is expected to be recognized over a weighted-average period of approximately 3.0 years.

8. Common Stock Warrants Outstanding

A summary of equity-classified common stock warrant activity for the three months ended March 31, 2020 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2019	27,484,249	$ 2.44	4.6
Issued	8,854,758	0.36	
Exercised	(21,048,907)	4.36	
Expired	(19,339)	140.40	
Outstanding at March 31, 2020	15,270,761	$ 1.86	4.4

All warrants outstanding at March 31, 2020 are exercisable, except for the warrants issued in January 2020 pursuant to the repricing and exchange transaction, which have a term of 5.5 years and will become exercisable on the six month anniversary of issuance, July 10, 2020. The intrinsic value of equity-classified common stock warrants outstanding at March 31, 2020 was zero.

9. Net Loss per Common Share

Basic and diluted net 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 months ended March 31, 2019 and 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. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

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

	For the three months ended March 31,	
	2019	2020
Preferred warrants outstanding (number of common stock equivalents)	17	—
Common warrants outstanding	17,799,468	15,270,761
RSUs outstanding	360	360
Convertible preferred stock outstanding (number of common stock equivalents)	472,719	471,393
Common options outstanding	202,081	2,569,437
Total anti-dilutive common share equivalents	18,474,645	18,311,951

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.

In February 2016, the Company signed a firm, non-cancelable, and unconditional commitment in an aggregate amount of $1,062,500 with a vendor to purchase certain inventory items, payable in minimum quarterly amounts of $62,500 through May 2020. At March 31, 2020, a balance of $29,000 remained outstanding under this purchase commitment.

During the three months ended March 31, 2019 and 2020, total expense recorded in the Company's unaudited condensed statements of operations and comprehensive loss for sales tax and maintenance obligations associated with equipment financing arrangements was approximately $24,000 and $32,000, respectively. At December 31, 2019 and March 31, 2020, approximately $78,000 and $74,000, 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 payments totaling approximately $277,000 for sales tax and maintenance obligations associated with financed equipment were due under equipment financing arrangements at March 31, 2020, 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 $19,000 and $26,000 during the years ended December 31, 2018 and 2019, 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 Biocept'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 March 31, 2020, the Company has accrued $5,000 for royalty expenses related to this arrangement.

12. Subsequent Events

On April 16, 2020, the Company received net cash proceeds of approximately $9.6 million from a registered direct offering to certain institutional investors of 22,300,000 shares of common stock at a negotiated purchase price of $0.46 per share.

Subsequent to the three months ended March 31, 2020, the Company financed certain business insurance premiums totaling approximately $567,000 through third-parties.

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, 2019 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, 2019, filed with the Securities and Exchange Commission on March 27, 2020. Past operating results are not necessarily indicative of results that may occur in future periods.

Company Overview

We are an early stage 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." Our 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, show progression or be used 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. Our 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.

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. Our patented Target-Selector™ CTC platform assays are based on an internally developed microfluidics-based cell capture and analysis platform, with enabling features that change how information provided by CTC testing is used by clinicians. In January 2020, we announced that our molecular and CTC technologies were validated on cerebral spinal fluid, or CSF, in order to provide information for patients with central nervous system, or CNS, tumors both primary and metastatic. Our patented Target-Selector™ molecular technology enables detection of mutations and genome alterations with enhanced sensitivity and specificity, and is applicable to nucleic acid from ctDNA, and could potentially be validated for other sample types such as bone marrow, or tissue (surgical resections and/or biopsies). Our Target-Selector™ CTC and molecular platforms provide both biomarker detection as well as monitoring capabilities and require only a patient blood sample. In January 2019, we began offering research use only, or RUO, liquid biopsy kits containing our patented and proprietary Target Selector™ testing to laboratories and researchers worldwide.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP. We also performed the research and development that led to our current assays, and continue to perform for our planned assays, at this same facility. In addition, we currently manufacture our microfluidic channels and various chemistries utilized 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 laboratory developed tests, or LDTs, under CLIA regulations. CLIA certification 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. Additionally, our 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 our patented 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, surgical oncologists, urologists, pulmonologists, pathologists and other physicians who use the biomarker information we provide in order to determine the best treatment plan for their patients;
- providing laboratory services utilizing both our CTC and ctDNA testing in order to help pharmaceutical and biopharmaceutical companies developing drug candidate therapies to treat cancer; and
- licensing and/or selling our proprietary testing and/or technologies, including our BCTs, to partners in the United States and abroad.

We plan to grow our business by directly offering medical oncologists, surgical oncologists, pulmonologists, pathologists and other physicians our Target-Selector™ liquid biopsy CTC and molecular assays. Based on our product development data, as well as discussions with our collaborators, we believe that our planned future assays should provide important information and clinical value to physicians. In particular, CTC and ctDNA assays could deliver important, actionable information not provided by other assays. For example, the historic clinical CTC test is the United States Food and Drug Administration, or FDA, approved CellSearch® test, which provides CTC enumeration, but is not FDA approved to perform biomarker analysis. We believe our ability to rapidly translate research insights about the utility of cytogenetic, immunocytochemical and molecular biomarkers to provide information to medical oncologists, surgical oncologists, urologists, pulmonologists, pathologists 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.

Assays, Products and Services

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.

Our current assays and clinical trial services include:

- *CTC and ctDNA Testing*. Our current assays and our other planned cancer diagnostic assays are based on our Target-Selector™ technologies and are currently intended to be performed only in our clinical laboratory. 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, 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 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.

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, and androgen receptor, or AR, protein in breast 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 multiple 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.

We plan to release additional blood-based biomarker assays, such as those that test for *ESR1*, to our current menu of liquid biopsy assays using blood samples. In addition, we plan to complete the development and offer multiplexed biomarker tests, which will allow the detection and quantitative monitoring of multiple biomarkers in a single 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.

In October 2017, we launched our pathology partnership initiative, branded as Empower TC, expanding access of our proprietary liquid biopsy testing to community pathologists and hospitals throughout the United States. The aim of this program is to incorporate community pathologists into the review of biomarkers found in liquid biopsy for patients diagnosed with cancer. Pathologists are now enabled to interpret our liquid biopsy results locally, while patient specimens will continue to be sent to us for processing in our CLIA-certified, CAP-accredited high complexity laboratory. In February 2019 we launched Version 2 of Empower TC which is intended to expand the capabilities of the program to allow for more tests to be interpreted by local pathologists.

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 launch of the Oncomine NGS lung cancer panel in collaboration with Thermo Fisher Scientific. This panel requires a local coverage determination, or LCD, for reimbursement and we started that process with a meeting with MOLDx in November 2018. In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on an LCD. We have applied for LCD's in several categories as the initial step for national coverage.

In June 2019 we announced launch of the Oncomine NGS breast cancer panel, a multi-gene liquid biopsy panel specifically developed for breast cancer, in collaboration with Thermo Fisher Scientific. This panel is being marketed to physicians and researches 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.

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 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 to the aggressiveness of a patient's prostate cancer.

Pharmaceutical and Research 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. In addition, we have distribution agreements in place in Mexico, Uruguay, Turkey, Columbia, Israel and Canada.

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 assay.

During 2016, we announced a pharmaceutical collaboration agreement that provides testing for a clinical trial, which includes metastatic lung cancer patients with leptomeningeal or brain metastases. In this exploratory trial, we tested both cerebrospinal fluid and blood for molecular alterations that could be impacted by treatment. A second pharmaceutical collaboration was announced in 2016, which entails a milestone-based assay development project focused on hepatocellular carcinoma, or HCC, or liver cancer. Custom assays utilizing both our CTC and ctDNA technologies were developed for identifying specified biomarkers and capturing HCC CTCs for potential clinical trial use.

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 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.

In November 2017, we announced a collaboration involving 100 patients in a clinical study with the University of California, San Diego. The study entails clinical validation of specified PD-L1 antibody clones on our Target-Selector™ CTC platform. Concordance of PD-L1 protein expression in tissue biopsy versus liquid biopsy, as well as correlation of therapeutic response with PD-L1 liquid biopsy status, are the study objectives.

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 vedontin (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 leptomeningeal metastases who were treated with tesevatib 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 circulating tumor cells, or CTCs, in a cohort of over 1,500 patients, representing various clinical and treatment stages of breast cancer.

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 progress. 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.

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.

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, Europe, Japan, China and South Korea for our novel switch blocker technology, solidifying our proprietary enrichment methodology for detecting ctDNA with very high sensitivity. 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 allowed 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 expire in 2031, and the patents for our ctDNA technology expire in the early 2030’s.

As of March 31, 2020, we owned 37 issued patents and 12 patents pending related to our current technologies. Of these, 10 were issued and 3 were pending patents in the U.S., while 27 were issued and 11 were pending patents in non-U.S. territories. Separately, we also owned 7 issued patents related to our earlier microarray and cell analysis technology.

Coronavirus (COVID-19) Pandemic

On March 11, 2020 the World Health Organization declared the disease cause by the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. In addition, as we are located in California, we are currently under a shelter-in-place mandate and many of our clients worldwide are similarly impacted. The global outbreak of the COVID-19 coronavirus continues to rapidly evolve, and the extent to which the COVID-19 coronavirus 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 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. We estimate that the COVID-19 pandemic led to an approximate 15 to 25% decline in commercial volume from current customers, and 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 will begin accepting physician-ordered testing requests. The testing volume has been limited by the national shortage of specimen collection kits. To address this issue, we will manufacture our own collection kits and plan to make them available in June.

Results of Operations

Three Months Ended March 31, 2019 and 2020

The following table sets forth certain information concerning our results of operations for the periods shown:

	Three months ended March 31,		Change	
	2019	2020	$	%
(dollars in thousands)				
Net revenues	$ 1,024	$ 1,447	$ 423	41%
Cost of revenues	2,599	2,947	348	13%
Research and development expenses	1,223	1,313	90	7%
General and administrative expenses	1,682	1,904	222	13%
Sales and marketing expenses	1,374	1,465	91	7%
Loss from operations	(5,854)	(6,182)	(328)	6%
Interest expense	(61)	(57)	4	(7%)
Warrant inducement expense	—	(2,102)	(2,102)	0%
Loss before income taxes	(5,915)	(8,341)	(2,426)	41%
Income tax expense	—	—	—	0%
Net loss	$ (5,915)	$ (8,341)	$ (2,426)	41%

Net Revenues

Net revenues were approximately $1,447,000 for the three months ended March 31, 2020, compared with approximately $1,024,000 for the same period in 2019, an increase of $423,000, or 41%, which is primarily due to an increase in the value per accession over the

same period in the prior year. In addition, we had an increase in the number of tests ordered per accession which is partially attributable to the launching of new assays in 2019.

The net estimated revenue per commercial accession delivered during the three months ended March 31, 2020 was $1,294, based on 1,018 commercial accessions delivered, while during the three months ended March 31, 2019 it was approximately $1,016, based on 961 commercial accessions delivered. The following table sets forth certain information regarding commercial accessions received during the three months ended March 31, 2019 and 2020:

	Three months ended March 31,		Change	
	2019	2020	# / $	%
# Commercial accessions received	1,011	985	(26)	(3%)
$ Value estimated per commercial accession received	$ 1,038	$ 1,543	$ 505	49%

*Commercial value per accession received is reflected as expected reimbursement (gross billed less contractual allowance).

Additionally, there was a $17,000 increase in development services revenues during the three months ended March 31, 2020 compared to the same period in the prior year, which was primarily related to an increase in values per development services accessions delivered as follows:

	Three months ended March 31,		Change	
	2019	2020	#	%
# Development services accessions delivered	137	150	13	9%
$ Value per development services accession delivered	$ 310	$ 402	$ 92	30%

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately $2,947,000 for the three months ended March 31, 2020, compared with approximately $2,599,000 for the same period in 2019 as we continued to leverage the fixed components of our costs. As a result, cost of revenues as a percentage of net revenues decreased by 50% for the three months ended March 31, 2020 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 $1,313,000 for the three months ended March 31, 2020, compared with approximately $1,223,000 for the same period in 2019, an increase of $90,000, or 7%. The increase was primarily attributable to development and validation costs related to additional tests. 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 $1,904,000 for the three months ended March 31, 2020, compared with approximately $1,682,000 during the same period in 2019, an increase of $222,000, or 13%. The increase was primarily due to reporting a department previously under sales and marketing under general and administrative costs beginning in mid-2019, as well as higher non-cash stock-based compensation expenses, and consulting costs as compared to the same period in the prior year. 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 $1,465,000 for the three months ended March 31, 2020 compared with approximately $1,374,000 for the same period in 2019, an increase of $91,000, or 7%. The increase was primarily attributable to higher volume and revenues during the period. Sales and marketing expenses are comprised of, but not limited to, personnel costs, trade show and other marketing related expenses, as well as office and other costs.

Interest Expenses. Interest expenses were approximately $57,000 for the three months ended March 31, 2020 stayed relatively flat compared with approximately $61,000 for the same period in 2019. Interest expenses are comprised of interest incurred related to finance leases used to obtain equipment.

Warrant Inducement Expense. Warrant inducement expenses were approximately $2,102,000 for the three months ended March 31, 2020 compared with $0 for the same period in 2019. Warrant inducement expenses related to recognizing the fair value of the inducement warrants issued in January 2020 and warrant modification costs in connection with the warrant exercise.

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 that multiple ownership changes likely occurred. As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

Liquidity and Capital Resources

Cash Flows

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

	Three months ended March 31,	
	2019	2020
(dollars in thousands)		
Cash provided by/ (used in):		
Operating activities	$ (5,248)	$ (5,279)
Investing activities	(33)	(19)
Financing activities	16,619	17,489
Net increase in cash	$ 11,338	$ 12,191

Cash Used in Operating Activities. Net cash used in operating activities was $5.3 million for the three months ended March 31, 2020, compared to net cash used in operating activities of $5.2 million for the same period in 2019. The net increase of $31,000 in cash used was primarily related to an increase in cash used to fund our net loss.

Cash Used in Investing Activities. Net cash used in investing activities was $19,000 for the three months ended March 31, 2020 compared to $33,000 in 2019, in the same quarter in the prior year. Cash used in investing activities was related to purchases of fixed assets in both periods.

Cash Provided by Financing Activities. Net cash provided by financing activities was $17.5 million for the three months ended March 31, 2020, compared to net cash provided by financing activities of $16.6 million for the same period in 2019. Our primary sources of cash from financing activities during the three months ended March 31, 2020 consisted of $660,000 in net proceeds from exercise of overallotment warrants from the December 2019 warrants in January 2020, net proceeds of $14.7 million from our sale of common stock in two financing transactions in March 2020, and $2.3 million in proceeds from exercise of common stock warrants. Net proceeds from financing transactions were partially offset by $0.1 million of principal payments made on indebtedness. Our primary sources of cash from financing activities during the three months ended March 31, 2019 consisted of $2.0 million in net proceeds from our offering of common stock in January 2019, $6.6 million in net proceeds from our sale of common stock and warrants in February 2019, $0.6 million in net proceeds from exercise of overallotment from the January 2019 transaction, $7.6 million in net proceeds from our sale of common stock and warrants in March 2019, and $5,000 in proceeds from exercise of common stock warrants. Net proceeds from financing transactions were partially offset by $0.2 million of principal payments made on indebtedness.

Liquidity, Capital Resources and Expenditure Requirements

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

In February 2020, we completed a Warrant Exercise Inducement offering and received net proceeds of approximately $2.3 million, as well as an additional $700,000 from the underwriter exercising its overallotment warrants from the December 2019 underwritten financing transaction. In addition, as inducement for these exercises, we issued 6,927,258 warrants to purchase shares of common stock at $0.3495 per share. The warrants are exercisable on the six-month anniversary of issuance and expire in five years from the date first exercisable. On March 2, 2020, we completed a registered direct offering to certain institutional investors of 23,000,000 shares of common stock at a purchase price of $0.40 per share raising net proceeds of received net cash proceeds of approximately $8.6 million. On March 4, 2020, we received net cash proceeds of approximately $6.1 million from an additional registered direct offering to certain institutional investors of 16,000,000 shares of common stock at a negotiated purchase price of $0.41 per share.

As of March 31, 2020, our cash totaled $21.5 million, and our outstanding net indebtedness totaled $1.8 million. While we currently are in the commercialization stage of operations, we have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. While we believe that, absent the COVID-19 pandemic, based on our historical and planned cash usage our current cash would have supported our operations through most of 2021, due to the uncertainty introduced by the impact of COVID-19 on revenues and cash usage, there is uncertainty as to the period of time for which existing cash can support our ongoing operations. We have determined that there is substantial doubt about our ability to continue as a going concern for the one-year period following the date that our unaudited condensed financial statements for the three months ended March 31, 2020 were issued, and we expect that we will need additional financing to execute on our current or future business strategies.

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.

We expect that we will need additional financing to execute on our current or future business strategies. 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, 2019. 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, 2019.

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 March 31, 2020, 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 March 31, 2020. There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. 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, 2019 filed with the Securities and Exchange Commission on March 27, 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 net losses of $25.1 million for year ended December 31, 2019 and $8.3 million for the three months ended March 31, 2020, respectively, and we have never been profitable. At March 31, 2020, our accumulated deficit was approximately $254.1 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. As a result, there is substantial doubt about our ability to continue as a going concern unless we are able to successfully raise additional capital. 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, 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, as well as our BCT 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.

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

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

The San Diego area has recently experienced 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 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 CLIA-certified, CAP accredited, and state-licensed laboratory became inoperable 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 epidemic diseases, such as the recent global outbreak of the COVID-19 coronavirus.***

The recent outbreak of COVID-19, which has been declared by the World Health Organization to be a pandemic, has spread across the globe and is impacting worldwide economic activity. 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. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The continued spread of COVID-19 and the measures taken by the governments of countries affected could disrupt the supply chain of material needed for our assays, interrupt our ability to receive samples, impair our ability to perform or deliver the results from our tests, impede patient movement or interrupt healthcare services causing a decrease in test volumes, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our tests and have a material adverse effect on our business, financial condition and results of operations. In addition, as we are located in California, we are currently under a shelter-in-place mandate and many of our clients worldwide are similarly impacted. As a healthcare provider, we are allowed to remain open in compliance with the shelter-in-place mandate and continue to provide critical information for patients diagnosed with cancer. We estimate that the COVID-19 pandemic led to an approximate 15 to 25% decline in commercial volume from current customers, and also impacted opportunities for us to gain new customers with the closing of many physician offices and labs. Beginning the week of March 16, 2020, substantially all of our workforce began working from home either all or substantially all of the time, except for a limited number of staff in our clinical laboratory. The effects of the 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. Moreover, the global outbreak of the COVID-19 coronavirus continues to rapidly evolve, and the extent to which the COVID-19 coronavirus may impact our business, results of operations and financial position 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.

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 mainstream diagnostic methods, used by medical oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians for many years, which focus on tumor tissue analysis. The methods or behavior of medical oncologists, surgical oncologists, urologists, pulmonologists, pathologists and other physicians may be difficult to change regarding the use of our CTC and ctDNA assays, including molecular diagnostic assays, in their practices in conjunction with or instead of tissue biopsies and analysis. In addition, companies offering capital equipment, BCTs, and kits or reagents to local pathology laboratories or laboratory supply distributors represent another source of potential competition. These kits are used directly by the pathologist, which can facilitate adoption. Historically, we have focused our marketing and sales efforts on medical oncologists rather than pathologists, although commencing in October 2017, our Empower TC offering 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.

We also face competition from companies that offer products or are conducting research to develop products for CTC or ctDNA assays in various cancers. CTC and ctDNA products, assays and services represent a new area of science 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. Competitors include but are not limited to companies such as Qiagen, Roche, Guardant Health, Cancer Genetics, Atossa, Agena Bioscience, Precipio, Illumina, Grail, Precision for Medicine, EPIC Sciences, Clearbridge Biomedics, Biodesix, Thermo Fisher Scientific, Foundation Medicine, Neogenomics, Cynvenio Biosystems, Genomic Health, Fluxion Biosciences, RareCells Diagnostics, ScreenCell, Menarini Silicon Biosystems, Alere (Adnagen), Sysmex, Natera, Inc., Circulogen, Angle PLC, Caris Life Sciences, Archer DX, DiaCarta and Tempus. Some of these groups, in addition to operating research and development laboratories, are establishing CLIA-certified testing laboratories while others are focused on selling equipment and reagents.

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 companies that are focused on the oncology diagnostic market such as Illumina, Biorad, Sysmex, Qiagen and Thermo Fisher Scientific that are selling equipment and reagents kits for ctDNA assays and assay panels to laboratories that are developing tests that are marketed to medical oncologists and pathologists.

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, 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 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 attention and resources on the personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics increases. For example, the FDA has approved three such agents: Xalkori® from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc., Zelboraf® from Daiichi-Sankyo/Genentech/Roche along with its companion BRAF kinase V600 mutation test from Roche Molecular Systems, Inc. and Tafinlar® from GlaxoSmithKline along with its companion BRAF kinase V600 mutation test from bioMerieux. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests such as ours would be considered an off-label use and this may limit our access to this market segment.

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, 2019, and the three months ended March 31, 2020 our research and development expenses were $4.7 million and $1.3 million, respectively, and our sales and marketing expenses were $5.9 million and $1.5 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, 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, 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, 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, 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, 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 on line, 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 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.

Intrusions into our computer systems could result in compromise of confidential information.

Despite the implementation of security measures, our technology or systems that we interface with, including the Internet and related systems, may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. The Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA 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. 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. As amended by HITECH and subsequently by the final omnibus rule adopted in 2013, or Final Omnibus Rule, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed: notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most 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 significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. For example, if we obtain certain personal information regarding residents in the European Union, we may be subject to the European Union General Data Protection Regulation. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We depend on our information technology and telecommunications systems, and any failure of these systems could harm our business.

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. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including 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, computer viruses and similar disruptive problems. 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, surgical oncologists, urologists, pulmonologists, pathologists, 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.

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, makes 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 remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, the President of the United States has signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has 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 the Medical Device Excise Tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allotted one hour for oral arguments. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA 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. Under the law, issued in 2016 and the reporting period 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. Also, under PAMA, the Centers for Medicare & Medicaid Services, or 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 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. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the

2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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.

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 to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. 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, 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 38% and 37% of total net revenues during the year ended December 31, 2019 and the three months ended March 31, 2020, respectively, were associated with Medicare reimbursement. Approximately 21% and 29% of total net revenues during the year ended December 31, 2019 and three months ended March 31, 2020, respectively, were associated with Blue Cross Blue Shield reimbursement, and approximately 8% and 6% of total net revenues for the years ended December 31, 2019 and three months ended March 31, 2020, respectively, were associated with United Healthcare reimbursement. 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.

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 78% and 75% of all billable cases received during the year ended December 31, 2019 and the three months ended March 31, 2020, 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.

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 the College of American Pathologists, or CAP, one of six 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 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, 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;

- 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;
- 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, as defined by such law, and teaching hospitals, and certain physician ownership and investment interests held by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party 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 required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of HIPAA, HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of protected health information used or disclosed by health care providers and other covered entities.

The privacy regulations 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.

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, must publicize the breach in 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. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. 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. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

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, international 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 European Union General Data Protection Regulation. The costs of compliance with these laws may be significant and compliance with regulatory requirements may result in delay. 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.

Legal, political and economic uncertainty surrounding the exit of the U.K., from the European Union, or EU, may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations or intended operations in the U.K. and pose additional risks to our business, revenue, financial condition and results of operations.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period.

The uncertainty concerning the U.K's legal, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the U.K. and the EU are unable to negotiate acceptable trading and customs terms or if other EU Member States pursue withdrawal, barrier-free access between the U.K. and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the U.K. and the EU and, in particular, any arrangements for the U.K. to retain access to EU markets after the Transition Period.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business. Any current or planned future operations in the U.K. as well as in other countries in the EU and European Economic Area, or EEA, could be disrupted by Brexit, particularly if there is a change in the U.K's relationship to the single market.

We may also face new regulatory costs and challenges as a result of Brexit that could have an adverse effect on our operations. For example, the U.K. could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Furthermore, at present, there are no indications of the effect Brexit will have on the pathway to obtaining marketing approval for any of our product candidates in the U.K., or what, if any, role the EMA may have in the approval process. There may continue to be economic uncertainty surrounding the consequences of Brexit which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations.

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 confidence in these individuals, organizations and systems, agreements or security measures may 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, 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.***

Before our initial public offering, there was no public market for our common stock. Market prices for securities of early-stage life sciences companies have historically been particularly 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 newly public companies for a number of reasons, including reasons that may be unrelated to our business or operating

performance. The ongoing COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility. 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 are 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 and January 2018 letter, we have not yet regained compliance with the $1.00 minimum closing bid price requirement that was the subject of the September 2019 letter from Nasdaq. In March 2020, we requested and received an additional 180-day extension to regain compliance with the $1.00 minimum closing bid price requirement that was the subject of the September 2019 letter from Nasdaq. and, in light of the COVID-19 pandemic, Nasdaq tolled the 180-day compliance period effective April 16, 2020 until July 1, 2020. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options, including a reverse stock split, to regain compliance with the minimum closing bid price requirement. We are seeking stockholder approval of a reverse stock split at our 2020 annual meeting of stockholders. There can be no assurance that we will be able to regain compliance with the $1.00 minimum closing bid price requirement or maintain compliance with the other continued listing requirements of the Nasdaq Capital Market. If we fail to regain and/or 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;
- 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.

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.

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 2018, 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 $50 million, subject to certain limitations for so long as our public float is less than $75 million. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. 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 131,100,133 shares of common stock as of April 20, 2020, of which no more than 31,415 are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of April 20, 2020, we had outstanding preferred stock convertible into 471,493 shares of our common stock, options to purchase 2,567,570 shares of our common stock, 360 shares of common stock were issuable upon the settlement of outstanding restricted stock units, or RSUs, and 15,178,020 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 “smaller reporting company,” 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 consolidated 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.

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.

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 Coronavirus Aid, Relief, and Economic Security Act, or 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.

Our ability to utilize our estimated federal net operating loss, carryforwards and federal tax credits may be limited under Sections 382 and 383 of the Code. 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, 2019, we had estimated federal and state net operating loss carryforwards of approximately $54.9 million and $13.9 million, respectively, and estimated federal and California research and development tax credits of approximately $366,000 and $3.7 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. 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.

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

Unregistered Sales of Equity Securities

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.

Exhibit No.	Description of Exhibit
3.1	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).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
3.3	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2016).
3.4	Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2017).
3.5	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on July 6, 2018).
3.6	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).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, and 3.6.
4.2	Specimen Common Stock certificate of Biocept, Inc. (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 28, 2017).
4.3	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).
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	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).
4.9	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).

Exhibit No.	Description of Exhibit
4.10	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).
4.11	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).
4.12	Form of Series 1 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).
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	Form of Securities Purchase Agreement, dated March 2, 2020, by and between the Registrant and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 3, 2020).
10.2	Placement Agency Agreement, dated March 2, 2020, by and between the Registrant and Maxim Group LLC (incorporated by reference to Exhibit 99.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 3, 2020).
10.3	Form of Securities Purchase Agreement, dated March 4, 2020, by and between the Registrant and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 5, 2020).
10.4	Placement Agency Agreement, dated March 4, 2020, by and between the Registrant and Maxim Group LLC (incorporated by reference to Exhibit 99.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 5, 2020).
10.5	Form of Securities Purchase Agreement, dated April 14, 2020, by and between the Registrant and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 15, 2020).
10.6	Placement Agency Agreement, dated April 14, 2020, by and between the Registrant and Maxim Group LLC (incorporated by reference to Exhibit 99.2 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 15, 2020).
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.

Exhibit No.	Description of Exhibit
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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: May 14, 2020

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

Date: May 14, 2020

By: /s/ Timothy C. Kennedy
Timothy C. Kennedy
Chief Financial Officer, Senior Vice President of Operations
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

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 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: May 14, 2020

/s/ Michael W. Nall
Michael W. Nall
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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 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: May 14, 2020

/s/ Timothy Kennedy
Timothy Kennedy
Chief Financial Officer, Senior Vice President of Operations
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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 March 31, 2020 (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: May 14, 2020

/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.

EXHIBIT 32.2

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 March 31, 2020 (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: May 14, 2020

/s/ Timothy Kennedy
Timothy Kennedy
Chief Financial Officer, Senior Vice President of Operations
(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.