Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019

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: 001-38984

CASTLE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0701774**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
820 S. Friendswood Drive, Suite 201, Friendswood, Texas	**77546**
(Address of principal executive offices)	(Zip Code)

(866) 788-9007

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**CSTL**	**The Nasdaq Global Market**

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of ''large accelerated filer,'' ''accelerated filer,'' ''smaller reporting company,'' and ''emerging growth company'' in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of August 30, 2019, there were 17,069,094 shares of common stock, par value $0.001 per share, issued and outstanding.

Table of Contents

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CASTLE BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS

	June 30, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 17,468,466	$ 4,478,512
Accounts receivable, net	9,730,319	12,089,719
Inventory	550,894	882,233
Prepaid expenses and other current assets	774,885	675,562
Total current assets	28,524,564	18,126,026
Long-term accounts receivable, net	1,266,098	2,532,011
Property and equipment, net	1,743,170	1,528,996
Intangible assets, net	—	4,167
Other assets – long-term	1,813,311	213,735
Total assets	$ 33,347,143	$ 22,404,935
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current Liabilities		
Accounts payable	$ 2,084,910	$ 1,450,766
Accrued compensation	2,784,746	4,571,011
Other accrued liabilities	1,616,866	715,244
Current portion of long-term debt	833,333	—
Convertible promissory notes (including $4,755,882 principal amount with related parties as of June 30, 2019) (Note 7)	4,425,819	—
Total current liabilities	11,745,674	6,737,021
Long-term debt	23,858,781	24,499,752
Preferred stock warrant liability	1,279,840	1,193,726
Deferred rent liability	56,690	43,587
Total liabilities	36,940,985	32,474,086
Commitments and Contingencies (Note 10)		
Convertible Preferred Stock		
Convertible preferred stock Series C, $0.001 par value, 503,056 shares authorized as of June 30, 2019 and December 31, 2018; 503,056 shares issued and outstanding as of June 30, 2019 and December 31, 2018; $2,486,645 and $2,417,195 aggregate liquidation preference as of June 30, 2019 and December 31, 2018, respectively.	1,500,994	1,500,994
Redeemable convertible preferred stock Series A, B, D, E-1, E-2, E-2A, E-3 and F, $0.001 par value, 11,846,877 and 9,640,493 shares authorized as of June 30, 2019 and December 31, 2018, respectively; 9,456,775 shares issued and outstanding as of June 30, 2019 and December 31, 2018; $59,368,051 and $57,570,036 aggregate liquidation preference as of June 30, 2019 and December 31, 2018, respectively.	45,107,730	44,995,157
Stockholders' Deficit		
Common stock, $0.001 par value; 17,308,384 and 15,102,000 shares authorized as of June 30, 2019 and December 31, 2018, respectively; 2,192,461 and 1,916,224 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively.	2,192	1,916
Additional paid-in capital	9,910,882	921,360
Accumulated deficit	(60,115,640)	(57,488,578)
Total stockholders' deficit	(50,202,566)	(56,565,302)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 33,347,143	$ 22,404,935

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

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
NET REVENUES	$ 10,738,569	$ 3,979,381	$ 19,455,556	$ 7,637,946
COST OF SALES	1,992,784	1,326,839	3,590,742	2,579,822
Gross margin	8,745,785	2,652,542	15,864,814	5,058,124
OPERATING EXPENSES				
Research and development	1,317,237	1,159,197	2,711,088	2,421,887
Selling, general and administrative	6,820,927	4,159,755	12,867,549	8,387,546
Total operating expenses	8,138,164	5,318,952	15,578,637	10,809,433
Operating income (loss)	607,621	(2,666,410)	286,177	(5,751,309)
Interest income	5,529	2,240	26,318	7,623
Interest expense	(1,692,582)	(524,843)	(2,716,982)	(1,055,068)
Other income (expense), net	(189,647)	34,038	(222,575)	13,340
Loss before income taxes	(1,269,079)	(3,154,975)	(2,627,062)	(6,785,414)
Income tax expense	—	—	—	—
Net loss and comprehensive loss	(1,269,079)	(3,154,975)	(2,627,062)	(6,785,414)
Convertible preferred stock cumulative dividends	938,892	869,008	1,867,467	1,678,330
Accretion of redeemable convertible preferred stock to redemption value	56,775	55,795	112,573	105,020
Net loss and comprehensive loss attributable to common stockholders	$ (2,264,746)	$ (4,079,778)	$ (4,607,102)	$ (8,568,764)
Loss per share attributable to common stockholders, basic and diluted	$ (1.05)	$ (2.15)	$ (2.26)	$ (4.52)
Weighted-average shares outstanding, basic and diluted	2,152,965	1,897,084	2,035,393	1,897,070

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

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(UNAUDITED)

	Convertible Preferred Stock Series C		Redeemable Convertible Preferred Stock Series A, B, D, E-1, E-2, E-2A, E-3 and F		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE, APRIL 1, 2018	503,056	$1,500,994	8,559,894	$39,613,737	1,897,084	$ 1,897	$ 822,729	$(54,752,023)	$(53,927,397)
Stock compensation expense	—	—	—	—	—	—	84,633	—	84,633
Exercise of common stock options	—	—	—	—	—	—	—	—	—
Issuance of Series F redeemable convertible preferred stock	—	—	868,959	5,022,592	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value:									
Series E-1	—	—	—	1,042	—	—	(1,042)	—	(1,042)
Series E-2A	—	—	—	96	—	—	(96)	—	(96)
Series E-3	—	—	—	2,889	—	—	(2,889)	—	(2,889)
Series F	—	—	—	51,768	—	—	(51,768)	—	(51,768)
Exercise of redeemable convertible preferred stock warrants:									
Series E-1	—	—	3,250	14,983	—	—	—	—	—
Series F	—	—	24,106	169,948	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(3,154,975)	(3,154,975)
BALANCE, JUNE 30, 2018	503,056	$1,500,994	9,456,209	$44,877,055	1,897,084	$ 1,897	$ 851,567	$(57,906,998)	$(57,053,534)
BALANCE, APRIL 1, 2019	503,056	$1,500,994	9,456,775	$45,050,955	1,916,701	$ 1,917	$ 9,412,490	$(58,846,561)	$(49,432,154)
Stock compensation expense	—	—	—	—	—	—	138,808	—	138,808
Exercise of common stock options	—	—	—	—	275,760	275	416,359	—	416,634
Accretion of redeemable convertible preferred stock to redemption value:									
Series E-1	—	—	—	1,043	—	—	(1,043)	—	(1,043)
Series E-2A	—	—	—	96	—	—	(96)	—	(96)
Series E-3	—	—	—	2,897	—	—	(2,897)	—	(2,897)
Series F	—	—	—	52,739	—	—	(52,739)	—	(52,739)
Net loss	—	—	—	—	—	—	—	(1,269,079)	(1,269,079)
BALANCE, JUNE 30, 2019	503,056	$1,500,994	9,456,775	$45,107,730	2,192,461	$ 2,192	$ 9,910,882	$(60,115,640)	$(50,202,566)

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

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERED STOCK AND STOCKHOLDERS' DEFICIT (CONTINUED)
(UNAUDITED)

	Convertible Preferred Stock Series C		Redeemable Convertible Preferred Stock Series A, B, D, E-1, E-2, E-2A, E-3 and F		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE, JANUARY 1, 2018	503,056	$1,500,994	7,611,010	$34,538,255	1,896,469	$ 1,896	$ 809,183	$(51,121,584)	$(50,310,505)
Stock compensation expense	—	—	—	—	—	—	146,340	—	146,340
Exercise of common stock options	—	—	—	—	615	1	1,064	—	1,065
Issuance of Series F redeemable convertible preferred stock	—	—	1,809,564	9,990,482	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value:									
Series E-1	—	—	—	2,072	—	—	(2,072)	—	(2,072)
Series E-2A	—	—	—	191	—	—	(191)	—	(191)
Series E-3	—	—	—	5,744	—	—	(5,744)	—	(5,744)
Series F	—	—	—	97,013	—	—	(97,013)	—	(97,013)
Exercise of redeemable convertible preferred stock warrants:									
Series E-1	—	—	3,250	14,983	—	—	—	—	—
Series F	—	—	32,385	228,315	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(6,785,414)	(6,785,414)
BALANCE, JUNE 30, 2018	503,056	$1,500,994	9,456,209	$44,877,055	1,897,084	$ 1,897	$ 851,567	$(57,906,998)	$(57,053,534)
BALANCE, JANUARY 1, 2019	503,056	$1,500,994	9,456,775	$44,995,157	1,916,224	$ 1,916	$ 921,360	$(57,488,578)	$(56,565,302)
Stock compensation expense	—	—	—	—	—	—	307,229	—	307,229
Exercise of common stock options	—	—	—	—	276,237	276	417,274	—	417,550
Accretion of redeemable convertible preferred stock to redemption value:									
Series E-1	—	—	—	2,074	—	—	(2,074)	—	(2,074)
Series E-2A	—	—	—	191	—	—	(191)	—	(191)
Series E-3	—	—	—	5,760	—	—	(5,760)	—	(5,760)
Series F	—	—	—	104,548	—	—	(104,548)	—	(104,548)
Recognition of beneficial conversion feature on convertible promissory notes	—	—	—	—	—	—	8,377,592	—	8,377,592
Net loss	—	—	—	—	—	—	—	(2,627,062)	(2,627,062)
BALANCE, JUNE 30, 2019	503,056	$1,500,994	9,456,775	$45,107,730	2,192,461	$ 2,192	$ 9,910,882	$(60,115,640)	$(50,202,566)

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

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Six Months Ended June 30,	
	2019	**2018**
OPERATING ACTIVITIES		
Net loss	$ (2,627,062)	$ (6,785,414)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	163,285	141,495
Stock compensation expense	307,229	146,340
Amortization of intangibles	4,167	18,673
Amortization of debt discounts and issuance costs	1,249,964	286,798
Change in fair value of preferred stock warrant liability	86,114	(13,341)
Change in fair value of embedded derivative	136,461	—
Other	337	—
Change in operating assets and liabilities:		
Accounts receivable	3,625,313	(621,175)
Prepaid expenses and other current assets	(99,323)	38,209
Inventory	331,339	(101,676)
Other assets	(12,057)	(100,968)
Accounts payable	(524,029)	(607,683)
Accrued compensation	(1,786,265)	331,465
Other accrued liabilities	901,622	33,305
Deferred rent liability	13,103	28,249
Net cash provided by (used in) operating activities	1,770,198	(7,205,723)
INVESTING ACTIVITES		
Purchases of property and equipment	(424,473)	(184,610)
Net cash used in investing activities	(424,473)	(184,610)
FINANCING ACTIVITIES		
Proceeds from issuance of preferred stock and preferred stock warrants (including exercised warrants)	—	10,382,507
Proceeds from issuance of convertible promissory notes (including $4,755,882 from related parties), net of issuance costs	11,695,495	—
Proceeds from issuance of term debt, net of issuance costs	1,776,145	—
Proceeds from line of credit	—	1,000,000
Repayments on line of credit	(1,791,145)	—
Payment of deferred offering costs	(453,816)	—
Proceeds from exercise of common stock options	417,550	1,065
Net cash provided by financing activities	11,644,229	11,383,572
NET CHANGE IN CASH AND CASH EQUIVALENTS	12,989,954	3,993,239
Beginning of period	4,478,512	1,212,063
End of period	$ 17,468,466	$ 5,205,302
SUPPLEMENTAL DISCLOSURE OF CASH PAID (REFUNDED) FOR:		
Interest	$ 1,137,965	$ 791,523
Income taxes	$ (150,000)	$ —
DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Accrued capital expenditures	$ 11,721	$ 7,168
Deferred offering costs and debt issuance costs incurred but not paid	$ 1,204,850	$ —

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

CASTLE BIOSCIENCES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(UNAUDITED)

1. Organization and Description of Business

Castle Biosciences, Inc. (the ‘‘Company’’) was incorporated in the state of Delaware on September 12, 2007. The Company is a commercial-stage dermatological cancer company focused on providing physicians and their patients with personalized, clinically actionable genomic information to make more accurate treatment decisions. The Company is based in Friendswood, Texas (a suburb of Houston, Texas) and its laboratory operations are conducted at the Company’s facility located in Phoenix, Arizona.

On July 11, 2019, the Company effected a 1-for-1.219 reverse stock split of its common stock. The par value and the authorized number of shares of common stock were not affected by the reverse stock split. The reverse stock split resulted in an adjustment to the Series A, B, C, D, E-1, E-2, E-2A, E-3, and F preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

On July 29, 2019, the Company completed the initial public offering of its common stock (the “IPO”). In the IPO, the Company issued and sold 4,600,000 shares of its common stock, including 600,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a price to the public of $16.00 per share. The Company received approximately $66.0 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the IPO, on July 29, 2019 all convertible preferred stock and all convertible promissory notes converted into shares of common stock and all outstanding warrants to purchase shares of convertible preferred stock converted into warrants to purchase shares of common stock. The condensed financial statements, including share and per share amounts, do not give effect to the IPO or the related conversion of securities into shares of common stock.

Going Concern, Liquidity and Capital Resources

The Company has incurred significant operating losses since its inception. As of June 30, 2019, the Company had an accumulated deficit of $60.1 million and cash and cash equivalents totaling $17.5 million. The Company also has substantial indebtedness, the terms of which require it to meet a monthly six-month trailing revenue covenant. At the time of issuance of the Company’s financial statements as of December 31, 2018 and 2017 and for each of the years then ended, the Company disclosed that substantial doubt was raised about the Company’s ability to continue as a going concern, because its projections indicated potential non-compliance with this covenant during the next 12 months. As discussed in Note 8, “Long-Term Debt,” on June 13, 2019, the Company entered into an amendment to its debt agreement, which among other changes, modified the revenue covenant from a trailing six-month calculation to a trailing three-month calculation with revised revenue targets tested monthly. As a result, management now expects to be in compliance with the amended covenant during the next 12 months. The Company intends to fund planned operations for the next 12 months using its cash on hand, including net cash proceeds from the IPO, and collections from test report sales.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company’s financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (‘‘U.S. GAAP’’). The Company has no subsidiaries and all operations are conducted by the Company.

Unaudited Interim Financial Information

The accompanying balance sheet as of June 30, 2019; the statements of operations and comprehensive loss, the statements of convertible preferred stock and stockholders’ deficit for the three and six months ended June 30, 2019 and 2018; and the statements of cash flows for the six months ended June 30, 2018 and 2019 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s financial position as of June 30, 2019 and the results of its operations and its cash flows for the three and six months ended June 30, 2018 and 2019. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2018 and 2019 are also unaudited. The results for the three and six months ended June 30, 2019 are not necessarily indicative of results to be expected for the year ending December 31, 2019, any other interim periods, or any future year or period. The balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date. Certain disclosures have been condensed or omitted from the interim financial statements. These financial

statements should be read in conjunction with the Company's audited financial statements included in the Company's final prospectus filed with Securities and Exchange Commission on July 26, 2019.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include revenue recognition, the determination of fair value of the Company's preferred stock warrants and convertible debt embedded derivatives, the valuation of stock options, assessing future tax exposure and the realization of deferred tax assets, the useful lives and recoverability of property and equipment, and contingent liabilities. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment. All revenues are attributable to U.S.-based operations and all assets are held in the United States.

Cash and Cash Equivalents including Concentrations of Credit Risk

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less. Cash equivalents consist primarily of amounts invested in money market accounts. A majority of the Company's cash and cash equivalents are deposited with a single financial institution. Deposits in this institution may exceed the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation for U.S. institutions. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Revenue Recognition

Revenue is recognized in accordance with Financial Accounting Standards Board (''FASB'') Accounting Standards Codification (''ASC'') Topic 606, *Revenue from Contracts with Customers* (''ASC 606''). In accordance with ASC 606, the Company follows a five-step process to recognize revenues: 1) identify the contract with the customer, 2) identify the performance obligations, 3) determine the transaction price, 4) allocate the transaction price to the performance obligations and 5) recognize revenues when the performance obligations are satisfied.

All of the Company's revenues from contracts with customers are associated with the provision of diagnostic and prognostic cancer testing services. Most of the Company's revenues are attributable to DecisionDx-Melanoma for cutaneous melanoma. The Company also provides a test for uveal melanoma, DecisionDx-UM. Information on the disaggregation of revenues by the Company's significant third-party payors is included under *Payor Concentration* below. The Company has determined that it has a contract with the patient when the treating clinician orders the test. The Company's contracts generally contain a single performance obligation, which is the delivery of the test report, and the Company satisfies its performance obligation at a point in time upon the delivery of the test report to the treating physician, at which point the Company can bill for the report. The amount of revenue recognized reflects the amount of consideration to which the Company expects to be entitled (the ''transaction price'') and considers the effects of variable consideration, which is discussed further below.

Once the Company satisfies its performance obligations and bills for the service, the timing of the collection of payments may vary based on the payment practices of the third-party payor and the existence of contractually established reimbursement rates. Most of the payments for the Company's services are made by third-party payors, including Medicare and commercial health insurance carriers. Certain contracts contain a contractual commitment of a reimbursement rate that differs from the Company's list prices. However, absent a contractually committed reimbursement rate with a commercial carrier or governmental program, the Company's diagnostic tests may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the tests in the event that their insurance provider declines to reimburse the Company. The Company may pursue, on a case-by-case basis, reimbursement from such patients in the form of co-payments and co-insurance, in accordance with the contractual obligations

that the Company has with the insurance carrier or health plan. These situations may result in a delay in the collection of payments.

The Medicare claims that are covered by policy under a Local Coverage Determination (''LCD'') are generally paid at the established rate by the Company's Medicare contractor within 30 days from receipt. Medicare claims that were either submitted to Medicare prior to the LCD coverage commencement date or are not covered by the terms of the LCD but meet the definition of being medically reasonable and necessary pursuant to the controlling Section 1862(a)(1)(A) of the Social Security Act are generally appealed and may ultimately be paid at the first (termed ''redetermination''), second (termed ''reconsideration'') or third level of appeal (de novo hearing with an Administrative Law Judge ("ALJ")). A successful appeal at any of these levels results in payment.

In the absence of LCD coverage or contractually established reimbursements rates, the Company has concluded that its contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than the Company's standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at the expected value using the ''most likely amount'' method under ASC 606. The amounts are determined by historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of the Company's past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of the Company's influence, such as the judgment and actions of third parties. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor. Variable consideration for Medicare claims is deemed to be fully constrained when the payment of such claims is subject to approval by an ALJ at an appeal hearing, due to factors outside the Company's influence (i.e., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Included in revenues for the three months ended June 30, 2019 and 2018 were $3,257,045 and $(834,707), respectively, of revenue increases (decreases) associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. Such amounts of variable consideration for the six months ended June 30, 2019 and 2018 were revenue increases of $2,794,250 and $856,881, respectively. These amounts include (i) adjustments for actual collections versus estimated amounts and (ii) cash collections and the related recognition of revenue in current period for tests delivered in prior periods due to the release of the constraint on variable consideration.

Because the Company's contracts with customers have an expected duration of one year or less, the Company has elected the practical expedient in ASC 606 to not disclose information about its remaining performance obligations. Any incremental costs to obtain contracts are recorded as selling, general and administrative expense as incurred due to the short duration of the Company's contracts. Contract balances consisted solely of accounts receivable (both current and noncurrent) as of June 30, 2019 and December 31, 2018.

DecisionDx-Melanoma Claims Consolidation

In June 2017, the Company submitted to the Office of Medicare Hearings and Appeals (''OMHA'') a formal request to participate in a program that OMHA developed with the intent of providing appellants a means to have large volumes of claim disputes adjudicated at an accelerated rate. The program consolidates outstanding claims at the ALJ level and uses a statistical-sampling approach where five ALJ's will determine reimbursement results for a sample of claims which are then extrapolated to the universe of claims. The consolidation includes 2,698 DecisionDx-Melanoma claims dating from 2013 through spring 2017. The judges who will review the sample sets have been identified and the hearings were held in April 2019 with a supplemental hearing in May 2019. No formal ruling has been issued to date. In accordance with ASC 606, the Company has not recognized (fully constrained the variable consideration) any revenues attributable to these claims in its financial statements pending the outcome of this matter. The Company expects to recognize any revenue adjudicated by the ALJ in the periodic reporting period in which the Company is notified of the ALJ hearing outcome.

Payor Concentration

The Company relies upon reimbursements from third-party government payors (primarily Medicare) and private-payor insurance companies to collect accounts receivable related to sales of its diagnostic tests.

CASTLE BIOSCIENCES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

The Company's significant third-party payors and their related revenues as a percentage of total revenues and accounts receivable balances are as follows:

	Percentage of Revenues		Percentage of Accounts Receivable (current)		Percentage of Accounts Receivable (non-current)	
	Six Months Ended June 30,					
	2019	2018	June 30, 2019	Dec 31, 2018	June 30, 2019	Dec 31, 2018
Medicare	45%	7%	9%	54%	—%	—%
Medicare Advantage plans	22%	25%	25%	9%	10%	18%
United Healthcare	9%	18%	12%	7%	—%	15%
BlueCross BlueShield plans	7%	27%	32%	18%	52%	41%

Accounts Receivable and Allowance for Doubtful Accounts

The Company classifies accounts receivable balances that are expected to be paid more than one year from the balance sheet date as non-current assets. The estimated timing of payment utilized as a basis for classification as non-current is determined by analyses of historical payor-specific payment experience, adjusted for known factors that are expected to change the timing of future payments.

The Company accrues an allowance for doubtful accounts against its accounts receivable when it is probable that an account is not collectible, based on write off history, credit risk of specific accounts, aging analysis and other information available on specific accounts. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral. Accounts receivable are written off when all efforts to collect the balance have been exhausted. Historically, the Company's bad debt expense has not been significant. The allowance for doubtful accounts was zero as of June 30, 2019 and December 31, 2018. Adjustments for implicit price concessions attributable to variable consideration, as discussed above, are incorporated into the measurement of the accounts receivable balances and are not part of the allowance for doubtful accounts.

Fair Value of Financial Instruments

The carrying amount of the Company's long-term debt approximates fair value due to its variable market interest rate and management's opinion that current rates and terms that would be available to the Company with the same maturity and security structure would be essentially equivalent to that of the Company's long-term debt. The estimated fair value of the Company's convertible promissory notes at June 30, 2019 was $15,820,026. These estimated fair values are ''Level 3'' fair value measurements, as defined in Note 9.

Accrued Compensation

The Company accrues for liabilities under discretionary employee and executive bonus plans. These estimated compensation liabilities are based on progress against corporate objectives approved by the Board of Directors, compensation levels of eligible individuals, and target bonus percentage levels. The Board of Directors reviews and evaluates the performance against these objectives and ultimately determines what discretionary payments are made. The Company also accrues for liabilities under employee sales incentive bonus plans with accruals based on performance achieved to date compared to established targets. As of June 30, 2019 and December 31, 2018, the Company accrued approximately $1,941,502 and $3,197,234, respectively, for liabilities associated with these bonus plans. These amounts are classified as current or noncurrent accrued liabilities in the balance sheets based on the expected timing of payment.

Deferred Offering Costs

Deferred offering costs consist primarily of legal and accounting fees, which are direct and incremental fees related to the IPO. The deferred offering costs will be offset against the IPO proceeds, which will be recorded in the third quarter of 2019. As of June 30, 2019 and December 31, 2018, the Company had incurred $1,670,747 and $91,307, respectively, in deferred offering costs, which are reported as other assets - long-term on the balance sheets. Additionally, as of June 30, 2019, the Company had incurred debt issuance costs of $79,226 associated with a new convertible promissory note that was issued in July 2019.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

Accounting Pronouncements Yet to be Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842),* which supersedes FASB ASC Topic 840, *Leases (Topic 840),* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. For companies that are not emerging growth companies (''EGCs''), the ASU is effective for fiscal years beginning after December 15, 2018. For EGCs, the ASU is effective for fiscal years beginning after December 15, 2019. The Company will adopt the new standard using the modified retrospective method, under which the Company will apply Topic 842 to existing and new leases as of January 1, 2020, but prior periods will not be restated and will continue to be reported under Topic 840 guidance in effect during those periods. The Company anticipates that the adoption will not have a material impact on its statements of operations and comprehensive loss or its statements of cash flows but expects to recognize right-of-use assets and liabilities for lease obligations associated with its operating leases.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments—Credit Losses*, which included an amendment of the effective date for nonpublic entities. For non-EGCs, the ASU is effective for fiscal years beginning after December 15, 2019. For EGCs, the standard is effective for fiscal years beginning after December 15, 2021. The Company does not believe the adoption of this standard will have a significant impact on its financial statements, given its history of minimal bad debt expense relating to trade accounts receivable.

3. Loss Per Share

Loss per share is computed by dividing net loss attributable to common stockholders for the period by the weighted-average number of common shares outstanding during the period. Diluted loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, as well as from the possible conversion of the Company's convertible preferred stock, convertible promissory notes and exercise of outstanding warrants. The treasury stock and if-converted methods are used to calculate the potential dilutive effect of these common stock equivalents. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive. Due to the Company reporting a net loss attributable to common stockholders for all periods presented, all potentially dilutive securities were antidilutive and have been excluded from the computation of diluted loss per share.

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

	June 30, 2019	June 30, 2018
Shares issuable upon conversion of Series A convertible preferred stock	437,822	437,822
Shares issuable upon conversion of Series B convertible preferred stock	669,933	669,933
Shares issuable upon conversion of Series C convertible preferred stock	412,678	412,678
Shares issuable upon conversion of Series D convertible preferred stock	620,522	620,522
Shares issuable upon conversion of Series E-1 convertible preferred stock	680,592	680,592
Shares issuable upon conversion of Series E-2 convertible preferred stock	766,553	766,553
Shares issuable upon conversion of Series E-2A convertible preferred stock	22,400	22,400
Shares issuable upon conversion of Series E-3 convertible preferred stock	675,964	675,964
Shares issuable upon conversion of Series F convertible preferred stock	3,883,998	3,883,522
Shares issuable upon exercise of stock options	1,883,016	1,551,999
Shares issuable upon exercise of preferred stock warrants	141,259	146,541
Shares issuable upon conversion of convertible promissory notes(1)	948,227	—
Total	11,142,964	9,868,526

(1) Based on conversion of the aggregate principal amount, plus accrued interest thereon, of the convertible promissory notes into shares of common stock based on the IPO price of $16.00 per share and assuming occurrence of the conversion on June 30, 2019. See Note 7 for additional information on the convertible promissory notes.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	June 30, 2019	December 31, 2018
Lab equipment	$ 1,297,463	$ 1,153,210
Computer equipment	715,067	629,437
Leasehold improvements	584,164	553,921
Furniture and fixtures	158,447	101,813
Total	2,755,141	2,438,381
Less accumulated depreciation	(1,011,971)	(909,385)
Property and equipment, net	$ 1,743,170	$ 1,528,996

Depreciation expense was recorded in the statements of operations and comprehensive loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of sales	$ 47,288	$ 38,883	$ 90,778	$ 77,500
Research and development	1,803	879	3,407	1,850
Selling, general and administrative	36,774	31,320	69,100	62,145
Total	$ 85,865	$ 71,082	$ 163,285	$ 141,495

5. Intangible Assets, Net

Intangible assets consist of capitalized license costs as follows:

	June 30, 2019		December 31, 2018	
	Value	Weighted-Average Remaining Life (Years)	Value	Weighted-Average Remaining Life (Years)
Licenses	$ 274,534	0	$ 274,534	0
Accumulated amortization	(274,534)		(270,367)	
Intangible assets, net	$ —		$ 4,167	

Amortization expense was $1,667 and $9,336, for the three months ended June 30, 2019 and 2018, respectively, and $4,167 and $18,673, for the six months ended June 30, 2019 and 2018, respectively.

6. Other Accrued Liabilities

Other accrued liabilities consisted of the following:

	June 30, 2019	December 31, 2018
Accrued state income taxes	$ 8,606	$ 8,606
Accrued interest	514,633	185,580
Accrued royalties	183,046	239,751
Accrued service fees	907,089	281,307
Other	3,492	—
Total	$ 1,616,866	$ 715,244

7. Convertible Promissory Notes

In January and February 2019, the Company issued $11,770,375 principal amount of unsecured convertible promissory notes (the "Q1 2019 Notes"), of which $4,755,882 was with related parties (executive officers, members of the Company's Board of Directors or entities affiliated with them). The Q1 2019 Notes bore simple interest at a rate of 8% per annum. Originally, the Q1 2019 Notes had a maturity date of January 31, 2020, but on July 3, 2019, the Company entered into an amendment with the holders of the Q1 2019 Notes to extend the maturity to June 30, 2020.

Prior to the actual conversion of the Q1 2019 Notes on July 29, 2019 (discussed below), on or before the maturity date, the entire outstanding principal amount of and accrued interest on the Q1 2019 Notes (the "Conversion Amount"), was automatically convertible into shares of the Company's equity securities issued and sold in a single or series of related transactions, with the principal purpose of raising capital, in which the Company sold shares of such equity securities for aggregate gross proceeds of at least $10.0 million (the "Next Equity Financing"). The number of shares of such equity securities issuable in the Next Equity Financing was equal to the quotient of the Conversion Amount as of the closing date of the Next Equity Financing divided by a per share price that is equal to 80% of the lowest per share purchase price of the equity securities sold in the Next Equity Financing. If the Q1 2019 Notes had not been repaid or converted prior to the maturity date, then, at the request of the holders of a majority of the then-outstanding principal amount of and accrued interest on the Q1 2019 Notes, the Conversion Amount as of the maturity date would have converted into shares of the Company's Series F redeemable convertible preferred stock, or any senior equity security issued by the Company after the first issuance of the Q1 2019 Notes, in each case at a conversion price equal to the price at which such security was last sold (which was $5.8208 for shares of the Company's Series F redeemable convertible preferred stock). If a change of control of the Company would have occurred while the Q1 2019 Notes were outstanding, the Company would have been required to repurchase each Note from each holder at a repurchase price equal to two times the principal amount of such Note, plus any accrued and unpaid interest on such Note as of the date of such repurchase.

The closing of the IPO on July 29, 2019 was considered to be the Next Equity Financing under the terms of the Q1 2019 Notes. Accordingly, on July 29, 2019, the Conversion Amount of the Q1 2019 Notes as of such date converted into 954,074 shares of common stock based on a price of $12.80 per share, or 80% of the IPO price of $16.00 per share.

The Company determined that the Q1 2019 Notes contained embedded derivatives that required bifurcation and separate accounting under ASC 815-15, *Embedded Derivatives*. The Company determined that two such features in the Q1 2019 Notes

were not considered clearly and closely related to the host debt instrument and therefore required separate accounting: a) the automatic conversion feature in connection with the Next Equity Financing and b) the acceleration upon a change of control feature. Under ASC 815-15, these features are bundled together and accounted for as a single, compound embedded derivative. The Company determined the fair value of the embedded derivative liability at the issuance date, creating a discount to the carrying value of the Q1 2019 Notes, which was being amortized over the life of the debt using the effective interest method. The embedded derivative was recorded at fair value each reporting period, with changes in fair value recorded as "other income (expense), net" in the statements of operations and comprehensive loss. The embedded derivative liability is included in the same line as the convertible promissory notes on the balance sheet, as detailed in the table below. No hedge accounting treatment was applied. For details regarding the fair value measurement of the embedded derivative, see Note 9.

The Company also assessed the optional conversion feature into Series F redeemable convertible preferred stock at maturity and determined that this feature did not meet the definition of a derivative instrument because the settlement terms involved the gross delivery of the underlying shares, which were not readily convertible to cash. The Company then assessed whether this feature caused the Q1 2019 Notes to be subject to ASC 470-20, *Debt with Conversion and Other Options* ("ASC 470-20"), and determined that the beneficial conversion feature guidance was applicable to the Q1 2019 Notes. At issuance, the Company concluded that the Q1 2019 Notes had a beneficial conversion feature because the fair value of the Series F preferred stock exceeded the conversion price of $5.8208 per share that would have been applicable under the optional conversion at maturity, assuming no other equity securities senior to Series F preferred stock were sold. Under ASC 470-20, this beneficial conversion feature was measured at intrinsic value as of the issuance date of the Q1 2019 Notes and was recognized as additional paid-in capital, creating a discount to the carrying value of the Q1 2019 Notes that was being amortized over the life of the debt using the effective interest method.

The following table summarizes the aggregate values recorded for the Q1 2019 Notes as of June 30, 2019 and at issuance:

	June 30, 2019	At Issuance [1]
Liability component:		
Principal (including $4,755,882 with related parties)	$ 11,770,375	$ 11,770,375
Unamortized issuance costs	(68,425)	(74,880)
Unamortized discount from beneficial conversion feature	(7,655,336)	(8,377,592)
Unamortized discount from embedded derivative	(2,573,202)	(2,815,946)
Net carrying amount of the liability component	1,473,412	501,957
Embedded derivative liability	2,952,407	2,815,946
Total	$ 4,425,819	$ 3,317,903
Equity Component:		
Carrying value of beneficial conversion feature recorded in additional paid-in capital	$ 8,377,592	$ 8,377,592

(1) The Q1 2019 Notes were issued on January 31, 2019, February 12, 2019 and February 27, 2019.

The Q1 2019 Notes were classified as current liabilities on the balance sheet due to their contractual maturity date. Amortization of discounts and issuance costs on the Q1 2019 Notes totaled $767,308 for the three months ended June 30, 2019, and $971,456 for the six months ended June 30, 2019, and were included in interest expense.

The amounts recognized in net loss for the three and six months ended June 30, 2019 for the embedded derivative liability are as follows:

		Gain (Loss) Recognized in Net Loss	
	Statement of Operations and Comprehensive Loss Location	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Derivatives Not Classified as Hedging Instruments			
Embedded derivative in convertible promissory notes	Other income (expense), net	$ (90,376)	$ (136,461)

The following table presents the fair value and balance sheet classification for the embedded derivative liability:

	June 30, 2019		
	Classification	Balance Sheet Location	Fair Value
Derivatives Not Classified as Hedging Instruments			
Embedded derivative in convertible promissory notes	Liability	Convertible promissory notes	$ 2,952,407

8. Long-Term Debt

The Company's long-term debt consists of term debt and a revolving line of credit and are presented in the table below:

	June 30, 2019	December 31, 2018
Term debt	$ 26,687,500	$ 21,350,000
Revolving line of credit	—	5,000,000
Total principal amount	26,687,500	26,350,000
Unamortized discount and issuance costs	(1,995,386)	(1,850,248)
Total long-term debt	24,692,114	24,499,752
Less: Current portion of long-term debt	(833,333)	—
Total long-term debt, less current portion	$ 23,858,781	$ 24,499,752

Term Debt

On November 30, 2018 (the ''Closing Date''), the Company entered into a new Loan and Security Agreement (the ''2018 LSA'') with Oxford Finance LLC (''Oxford''), as collateral agent, and Oxford and Silicon Valley Bank (''SVB'') as equal syndicated lenders (collectively, the ''Lenders''). The 2018 LSA replaced the Company's previous lending arrangement and provided for a $20.0 million secured term loan credit facility (the ''2018 Term Loan'') and a credit line of up to $5.0 million (discussed in the ''Revolving Line of Credit'' section below), prior to amendment of the 2018 LSA on June 13, 2019, as discussed below. The Company's obligations under the 2018 LSA are secured by substantially all of its assets, excluding intellectual property and subject to certain other exceptions and limitations. The Company has the right to prepay the 2018 Term Loan in whole or in part at any time, subject to a prepayment fee of 2.50% if prepaid on or prior to November 30, 2019, 1.50% if prepaid after November 30, 2019 and on or prior to November 30, 2020, and 0.75% thereafter. Upon prepayment, the Company is also obligated to pay a non-refundable early termination fee of $496,785. Amounts prepaid or repaid under the 2018 Term Loan may not be reborrowed. Initially, the 2018 LSA contained a financial covenant that required the Company to achieve a monthly trailing six-month revenue target each month throughout the term of the agreement, but the covenant was amended on June 13, 2019 and changed to a monthly trailing three-month target, as discussed further below. As of June 30, 2019 and December 31, 2018, the Company was in compliance with this covenant.

On June 13, 2019, the Company entered into an amendment to the 2018 LSA (the "Amendment"), which, among other things, (i) eliminated the $5.0 million revolving line and increased the 2018 Term Loan by $5.0 million and (ii) amended the financial covenant to require the Company to achieve a monthly trailing three-month revenue target each month throughout the term of the agreement. The financial covenant was amended primarily to align with a more current reflection of the Company's revenue projections after taking into account the impact on the Company's revenue recognition following the Company's early adoption of ASC 606. The Amendment was accounted for as a modification of the 2018 LSA, and therefore no extinguishment gain or loss was recognized.

For each month through December 31, 2019, the trailing three-month revenue requirements are calculated as a percentage of the Company's previously approved applicable monthly revenue projections. For monthly periods ending after December 31, 2019, the trailing three-months revenue requirements will be determined by the Lenders upon receipt and review of the Company's monthly financial projections for the year, subject to certain specified criteria regarding minimum requirements. Revenues, if any, that the Company recognizes as a result of an ALJ appeal process from consolidated claims initiatives for DecisionDx-Melanoma do not count toward the minimum revenue requirements.

In addition, the 2018 LSA contains customary conditions of borrowing, events of default and covenants, including covenants that restrict the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. Should an event of default occur, including the occurrence of a material adverse change, the Company could be liable for immediate repayment of all obligations under the 2018 LSA. Should the Company seek to further amend the terms of the 2018 LSA, the consent of Oxford and SVB would be required.

The 2018 Term Loan bears interest at a floating rate equal to the greater of 1) 8.55% and 2) the 30-day U.S. LIBOR rate as reported in the Wall Street Journal on the last business day of the month that precedes the month in which the interest will accrue, plus 6.48%. The applicable interest rate on the 2018 Term Loan was 8.88% and 8.98% at June 30, 2019 and December 31, 2018, respectively. Interest on the 2018 Term Loan is payable monthly in arrears. The Company is permitted to make interest-only payments on the 2018 Term Loan for the 18 months following the Closing Date. The principal is required to be repaid in 30 equal monthly installments beginning on June 1, 2020. All unpaid principal and accrued and unpaid interest is due on November 1, 2022 (the "2018 Term Loan Maturity Date"). The Company is also obligated to make an additional final payment of 6.75% of the aggregate original principal amount, or $1,687,500 as of June 30, 2019, upon any prepayment or on the 2018 Term Loan Maturity Date. The final payment amount is being amortized as additional interest expense using the effective interest method over the term of the debt.

The 2018 Term Loan was fully funded on the Closing Date and the 2018 Revolving Line (defined and discussed below) was fully drawn upon on the Closing Date. Proceeds from the 2018 LSA were used to repay all outstanding obligations under the Company's previous lending arrangement and to provide working capital. As a condition of the loan, the Company issued Series F preferred stock warrants to the Lenders with an aggregate initial fair value of $158,000. In accordance with ASC 480-10, the warrants are liability-classified as the underlying to the warrant is a puttable security. The initial recognition of the warrant liability created a discount to the debt, which is being amortized over the debt term using the effective interest method. The 2018 LSA was accounted for as a modification of the previous lending arrangement with SVB and Oxford, and therefore no extinguishment gain or loss was recognized.

Revolving Line of Credit

Under the 2018 LSA, the Company had a $5.0 million revolving line of credit (the ''2018 Revolving Line''), contingent on the Company's satisfaction of borrowing base eligibility requirements. The 2018 Revolving Line bore interest at a floating per annum rate equal to the greater of 1) 6.25% and 2) 5.48% above the U.S. LIBOR rate. The applicable interest rate on the 2018 Revolving Line December 31, 2018 was 7.98%. The 2018 Revolving Line was to be due in full no later than November 30, 2020, but was eliminated in connection with the Amendment, as discussed above.

9. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. The fair value hierarchy prioritizes the inputs to valuation techniques used in measuring fair value. There are three levels to the fair value hierarchy based on the reliability of inputs, as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs in which little or no market data exists, therefore requiring the Company to develop its own assumptions.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed, or amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

CASTLE BIOSCIENCES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

The table below provides information, by level within the fair value hierarchy, of the Company's financial assets and liabilities that are accounted for at fair value on a recurring basis as of June 30, 2019 and December 31, 2018:

	As of June 30, 2019			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Liabilities:				
Preferred stock warrants	$ —	$ —	$ 1,279,840	$ 1,279,840
Embedded derivative in convertible promissory notes[1]	$ —	$ —	$ 2,952,407	$ 2,952,407

(1) Included in the convertible promissory notes line on the balance sheet.

	As of December 31, 2018			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Liabilities:				
Preferred stock warrants	$ —	$ —	$ 1,193,726	$ 1,193,726

The following table discloses the summary of changes in the fair value of the Level 3 fair value measurements:

	Six Months Ended June 30, 2019	
	Preferred stock warrants	Embedded derivative in convertible promissory notes
Balance, December 31, 2018	$ 1,193,726	$ —
Issuance of convertible promissory notes	—	2,815,946
Change in fair value included in net loss	86,114	136,461
Balance, June 30, 2019	$ 1,279,840	$ 2,952,407

The changes in fair value of the preferred stock warrant liability and the embedded derivative liability are recorded as ''other income (expense), net'' in the statements of operations and comprehensive loss.

The fair value of the warrants to purchase shares of Series A, Series B, Series E-1, Series E-2, Series E-2A, Series E-3, and Series F redeemable convertible preferred stock was estimated by management using the Black-Scholes option pricing model with the following assumptions:

	June 30, 2019	December 31, 2018
Average expected life (years)	7	9
Expected stock price volatility	68%	64%
Risk-free interest rate	1.72% - 1.97%	2.51% - 2.69%
Dividend yield	—%	—%

Certain features of the Q1 2019 Notes were determined to be an embedded derivative requiring bifurcation and separate accounting, as discussed in Note 7. The fair value of the embedded derivative was determined based on a probability-weighted income approach discounted at an interest rate that is consistent with the appropriate market interest rate (8.93% as of June 30, 2019) considering management's estimates of the probability of the possible settlement outcomes. As of June 30, 2019, management assessed the probability of the occurrence of the Next Equity Financing at 90%.

10. Commitments and Contingencies

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company believes there is no threatened litigation or litigation pending that could have, individually or in the aggregate, a material adverse effect on the Company's financial position, results of operations or cash flows.

11. Convertible Preferred Stock and Preferred Stock Warrants

Convertible Preferred Stock

Convertible preferred stock consists of the following:

Convertible Preferred Stock

	As of June 30, 2019						
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price per Share	Original Issue Value	Accumulated and Undeclared Dividends	Aggregate Liquidation Preference	Carrying Value
Series C	503,056	503,056	$ 3.4800	$ 1,750,635	$ 736,010	$ 2,486,645	$ 1,500,994

Redeemable convertible preferred stock

	As of June 30, 2019						
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price per Share	Original Issue Value	Accumulated and Undeclared Dividends	Aggregate Liquidation Preference	Carrying Value
Series A	533,711	533,711	$2.1400	$ 1,142,142	$ 758,808	$ 1,900,950	$ 1,142,142
Series B	816,654	816,654	$2.2500	1,837,472	1,055,734	2,893,206	1,931,635
Series D	756,416	756,416	$3.7700	2,851,688	1,452,919	4,304,607	2,851,688
Series E-1	842,641	829,642	$3.7700	3,127,750	1,219,362	4,347,112	3,100,652
Series E-2	949,725	934,433	$4.5776	4,277,461	1,672,509	5,949,970	4,277,461
Series E-2A	27,306	27,306	$4.5776	124,996	43,696	168,692	124,953
Series E-3	830,554	824,000	$5.3405	4,400,572	1,538,248	5,938,820	4,399,269
Series F	7,089,870	4,734,613	$5.8208	27,559,235	6,305,459	33,864,694	27,279,930
Total	11,846,877	9,456,775		$45,321,316	$14,046,735	$59,368,051	$45,107,730

Convertible preferred stock

	As of December 31, 2018						
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price per Share	Original Issue Value	Accumulated and Undeclared Dividends	Aggregate Liquidation Preference	Carrying Value
Series C	503,056	503,056	$3.4800	$1,750,635	$ 666,560	$ 2,417,195	$ 1,500,994

CASTLE BIOSCIENCES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

Redeemable convertible preferred stock

	As of December 31, 2018						
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price per Share	Original Issue Value	Accumulated and Undeclared Dividends	Aggregate Liquidation Preference	Carrying Value
Series A	533,711	533,711	$2.1400	$ 1,142,142	$ 713,498	$ 1,855,640	$ 1,142,142
Series B	816,654	816,654	$2.2500	1,837,472	982,840	2,820,312	1,931,634
Series D	756,416	756,416	$3.7700	2,851,688	1,339,789	4,191,477	2,851,688
Series E-1	842,641	829,642	$3.7700	3,127,750	1,095,281	4,223,031	3,098,578
Series E-2	949,725	934,433	$4.5776	4,277,461	1,502,821	5,780,282	4,277,461
Series E-2A	27,306	27,306	$4.5776	124,996	38,738	163,734	124,762
Series E-3	830,554	824,000	$5.3405	4,400,572	1,363,688	5,764,260	4,393,509
Series F	4,883,486	4,734,613	$5.8208	27,559,235	5,212,065	32,771,300	27,175,383
Total	9,640,493	9,456,775		$ 45,321,316	$12,248,720	$57,570,036	$44,995,157

As a result of a 1-for-1.219 reverse stock split effected on July 11, 2019, the conversion price for each series of preferred stock was adjusted to be the original issue price multiplied by 1.219. In connection with the IPO, effective July 29, 2019, all shares of preferred stock automatically converted into shares of common stock at rate of one common share for each 1.219 shares of preferred stock.

Preferred Stock Warrant Liabilities

Warrants to purchase redeemable convertible preferred shares consist of the following:

	As of June 30, 2019						
Warrants	Year of First Issuance	Shares	Exercise Price	Year of Expiration	Exercised	Expired	Outstanding
Series A Preferred Stock	2008	108,057	$2.1400	2015	(96,375)	(11,682)	—
Series B Preferred Stock	2010	86,667	$2.2500	2017	(86,667)	—	—
Series E-1 Preferred Stock	2014	16,249	$3.7700	2024	(3,250)	—	12,999
Series E-2 Preferred Stock	2014	15,292	$4.5776	2024	—	—	15,292
Series E-3 Preferred Stock	2015	6,554	$5.3405	2024	—	—	6,554
Series F Preferred Stock	2016	103,090	$5.8208	2026-2028	—	—	103,090
Series F Preferred Stock	2018	67,233	$0.0100	2023	(32,951)	—	34,282
Total		403,142			(219,243)	(11,682)	172,217

	As of December 31, 2018						
Warrants	Year of First Issuance	Shares	Exercise Price	Year of Expiration	Exercised	Expired	Outstanding
Series A Preferred Stock	2008	108,057	$2.1400	2015	(96,375)	(11,682)	—
Series B Preferred Stock	2010	86,667	$2.2500	2017	(86,667)	—	—
Series E-1 Preferred Stock	2014	16,249	$3.7700	2024	(3,250)	—	12,999
Series E-2 Preferred Stock	2014	15,292	$4.5776	2024	—	—	15,292
Series E-3 Preferred Stock	2015	6,554	$5.3405	2024	—	—	6,554
Series F Preferred Stock	2016	103,090	$5.8208	2026-2028	—	—	103,090
Series F Preferred Stock	2018	67,233	$0.0100	2023	(32,951)	—	34,282
Total		403,142			(219,243)	(11,682)	172,217

In connection with the IPO, effective July 29, 2019, all warrants to purchase shares of convertible preferred stock that were outstanding as of that date were converted into warrants to purchase shares of common stock at a rate of one common stock warrant for every 1.219 warrants to purchase shares of preferred stock. Exercise prices of the warrants were also adjusted upon conversion by multiplying each of the exercise prices by 1.219.

12. Stock Incentive Plan and Stock Based Compensation

Stock Incentive Plan

Activity under the Company's 2008 Stock Plan and the 2018 Stock Plan for the six months ended June 30, 2019 is set forth below:

	Shares Available for Grant	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance as of December 31, 2018	458,682	1,659,596	$ 1.99		
Granted	(510,355)	510,355	$ 3.46		
Exercised	—	(276,237)	$ 1.52		
Forfeited/Cancelled	10,698	(10,698)	$ 2.94		
Balance as of June 30, 2019	(40,975)	1,883,016	$ 2.46	7.62	$ 4,529,010
Exercisable at June 30, 2019[1]		838,975	$ 1.98	5.88	$ 2,416,122

(1) Vested and exercisable options. Additionally, outstanding unvested options to purchase an aggregate of 154,991 shares of common stock with a weighted-average exercise price of $2.39 per share may be exercised prior to vesting as of June 30, 2019 under early-exercise provisions. In the event of such exercise, the shares obtained upon exercise would be restricted and subject to forfeiture prior to vesting. No such early exercises have occurred as of June 30, 2019.

As of June 30, 2019, the number of options granted was in excess of the number of shares of common stock authorized to be issued under the 2018 Equity Incentive Plan. As discussed in Note 14, in July 2019 the Company's Board of Directors approved an increase in the share reserve by 144,878 shares.

Determining Fair Value of Stock Options - Summary of Assumptions

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options:

	Six Months Ended June 30,	
	2019	2018
Average expected term (years)	6	6
Expected stock price volatility	58.22% - 58.84%	57.91% - 57.96%
Risk-free interest rate	1.82% - 2.47%	2.88% - 2.89%
Dividend yield	—%	—%

Stock-based compensation expense related to stock options is included in the statements of operations and comprehensive loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of sales	$ 11,995	$ 9,625	$ 22,119	$ 14,399
Research and development	26,768	12,435	46,952	25,116
Selling, general and administrative	100,045	62,573	238,158	106,825
Total stock-based compensation expense	$ 138,808	$ 84,633	$ 307,229	$ 146,340

The weighted-average grant date fair value of options granted during the six months ended June 30, 2019 and 2018 was $1.95 and $1.35 per option, respectively. As of June 30, 2019, there was $1,553,975 of total unrecognized compensation cost, which is expected to be recognized on a straight-line basis over a weighted-average period of 3.2 years. The total unrecognized compensation costs will be adjusted for forfeitures in future periods as they occur.

13. Income Taxes

No income tax expense or benefit was recorded for the three or six months ended June 30, 2019 and 2018 due to the full valuation allowance on the Company's net deferred tax assets, based on the Company's assessment that it is more likely than not that the benefits of those deferred tax assets will not be realized.

14. Subsequent Events

On July 10, 2019, the Company amended its Amended and Restated Certificate of Incorporation to increase the number of authorized shares of its common stock to 17,650,824 and to change the provisions for determining the earliest redemption date of its redeemable convertible preferred stock, the result of which effectively changed such earliest redemption date to July 15, 2025.

On July 11, 2019, the Company effected a 1-for-1.219 reverse stock split of its common stock. The par value and the authorized number of shares of the common stock were not affected by the reverse stock split. The reverse stock split resulted in an adjustment to the Series A, B, C, D, E-1, E-2, E-2A, E-3, and F preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

On July 11, 2019, the Company's Board of Directors approved an increase of 144,878 in the number of shares authorized for issuance under the 2018 Equity Incentive Plan.

On July 12, 2019, the Company issued an unsecured convertible promissory note having a principal amount of $10,000,000 (the ''July 2019 Note''). The July 2019 Note bore simple interest at a rate of 8% per annum and had an original maturity date of June 30, 2020. As a result of the IPO, the outstanding principal amount plus accrued interest on the July 2019 Note converted into 707,032 shares of common stock on July 29, 2019, based on a price derived from a minimum valuation calculated pursuant to the terms of the July 2019 Note. In connection with the July 2019 Note issuance, the Company issued the purchaser of the July 2019 Note a warrant to purchase up to 209,243 shares of common stock at an exercise price of approximately $0.001 per share (the ''July 2019 Warrant''). The July 2019 Warrant, which expires on July 12, 2026, was initially exercisable for 50% of the shares subject to the warrant and became exercisable for the remaining 50% of the shares subject to the warrant upon the holder's satisfaction of a requirement to purchase a certain amount of equity securities of the Company. The holder satisfied such requirement on July 29, 2019 in connection with a purchase of common stock in the IPO.

On July 24, 2019, the Company's 2019 Equity Incentive Plan (the "2019 Plan") and the 2019 Employee Stock Purchase Plan (the "ESPP") became effective. The 2019 Plan authorizes 1,931,020 new shares plus the number of shares (not to exceed 1,976,756 shares) that remained available under the 2018 Stock Plan at the time the 2019 Plan became effective and any shares underlying outstanding stock awards granted under the 2018 Plan and 2008 Stock Plan that expire or are repurchased, forfeited, cancelled or withheld. The 2019 Plan also provides for certain automatic increases in the number of shares of common stock reserved for issuance. Under the ESPP, 411,935 shares of common stock are reserved for future issuance plus any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

Effective July 24, 2019, the Company granted an aggregate of 185,370 options to purchase common stock to its non-employee directors in connection with their service on the board of directors. The options were granted under the 2019 Plan at an exercise price equal to the IPO price of $16.00 per share. Each option has a vesting commencement date of August 1, 2019 and is subject to a four-year vesting schedule, with 25% vesting one year after the vesting commencement date and the balance vesting monthly over the remaining 36 months, subject to the respective optionholder's continued service with the Company. The options provide for full acceleration of all of the shares subject to the option in the event of a change in control. The post-termination exercise period for the options will be up to three months from the date of termination, if such termination is other than for death, disability or cause.

On July 29, 2019, the Company completed the initial public offering of its common stock. In connection with the IPO, the Company issued and sold 4,600,000 shares of its common stock, including 600,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share. The Company received approximately $66.0 million in net proceeds from the IPO, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The condensed financial statements, including share and per share amounts, do not give effect to the IPO. Immediately prior to the closing of the IPO, 9,973,884 shares of outstanding convertible preferred stock were automatically converted into 8,181,992 shares of common stock. In addition, immediately prior to the closing of the IPO, certain outstanding warrants to purchase shares of Series F convertible redeemable preferred stock were net exercised for an aggregate of 27,207 shares of common stock. Further, upon the closing of the IPO, the combined outstanding principal amount of $21.8 million of the Q1 2019 Notes and the July 2019 Note, plus accrued interest thereon, was converted into a total of

CASTLE BIOSCIENCES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

1,661,106 shares of common stock (comprised of 954,074 shares issued upon conversion of the Q1 2019 Notes and 707,032 shares issued upon conversion of the July 2019 Note).

On July 29, 2019, in connection with the closing of the IPO, a new Amended and Restated Certificate of Incorporation became effective for the Company, which changed the number of authorized shares of common stock, $0.001 par value, to 200,000,000 shares and the number of authorized shares of preferred stock, $0.001 par value, to 10,000,000 shares.

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

You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and the related notes and other financial information included in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto as of and for the years ended December 31, 2017 and 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, including Contractual Obligations and Critical Accounting Policies and Significant Judgments and Estimates, included in our final prospectus, or the Prospectus, filed with the Securities and Exchange Commission, or the SEC, on July 26, 2019 relating to our Registration Statements on Form S-1 (File Nos. 333-232369 and 333-232796). Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Castle Biosciences, Inc.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information 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, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

Overview

We are a commercial-stage dermatological cancer company focused on providing physicians and their patients with personalized, clinically actionable genomic information to make more accurate treatment decisions. We believe that the traditional approach to developing a treatment plan for certain cancers using clinical and pathology factors alone is inadequate and can be improved by incorporating personalized genomic information. Our non-invasive products utilize proprietary algorithms to provide an assessment of a patient's specific risk of metastasis or recurrence of their cancer, allowing physicians to identify patients who are likely to benefit from an escalation of care as well as those who may avoid unnecessary medical and surgical interventions. Our lead product, DecisionDx-Melanoma, is a proprietary multi-gene expression profile, or GEP, test that predicts the risk of metastasis or recurrence for patients diagnosed with invasive cutaneous melanoma, a deadly skin cancer. We estimate more than 100,000 patients are diagnosed with invasive cutaneous melanoma each year in the United States. We launched DecisionDx-Melanoma in May 2013. We also market DecisionDx-UM, which is a proprietary GEP test that predicts the risk of metastasis for patients with uveal melanoma, a rare eye cancer. We launched DecisionDx-UM in January 2010. Based on the substantial clinical evidence that we have developed, we have received Medicare coverage for both of our products, which represents approximately 50% of our addressable patient population.

We also have two late-stage proprietary products in development that address SCC and suspicious pigmented lesions which are indications with high clinical need in dermatological cancer. These indications are areas of high clinical need in dermatological cancer and, together, represent an additional addressable market of approximately 500,000 patients in the United States.

We have processed over 40,000 clinical samples since commercial launch and our annual revenue increased from $13.8 million in 2017 to $22.8 million in 2018. New ordering clinicians (first time ordering a test) grew by 23% for the six months ended June 30, 2019 compared to the six months ended June 30, 2018.

The numbers of DecisionDx-Melanoma and DecisionDx-UM test reports delivered by us during the six months ended June 30, 2019 and 2018 are presented in the table below:

	DecisionDx-Melanoma	DecisionDx-UM	Total
Q1 2018	2,727	322	3,049
Q2 2018	2,899	382	3,281
For the six months ended June 30, 2018	5,626	704	6,330
Q1 2019	3,232	360	3,592
Q2 2019	3,691	376	4,067
For the six months ended June 30, 2019	6,923	736	7,659

Since our inception in 2008, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, discovering product candidates, conducting clinical study activities to generate evidence demonstrating the clinical validity, clinical utility, economic benefits, and patient outcomes of our products, and commercialization activities for those products. We currently market two proprietary GEP products and generate substantially all of our revenue from those activities.

On July 29, 2019, we completed the initial public offering of our common stock, or the IPO. In connection with the IPO, we issued and sold 4,600,000 shares of our common stock, including 600,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share. We received approximately $66.0 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us. Prior to the IPO, we financed our operations primarily through private placements of preferred stock, revenue generated from sales of our products, bank debt and convertible notes.

The principal focus of our current commercial efforts is to distribute our molecular diagnostic testing products through our direct sales force. The number of test reports we generate is a key indicator that we use to assess our business. A test report is generated when we receive a sample in our laboratory, the relevant information relating to that test is entered into our Laboratory Information Management System, the genomic profile of the sample is performed and a report providing the results of that profile is sent to the physician who ordered the test.

We bill third-party payors and patients for the tests we perform. The majority of our revenue collections is paid by third-party insurers, including Medicare. We have received Local Coverage Determinations, or LCDs, which provide coverage for our tests that meet certain criteria for Medicare and Medicare Advantage beneficiaries, representing approximately 60 million covered lives. As it relates to DecisionDx-UM, we have contracts or have received positive medical policy decisions from additional payors representing approximately 83 million covered lives. A ''covered life'' means a subscriber, or a dependent of a subscriber, who is insured under an insurance policy for such an insurance carrier.

On May 17, 2019, the Centers for Medicare & Medicaid Services, or CMS, determined that DecisionDx-UM meets the criteria for existing advanced diagnostic laboratory test, or ADLT, status, also referred to as "existing ADLT" status. This means that beginning in 2021, the DecisionDx-UM Medicare rate will be set annually based upon the median private payor rate for the first half of the second preceding calendar year. Specifically, the median private payor rate from January 1 to June 30, 2019 will be used to set the Medicare rate for the calendar year 2021. From May 17, 2019 through December 31, 2020, our rate will be set by Noridian Healthcare Solutions, LLC, or Noridian, our local Medicare Administrative Contractor, or MAC. Also, on May 17, 2019, CMS determined that DecisionDx-Melanoma meets the criteria for ''new ADLT'' status. This means that from July 1, 2019 through March 31, 2020 the Medicare reimbursement rate will equal the initial list price of $7,193. The rate for April 1, 2020 through December 31, 2021 will be calculated based upon the median private payor rate from July 1, 2019 to November 30, 2019. Accordingly, beginning in 2022, the rate will be set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2022 will be set using median private payor rate data from January 1, 2020 to June 30, 2020. If CMS determines the list charge amount for DecisionDx-Melanoma was greater than 130% of the weighted median of private payor rates, CMS will recoup from us the difference between the actual list charge and 130% of the weighted median.

Since our inception, we have incurred significant operating losses and negative cash flows. For the year ended December 31, 2018, our net loss was $6.4 million, our net cash used in operating activities was $12.3 million and we had an accumulated deficit of $57.5 million as of December 31, 2018. For the six months ended June 30, 2019, our net loss was $2.6 million, our net cash provided by operating activities was $1.8 million and we had an accumulated deficit of $60.1 million as of June 30,

2019. We also have substantial indebtedness, the terms of which require us to meet a monthly three-month trailing revenue covenant. Although we were in compliance with this covenant as of December 31, 2018 and the most recently tested month, management's projections, including consideration of certain revenue recognition policies, previously indicated potential non-compliance with the revenue covenant during the next 12 months from the date of issuance of our annual financial statements. For these reasons, the report of our independent registered public accounting firm on our financial statements as of December 31, 2017 and 2018 and for each of the periods then ended includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Subsequently, in June 2019, we entered into an amendment to our 2018 Loan and Security Agreement, or the 2018 LSA, which, among other changes, modified the revenue covenant. As a result, management now expects to be in compliance with the amended covenant for at least the next 12 months.

Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful commercialization of our currently marketed products and the products we plan to launch in the future. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on the commercialization of our existing products, the development of our future product candidates, and the potential commercialization of our product candidates.

We expect to continue to incur significant expenses and increasing operating losses for at least the next two years. We believe that the net proceeds from the IPO, together with our existing cash and cash equivalents and anticipated cash generated from sales of our products, will be sufficient to fund our operating expenses through at least the next 24 months. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Our net losses may fluctuate significantly from period to period, depending on the timing of our planned development activities, the growth of our sales and marketing activities and the timing of revenue recognition under Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers,* or ASC 606. We expect our expenses will increase substantially over time as we:

- execute clinical studies to generate evidence supporting our current and future product candidates;
- execute our commercialization strategy for our current and future products;
- continue our ongoing and planned development of new products;
- seek to discover and develop additional product candidates;
- hire additional scientific and research and development staff; and
- add additional operational, financial and management information systems and personnel.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

Factors affecting our performance

We believe there are several important factors that have impacted and that we expect will impact our operating performance and results of operations, including:

- **Report volume.** We believe that the number of reports we deliver to physicians is an important indicator of growth of adoption among the healthcare provider community. Our revenue and costs are affected by the volume of testing and mix of customers. Our performance depends on our ability to retain and broaden adoption with existing prescribing physicians, as well as attract new physicians.
- **Reimbursement.** We believe that expanding reimbursement is an important indicator of the value of our products. Payors require extensive evidence of clinical utility, clinical validity, patient outcomes and health economic benefits in order to provide reimbursement for diagnostics products. Our revenue depends on our ability to demonstrate the value of our products to these payors.
- **Gross margin.** We believe that our gross margin is an important indicator of the operating performance of our business. Higher gross margins reflect the average selling price of our tests, as well as the operating efficiency of our laboratory operations.
- **New product development.** A significant aspect of our business is our investment in research and development activities, including activities related to the development of new products. In addition to the development of new

product candidates, we believe these studies are critical to gaining physician adoption of new products and driving favorable coverage decisions by payors for such products.

Components of the Results of Operations

Net Revenues

We generate revenues from the sale of our products, primarily from the sale of DecisionDx-Melanoma and DecisionDx-UM. We bill third-party payors and patients for the tests we perform.

We adopted the new revenue recognition guidance, ASC 606, on January 1, 2018 using the full retrospective method and adjusted the comparative reporting period for the year ended December 31, 2017. Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating physicians. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved. We consider variable consideration to be fully constrained (and therefore not recognized) for Medicare claims when the payment of such claims is subject to approval by an ALJ at an appeal hearing, due to the level of uncertainty and timing of the outcome. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Importantly, we expect to recognize any revenue adjudicated by the ALJ in the reporting period in which we are notified of the ALJ hearing outcome. Due to ALJ hearings, potential future changes in insurance coverage policies, contractual rates, and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period.

Our ability to increase our revenues will depend on our ability to further penetrate our target market, and, in particular, generate sales through our direct sales force, develop and commercialize additional tests, obtain reimbursement from additional third-party payors and increase our reimbursement rate for tests performed. In the near term, our financial performance will be highly dependent on reimbursement for DecisionDx-Melanoma. The use of DecisionDx-Melanoma is not yet broadly covered under positive coverage policies, although many third-party payors have begun to reimburse for this test.

Cost of Sales

The components of our cost of sales are material and service costs, personnel costs, which includes stock-based compensation expense, equipment and infrastructure expenses associated with testing samples, electronic medical records, order and delivery systems, shipping charges to transport samples, third-party test fees, and allocated overhead including rent, information technology costs, equipment depreciation and utilities. Costs associated with performing tests are recorded when the test is accessioned regardless of whether and when revenues are recognized with respect to that test. As a result, our cost of sales as a percentage of revenues may vary significantly from period to period because we do not recognize all revenues in the period in which the associated costs are incurred. We expect cost of sales in absolute dollars to increase as the number of tests we perform increases.

Gross margin, calculated as net revenue minus cost of sales, is a key indicator we use to assess our business. For example, in 2016, we transitioned the performance of our genomic tests to our own dedicated clinical lab from a third-party contract lab. This transition increased the gross margin from our genomic tests while also increasing our level of control of the performance of our tests and laboratory quality metrics.

Research and Development

Research and development expenses include costs incurred to develop our genomic tests, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs, including stock-based compensation expense, prototype materials, laboratory supplies, consulting costs, regulatory costs, electronic medical records set up costs, costs associated with setting up and conducting clinical studies and allocated overhead, including rent, information technology, equipment depreciation and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase in absolute dollars as we continue to invest in research and development activities related to developing enhanced and new products.

Selling, General and Administrative

Selling, general and administrative, or SG&A, expenses include executive, selling and marketing, legal, finance and accounting, human resources, billing and client services. These expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, audit and legal expenses, consulting costs, training and medical education

activities, payor outreach programs and allocated overhead, including rent, information technology, equipment depreciation, and utilities. In the near term, we expect increases in SG&A expenses related to compliance with the rules and regulations of the SEC and Nasdaq, investor relations activities, and additional insurance expenses. Other administrative and professional services expenses within SG&A are expected to increase with the scale of our business, but selling and marketing-related expenses are expected to increase significantly, consistent with our growth strategy.

Interest Expense

Interest expense is attributable to borrowings under our term debt, revolving line of credit and the convertible promissory notes issued in January and February of 2019, or the Q1 2019 Notes, and also includes the amortization of debt discount and issuance costs.

Income Tax Expense

Our financial statements do not reflect any federal or state income tax benefits attributable to the net losses we have incurred, due to the uncertainty of realizing a benefit from those items. As of December 31, 2018, we had federal net operating loss carryforwards of $62.2 million, of which $48.3 million will begin to expire in 2028 if not utilized to offset taxable income, and $13.9 million may be carried forward indefinitely. Also, as of December 31, 2018, we had state net operating loss carryforwards of $60.8 million, which begin to expire in 2028 if not utilized to offset state taxable income.

Results of Operations

Comparison of the three months ended June 30, 2019 and 2018

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Three Months Ended June 30,			
	2019	2018	Increase (Decrease)	
	(unaudited)			
Net revenues	$ 10,739	$ 3,979	$ 6,760	169.9 %
Cost of sales	1,993	1,326	667	50.3 %
Gross margin	8,746	2,653	6,093	229.7 %
Operating expenses:				
Research and development	1,317	1,159	158	13.6 %
Selling, general and administrative	6,821	4,160	2,661	64.0 %
Total operating expenses	8,138	5,319	2,819	53.0 %
Operating income (loss)	608	(2,666)	3,274	122.8 %
Interest income	6	2	4	200.0 %
Interest expense	(1,693)	(525)	(1,168)	(222.5)%
Other income (expense), net	(190)	34	(224)	(658.8)%
Loss before income taxes	(1,269)	(3,155)	1,886	59.8 %
Income tax expense	—	—	—	—
Net loss	$ (1,269)	$ (3,155)	$ 1,886	59.8 %

Net Revenues

Net revenues increased by $6.8 million, or 169.9%, to $10.7 million due to a combination of increased test volume and higher per-unit revenues. Approximately 95% of the increase is attributable to DecisionDx-Melanoma test revenues with the remainder primarily attributable to DecisionDx-UM. For the three months ended June 30, 2019, we experienced an increase in DecisionDx-Melanoma and DecisionDx-UM test volume of 23.9% compared to the three months ended June 30, 2018. Also contributing to the increase in revenue is the effect of the issuance of the final LCD for DecisionDx-Melanoma, issued by Palmetto GBA, or Palmetto, and effective December 3, 2018. Coincident with the issuance of the LCD, a Medicare reimbursement rate for the test was established along with an agreement for payment of covered claims submitted for reimbursement beginning in February 2018. Note that as the Medicare LCD was not effective and the reimbursement rate was not known until the fourth quarter of 2018, the associated revenues were not recognized until the fourth quarter of 2018, which

is when the criteria for revenue recognition was met. Medicare revenues for DecisionDx-Melanoma associated with test reports delivered in the second quarter of 2018, but not recognized in revenue until the fourth quarter of 2018, were $2.2 million. For the three months ended June 30, 2019 and 2018, we recorded net revenue adjustments of positive $3.3 million and negative $0.8 million, respectively, related to tests delivered in previous periods, associated with changes in estimated variable consideration.

Cost of Sales

Cost of sales for the three months ended June 30, 2019 increased by $0.7 million, or 50.3%, compared to the three months ended June 30, 2018, primarily due to higher personnel costs due to additional headcount in our laboratory testing operations as well as increased costs of supplies and services, attributable to the higher activity levels. Our gross margin percentage was 81.4% for the three months ended June 30, 2019, compared to 66.7% for the same period in 2018, with the improvement principally a result of the increased operating leverage on the higher revenues. Due to the nature of our business, a significant portion of our cost of sales expenses represent fixed costs associated with our testing operations. Accordingly, our cost of sales expense will not necessarily increase or decrease commensurately with the change in net revenues from period to period.

Research and Development

Research and development expenses increased by $0.2 million, or 13.6%, for the three months ended June 30, 2019, compared to the three months ended June 30, 2018, primarily associated with increases in personnel costs and clinical studies expense, partially offset by lower legal fees and other variations.

Selling, General and Administrative

SG&A expense increased by $2.7 million, or 64.0%, for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. Approximately 47% of the increase is attributable to higher personnel costs, particularly within our sales function due to headcount expansion. In early 2019, we expanded our sales organization from 14 territories to 23 territories. The remainder of the increase was primarily associated with higher professional fees and increased travel costs. The higher professional fees were primarily attributable to accounting and reimbursement services.

Interest Expense

Interest expense increased by $1.2 million, or 222.5%, for the three months ended June 30, 2019 compared to the three months ended June 30, 2018. The effect of the issuance of the Q1 2019 Notes in January and February 2019 added $1.0 million in interest expense for the three months ended June 30, 2019 and consisted of the accrual of the contractual 8% interest plus the amortization of issuance costs and debt discount. The remainder of the increase is due to a combination of higher average outstanding balances and higher interest rates on our variable-rate term debt and revolving line of credit under our banking credit facility. Average outstanding bank debt balances were approximately $4.4 million higher during the three months ended June 30, 2019 compared to the three months ended June 30, 2018 and average interest rates increased by approximately 0.8% from the same period in 2018.

Other Income (Expense), Net

Other income (expense), net, consists of the change in fair value of our liability for convertible preferred stock warrants and, beginning in 2019, the change in fair value of the embedded derivative liability associated with the Q1 2019 Notes. These liabilities are adjusted to their current fair values each period.

Comparison of the six months ended June 30, 2019 and 2018

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Six Months Ended June 30,			
	2019	2018	Increase (Decrease)	
	(unaudited)			
Net revenues	$ 19,456	$ 7,638	$ 11,818	154.7 %
Cost of sales	3,591	2,580	1,011	39.2 %
Gross margin	15,865	5,058	10,807	213.7 %
Operating expenses:				
Research and development	2,711	2,422	289	11.9 %
Selling, general and administrative	12,868	8,387	4,481	53.4 %
Total operating expenses	15,579	10,809	4,770	44.1 %
Operating income (loss)	286	(5,751)	6,037	105.0 %
Interest income	26	8	18	225.0 %
Interest expense	(2,717)	(1,055)	(1,662)	(157.5)%
Other income (expense), net	(222)	13	(235)	(1,807.7)%
Loss before income taxes	(2,627)	(6,785)	4,158	61.3 %
Income tax expense	—	—	—	— %
Net loss	$ (2,627)	$ (6,785)	$ 4,158	61.3 %

Net Revenues

Net revenues increased by $11.8 million, or 154.7%, to $19.5 million due to a combination of increased test volume and higher per-unit revenues. Approximately 92% of the increase is attributable to DecisionDx-Melanoma test revenues with the remainder primarily attributable to DecisionDx-UM. For the six months ended June 30, 2019, we experienced an increase in DecisionDx-Melanoma and DecisionDx-UM test volume of 21.0%, compared to the six months ended June 30, 2018. Also contributing to the increase in revenue is the effect of the issuance of the final LCD for DecisionDx-Melanoma, issued by Palmetto and effective December 3, 2018. Coincident with the issuance of the LCD, a Medicare reimbursement rate for the test was established along with an agreement for payment of covered claims submitted for reimbursement beginning in February 2018. Note that as the Medicare LCD was not effective and the reimbursement rate was not known until the fourth quarter of 2018, the associated revenues were not recognized until the fourth quarter of 2018, which is when the criteria for revenue recognition was met. Medicare revenues for DecisionDx-Melanoma associated with test reports delivered in the six months ended June 30, 2018, but not recognized in revenue until the fourth quarter of 2018, were $3.0 million. For the six months ended June 30, 2019 and 2018, we recorded net positive revenue adjustments of $2.8 million and $0.9 million, respectively, related to tests delivered in previous periods, associated with changes in estimated variable consideration. Additionally, for the six months ended June 30, 2019, revenues included $0.2 million for tests delivered associated with contract research activities.

Cost of Sales

Cost of sales for the six months ended June 30, 2019 increased by $1.0 million, or 39.2%, compared to the six months ended June 30, 2018, primarily due to higher personnel costs due to additional headcount in our laboratory testing operations as well as increased costs of supplies and services, attributable to the higher activity levels. Our gross margin percentage was 81.5% for the six months ended June 30, 2019, compared to 66.2% for the same period in 2018, with the improvement principally a result of the increased operating leverage on the higher revenues. Due to the nature of our business, a significant portion of our cost of sales expenses represent fixed costs associated with our testing operations. Accordingly, our cost of sales expense will not necessarily increase or decrease commensurately with the change in net revenues from period to period.

Research and Development

Research and development expenses increased by $0.3 million, or 11.9%, for the six months ended June 30, 2019, compared to the six months ended June 30, 2018, primarily associated with increases in personnel costs, legal fees and other costs, partially offset by lower clinical studies expense.

Selling, General and Administrative

SG&A expense increased by $4.5 million, or 53.4%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. Approximately 53% of the increase is attributable to higher personnel costs, particularly within our sales function due to headcount expansion. In early 2019, we expanded our sales organization from 14 territories to 23 territories. The remainder of the increase was primarily associated with higher professional fees and increased travel costs. The higher professional fees were primarily attributable to accounting and reimbursement services.

Interest Expense

Interest expense increased by $1.7 million, or 157.5%, for the six months ended June 30, 2019 compared to the six months ended June 30, 2018. The effect of the issuance of the 2019 Notes in January and February 2019 added $1.3 million in interest expense for the six months ended June 30, 2019 and consisted of the accrual of the contractual 8% interest plus the amortization of issuance costs and debt discount. The remainder of the increase is due to a combination of higher average outstanding balances and higher interest rates on our variable-rate term debt and revolving line of credit under our banking credit facility. Average outstanding bank debt balances were approximately $5.0 million higher during the six months ended June 30, 2019 compared to the six months ended June 30, 2018 and average interest rates increased by approximately 0.9% from the same period in 2018.

Other Income (Expense), Net

Other income (expense), net, consists of the change in fair value of our liability for convertible preferred stock warrants and, beginning in 2019, the change in fair value of the embedded derivative liability associated with the Q1 2019 Notes. These liabilities are adjusted to their current fair values each period.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses and negative cash flows. For the year ended December 31, 2018, our net loss was $6.4 million, our net cash used in operating activities was $12.3 million and we had an accumulated deficit of $57.5 million as of December 31, 2018. For the six months ended June 30, 2019, our net loss was $2.6 million, our net cash provided by operating activities was $1.8 million and we had an accumulated deficit of $60.1 million as of June 30, 2019. We also have substantial indebtedness, the terms of which require us to meet a monthly three-month trailing revenue covenant. Although we were in compliance with this covenant as of December 31, 2018 and the most recently tested month, management's projections, including consideration of certain revenue recognition policies, previously indicated potential non-compliance with the revenue covenant during the 12 months following the date of issuance of our annual financial statements. For these reasons, the report of our independent registered public accounting firm on our financial statements as of December 31, 2017 and 2018 and for each of the years then ended includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Subsequently, in June 2019, we entered into an amendment to our 2018 LSA which, among other changes, modified the revenue covenant. As a result, management now expects to be in compliance with the amended covenant for at least the next 12 months.

As of June 30, 2019, we had raised aggregate cash proceeds of $46.6 million from the sale of our convertible preferred stock, in various private placements beginning in 2008, which we have used to fund our operations. In addition, we have obtained financing through term debt, a revolving line of credit and convertible promissory notes, which are discussed further below.

Initial Public Offering

In connection with the closing of the IPO on July 29, 2019, we issued and sold 4,600,000 shares of our common stock, including 600,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share. We received approximately $66.0 million in net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses and general administrative costs. We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on the commercialization of our existing products, the development of our future product candidates the potential commercialization of our product candidates, should their development be successful, and general administrative costs.

We have two product candidates in the late stage development that we plan to launch commercially in the second half of 2020. The successful development of other product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the clinical development of all our product candidates. We are also unable to predict when, if ever, revenue will commence from sales of our product candidates. This is due to the numerous risks and uncertainties associated with developing genomic tests, including, among others, the uncertainty of:

- successful commencement and completion of clinical study protocols;
- successful identification and acquisition of tissue samples;
- the development and validation of genomic classifiers; and
- acceptance of new genomic tests by physicians, patients and third-party payors.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

We will also incur costs as a public company that we have not previously incurred or have previously incurred at lower rates, including increased costs and expenses for fees to members of our board of directors, increased personnel costs, increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with public-company reporting requirements under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and rules implemented by the SEC and The Nasdaq Stock Market LLC, or Nasdaq.

As of June 30, 2019 and December 31, 2018, we had cash and cash equivalents of $17.5 million and $4.5 million, respectively. In the first quarter of 2019, we received proceeds of $11.8 million from the sale of the Q1 2019 Notes. In July 2019, we received proceeds of $10.0 million from the issuance of a convertible promissory note to an investor, or the July 2019 Note. We believe that the net proceeds from the IPO, together with our existing cash and cash equivalents and anticipated cash generated from sales of our products, will be sufficient to fund our operating expenses through at least the next 24 months.

We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including those listed above.

Until such time, if ever, as we can generate revenue sufficient to achieve profitability, we expect to finance our operations through our cash on hand (including the proceeds from the IPO) and a combination of equity and debt financings, which may not be available to us on the timing needed or on terms that we deem to be favorable. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product discovery and development activities or future commercialization efforts.

Long-Term Debt

Our long-term debt consists of term debt and a revolving line of credit and are presented in the table below (in thousands):

	June 30, 2019	December 31, 2018
	(unaudited)	
Term debt	$ 26,688	$ 21,350
Revolving line of credit	—	5,000
Total principal amount	26,688	26,350
Unamortized discount and issuance costs	(1,996)	(1,850)
Total long-term debt	24,692	24,500
Less: Current portion of long-term debt	(833)	—
Long-term debt, less current portion	$ 23,859	$ 24,500

The table above excludes the Q1 2019 Notes, which are classified as current liabilities in the balance sheet. See the ‘‘Convertible Promissory Notes’’ section below for details.

Term Debt

On November 30, 2018, we entered into the 2018 LSA with Oxford Finance LLC, or Oxford, as collateral agent, and Oxford and Silicon Valley Bank, or SVB, as equal syndicated lenders, or the Lenders. The 2018 LSA replaced the 2017 Loan and Security Agreement and provided for a $20.0 million term loan, or the 2018 Term Loan, and a credit line of up to $5.0 million (discussed in the ‘‘Revolving Line of Credit’’ section below), prior to amendment of the 2018 LSA on June 13, 2019, as discussed below. Our obligations under the 2018 LSA are secured by substantially all of our assets, excluding intellectual property and subject to certain other exceptions and limitations. We have the right to prepay the 2018 Term Loan in whole or in part at any time, subject to a prepayment fee of 2.50% if prepaid on or prior to November 30, 2019, 1.50% if prepaid after November 30, 2019 and on or prior to November 30, 2020, and 0.75% thereafter. Upon prepayment, we are also obligated to pay a non-refundable early termination fee of $496,785. Amounts prepaid or repaid under the 2018 Term Loan may not be reborrowed. Initially, the 2018 LSA contained a financial covenant that requires us to achieve a monthly trailing six-month revenue target each month throughout the term of the agreement, but the covenant amended on June 13, 2019 and changed to a monthly trailing three-month revenue target, as discussed further below. As of June 30, 2019 and December 31, 2018, we were in compliance with this covenant.

On June 13, 2019, we entered into an amendment to the 2018 LSA, or the Amendment, which, among other things, (i) eliminated the $5.0 million revolving line and increased the 2018 Term Loan by $5.0 million and (ii) amended the financial covenant to require us to achieve a monthly trailing three-month revenue target each month throughout the term of the agreement. The financial covenant was amended primarily to align with a more current reflection of our revenue projections after taking into account the impact on our revenue recognition following our early adoption of ASC 606. The Amendment was accounted for as a modification of the 2018 LSA, and therefore no extinguishment gain or loss was recognized.

For each month through December 31, 2019, the trailing three-month revenue requirements are calculated as a percentage of our previously approved applicable monthly revenue projections, which requirements, for the monthly periods from April to December 2019, are equal to increasing dollar amounts, in millions, in the mid-single digits to high single digits. For monthly periods ending after December 31, 2019, the trailing three-month revenue requirements will be determined by the Lenders upon receipt and review of our monthly financial projections for the year, subject to certain specified criteria regarding minimum requirements. Revenues, if any, that we recognize as a result of an ALJ appeal process from consolidated claims initiatives for DecisionDx-Melanoma do not count toward the minimum revenue requirements. We were in compliance with this covenant as of the most recently tested month.

In addition, the 2018 LSA contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be liable for immediate repayment of all obligations under the 2018 LSA. Should we seek to further amend the terms of the 2018 LSA, the consent of Oxford and SVB would be required, and there can be no assurance that any such amendment would be available on terms acceptable to us, if at all.

The 2018 Term Loan bears interest at a floating rate equal to the greater of 8.55% and the 30-day U.S. LIBOR rate as reported in The Wall Street Journal on the last business day of the month that precedes the month in which the interest will accrue, plus 6.48%. The applicable interest rate on the 2018 Term Loan was 8.88% as of June 30, 2019 and 8.98% as of December 31, 2018,

respectively. Interest on the 2018 Term Loan is payable monthly in arrears. We are permitted to make interest-only payments on the 2018 Term Loan through May 31, 2020. The principal is required to be repaid in 30 equal monthly installments beginning on June 1, 2020. All unpaid principal and accrued and unpaid interest is due on November 1, 2022, or the 2018 Term Loan Maturity Date. We are also obligated to make an additional final payment of 6.75% of the aggregate original principal amount, or $1,687,500 as of June 30, 2019, upon any prepayment or on the 2018 Term Loan Maturity Date. The final payment amount is being amortized as additional interest expense using the effective interest method of the term of the debt.

The 2018 Term Loan was fully funded on November 30, 2018 and the 2018 Revolving Line (defined and discussed below) was fully drawn upon on November 30, 2018. Proceeds from the 2018 LSA were used to repay all outstanding obligations under the 2017 LSA and to provide working capital. As a condition of the loan, we issued Series F preferred stock warrants to the Lenders with an aggregate initial fair value of $158,000. In accordance with ASC 480-10, the warrants are liability-classified as the underlying to the warrant is a puttable security. The initial recognition of the warrant liability created a discount to the debt, which is being amortized over the debt term using the effective interest method. The 2018 LSA was accounted for as a modification of the previous lending arrangement with SVB and Oxford, and therefore no extinguishment gain or loss was recognized.

Revolving Line of Credit

Under the 2018 LSA, the Company had a $5.0 million revolving line of credit (the "2018 Revolving Line"), contingent on the Company's satisfaction of borrowing base eligibility requirements. The 2018 Revolving Line bore interest at a floating per annum rate equal to the greater of 1) 6.25% and 2) 5.48% above the U.S. LIBOR rate. The applicable interest rate on the 2018 Revolving Line at December 31, 2018 was 7.98%. The 2018 Revolving Line was to be due in full no later than November 30, 2020, but was eliminated in connection with the Amendment.

Q1 2019 Convertible Promissory Notes

In January and February 2019, we issued $11,770,375 principal amount of unsecured convertible promissory notes of which $4,755,882 was with related parties (executive officers, members of our board of directors or entities affiliated with them). The Q1 2019 Notes bear simple interest at a rate of 8% per annum. Originally, the Q1 2019 Notes had a maturity date of January 31, 2020, but on July 3, 2019 we entered into an amendment with the holders of the Q1 2019 Notes to extend the maturity date to June 30, 2020.

Prior to the actual conversion of the Q1 2019 Notes on July 29, 2019 (discussed below), on or before the maturity date, the entire outstanding principal amount of and accrued interest on the Q1 2019 Notes, or the Conversion Amount, was automatically convertible into shares of our equity securities issued and sold in a single or series of related transactions, with the principal purpose of raising capital, in which we sell shares of such equity securities for aggregate gross proceeds of at least $10.0 million, or the Next Equity Financing. The number of shares of such equity securities issuable in the Next Equity Financing was equal to the quotient of the Conversion Amount as of the closing date of the Next Equity Financing divided by a per share price that is equal to 80% of the lowest per share purchase price of the equity securities sold in the Next Equity Financing. If the Q1 2019 Notes had not been repaid or converted prior to the maturity date, then, at the request of the holders of a majority of the then-outstanding principal amount of and accrued interest on the Q1 2019 Notes, then the Conversion Amount as of the maturity date would have converted into shares of our Series F redeemable convertible preferred stock, or any senior equity security issued by us after the first issuance of the Q1 2019 Notes, in each case at a conversion price equal to the price at which such security was last sold (which was $5.8208 for shares of our Series F redeemable convertible preferred stock). If we had undergone a change of control while the Q1 2019 Notes are outstanding, we would have been required to repurchase each Note from each holder at a repurchase price equal to two times the principal amount of such Note, plus any accrued and unpaid interest on such Note as of the date of such repurchase.

The closing of the IPO on July 29, 2019 was considered to be the Next Equity Financing under the terms of the Q1 2019 Notes. Accordingly, on July 29, 2019, the Conversion Amount of the Q1 2019 Notes as of such date converted into 954,074 shares of common stock based on a price of $12.80 per share, or 80% of the IPO price of $16.00 per share.

As discussed further in Note 7 to the unaudited interim condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, the Q1 2019 Notes contained a beneficial conversion feature and an embedded derivative, both of which created a significant debt discount that was being amortized over the life of the debt (that is, through June 30, 2020) using the effective interest method, which resulted in increases in non-cash interest expense in each succeeding reporting period until the Notes were converted on July 29, 2019.

The following table summarizes the aggregate values recorded for the Q1 2019 Notes at issuance and as of June 30, 2019 (in thousands):

	June 30, 2019	At Issuance[1]
	(unaudited)	
Liability component:		
Principal	$ 11,770	$ 11,770
Unamortized issuance costs	(68)	(74)
Unamortized discount from beneficial conversion feature	(7,655)	(8,378)
Unamortized discount from embedded derivative	(2,573)	(2,816)
Net carrying amount of the liability component	1,474	502
Embedded derivative liability	2,952	2,816
Total	$ 4,426	$ 3,318
Equity component:		
Carrying value of beneficial conversion feature recorded in additional paid-in capital	$ 8,378	$ 8,378

(1) The Q1 2019 Notes were issued on January 31, 2019, February 12, 2019 and February 27, 2019.

The Q1 2019 Notes are classified as current liabilities on the balance sheet due to their contractual maturity date.

July 2019 Convertible Promissory Note

On July 12, 2019, we issued an unsecured convertible promissory note having a principal amount of $10,000,000. The July 2019 Note bore simple interest at a rate of 8% per annum and had an original maturity date of June 30, 2020. As a result of the IPO, the outstanding principal amount plus accrued interest on the July 2019 Note converted into 707,032 shares of common stock on July 29, 2019, based on a price derived from a minimum valuation calculated pursuant to the terms of the July 2019 Note.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Six Months Ended June 30,	
	2019	2018
	(unaudited)	
Net cash provided by (used in) operating activities	$ 1,770	$ (7,206)
Net cash used in investing activities	(424)	(185)
Net cash provided by financing activities	11,644	11,384
Net increase in cash and cash equivalents	$ 12,990	$ 3,993

Operating Activities

Net cash provided by operating activities was $1.8 million for the six months ended June 30, 2019 and was primarily attributable to decrease in accounts receivable of $3.6 million and net non-cash charges of $1.9 million (consisting primarily of $1.2 million in amortization of debt discount and issuance costs, stock compensation expense of $0.3 million, depreciation expense of $0.2 million and change in fair value of embedded derivatives of $0.1 million) and increases in other accrued liabilities of $0.9 million, partially offset by the net loss of $2.6 million and decreases in accrued compensation of $1.8 million.

Net cash used in operating activities was $7.2 million for the six months ended June 30, 2018 and was primarily attributable to the net loss of $6.8 million and increases in accounts receivable of $0.6 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2019 and 2018 consisted entirely of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $11.6 million for the six months ended June 30, 2019 and consisted primarily of $11.7 million of net proceeds from the issuance of the Q1 2019 Notes, $1.8 million of net proceeds associated with an increase

in the 2018 Term Loan in connection with an amendment to the 2018 LSA, partially offset by principal repayments of $1.8 million on our line of credit.

Net cash provided by financing activities was $11.4 million for the six months ended June 30, 2018 and consisted primarily of $10.4 million attributable to proceeds received from the issuance of preferred stock, and $1.0 million in proceeds from additional borrowings on the line of credit.

Off-Balance Sheet Arrangements

We do not currently have, nor did we have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, during the periods presented.

Critical Accounting Policies and Significant Judgments and Estimates

During the six months ended June 30, 2019, there were no significant changes to the information discussed under "Critical Accounting Policies and Significant Judgments and Estimates" included in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of the Prospectus.

Recent Accounting Pronouncements

Refer to Note 2, ''Summary of Significant Accounting Policies,'' in the accompanying notes to our unaudited condensed financial statements included in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

JOBS Act Accounting Election

We are an emerging growth company within the meaning of the JOBS Act. Section 107(b) of the JOBS Act provides that an emerging growth company can leverage the extended transition period, provided in Section 102(b) of the JOBS Act, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended.

We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year following the fifth anniversary of the consummation of the IPO (that is, July 29, 2024), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a ''large accelerated filer'' as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Item 3. Qualitative and Quantitative Disclosures About Market Risk.

Interest Rate Risk

Our primary market risk exposure relates to interest rates on our outstanding long-term debt, which bears interest at variable market rates. Based on bank borrowings outstanding as of June 30, 2019, if market interest rates were to increase by 1.0%, our interest expense and operating cash flows would be adversely impacted by approximately $250,000 on an annual basis.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weaknesses that existed in our internal control over financial reporting as described below. These material weaknesses related to a lack of (i) appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations, (ii) personnel with appropriate knowledge, experience and training commensurate with accounting and reporting requirements and (iii) appropriately designed and implemented controls to evaluate variable consideration and the related constraint in accordance with ASC 606, and resulted in certain material corrections to the financial statements.

Material Weaknesses in Internal Control over Financial Reporting

In connection with the audit of our financial statements as of and for each of the years ended December 31, 2017 and 2018, we identified material weaknesses in our internal control over financial reporting.

We are implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including the following:

- We have hired a full-time director of SEC reporting and technical accounting, a certified public accountant with an active license, with public company reporting experience to provide oversight and technical expertise with respect to financial reporting and technical accounting matters. Further, we have added an additional full-time accounting resource, also a certified public accountant with an active license, to assist with financial reporting and technical accounting activities.
- We commenced development of a new information technology tool designed to improve the efficiency of our processes with respect to revenue recognition under ASC 606.
- We began an evaluation of third parties to assist us with formalizing our internal control documentation and implementation of enhancements to our internal control over financial reporting.

These additional resources and activities are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. With the oversight of senior management and our audit committee, we have begun taking steps and plan to take additional measures to remediate the underlying causes of the material weaknesses.

Changes in Internal Control over Financial Reporting.

Other than the implementation of measures described above under *Material Weaknesses in Internal Control over Financial Reporting*, there were no changes in our internal control over financial reporting during the quarter ended June 30, 2019 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.

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company believes there is no threatened litigation or litigation pending that could have, individually or in the aggregate, a material adverse effect on the Company's financial position, results of operations or cash flows.

Item 1A. Risk Factors.

You should consider carefully the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, 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 factors described as well as the other information in the Prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" when evaluating our business. The risk factors set forth below that are marked with an asterisk (*) contain changes to the similarly titled risk factors included in the Prospectus. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline and you may lose all or part of your investments. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Condition

Our reliance upon a small number of third-party payors for a significant portion of our revenue may materially adversely affect our financial condition and results of operations.

We receive a substantial portion of our revenue from a small number of third-party payors, primarily Medicare and United Healthcare. Our revenue for our test reports provided for patients covered by Medicare and United Healthcare as a percentage of total revenue, was 9% and 11%, respectively, for the year ended December 31, 2017, and 36% and 12%, respectively, for the year ended December 31, 2018. In addition, our current accounts receivable balances for Medicare and United Healthcare, as a percentage of our total current accounts receivable, were 0% and 10%, respectively, as of December 31, 2017, and 54% and 7%, respectively, as of December 31, 2018. Our long-term accounts receivable balances for Medicare and United Healthcare, as a percentage of our total long-term accounts receivable, were 0% and 15%, respectively, as of December 31, 2017, and 0% and 15%, respectively, as of December 31, 2018. If our largest current payors were to significantly reduce, or cease to pay, the amount they reimburse for our products, or if they do not reach favorable coverage and reimbursement decisions for our products, or attempt to recover amounts they had already paid, it could have a material adverse effect on our business, financial condition and results of operations and cause significant fluctuations in our results of operations.

Due to how we recognize revenue, our quarterly revenues may not reflect our underlying business.

We have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at the expected value using the ''most likely amount'' method under ASC 606. The amounts are determined by historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor. Variable consideration for Medicare claims is deemed to be fully constrained when the payment of such claims is subject to approval by an Administrative Law Judge, or ALJ, at an appeal hearing, due to factors outside our influence (i.e., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. As a result of the timing and amount of adjustments for variable consideration, our operating results and comparisons of such results on a period-to-period basis may be difficult to understand and may not be meaningful. In addition, these fluctuations in revenue may make it difficult for us, for research analysts and for

investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

We have incurred significant losses since inception, and we may never achieve or sustain profitability.*

Since our inception, we have had a history of net losses. As of June 30, 2019, we had a cash balance of approximately $17.5 million and an accumulated deficit of approximately $60.1 million. We cannot predict if we will achieve sustained profitability in the near future or at all. We expect that our losses will continue for the foreseeable future as we plan to invest significant additional funds toward the expansion of our commercial organization, the conduct of clinical utility and validity studies to support adoption of our products and the development or acquisition of additional products. Our auditors have issued a going concern opinion on our financial statements as of and for the years ended December 31, 2017 and 2018, expressing substantial doubt about our ability to continue as a going concern. As a public company, we will also incur significant legal, accounting and other expenses that we did not incur as a private company. These increased expenses will make it harder for us to achieve and sustain future profitability. We may also incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this Quarterly Report on Form 10-Q, adoption of our products, coverage of and reimbursement rates for our products from third-party payors, and future research and development activities. Our failure to achieve and sustain profitability in the future could cause the market price of our common stock to decline.

We are an early, commercial-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.*

We are an early commercial-stage company and have a limited operating history. Our limited operating history may make it difficult to evaluate our current business and this makes predictions about our future success or viability subject to significant uncertainty. In particular, we intend to use a portion of our working capital to increase our headcount, including through the expansion of our sales and marketing and research and development teams, which will increase our operating costs in a manner not historically reflected in our financial statements. In combination with our other anticipated increased operating expenses in connection with becoming a public company, these anticipated changes in our operating expenses may make it difficult to evaluate our current business, assess our future performance relative to prior performance and accurately predict our future performance.

We will continue to encounter risks and difficulties frequently experienced by early commercial-stage companies, including those associated with increasing the size of our organization and the prioritization of our commercial, research and business development activities. If we do not address these risks successfully, our business could suffer.

The terms of our credit facility place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the credit facility may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our securities to decline.*

Our 2018 LSA, which we amended in June 2019, with Oxford and SVB, is secured by a lien covering substantially all of our assets, excluding intellectual property. The 2018 LSA provides for a five-year $25.0 million term-loan facility, all of which has been disbursed to us.

The 2018 LSA requires us to achieve certain revenue levels tested monthly on a trailing three-month basis. As of the most recently tested month, we were in compliance with this covenant. However, there can be no assurance of our ability to maintain compliance with the revenue covenant as of any future date. For example, prior to the amendment of the 2018 LSA, our projections indicated that we were at risk of noncompliance with the financial covenant existing under the 2018 LSA prior to the June 2019 amendment. Among other things, the June 2019 amendment revised our financial covenant to require us to achieve a monthly trailing three-month revenue target, tested on a monthly basis. The financial covenant was amended primarily to align with a more current reflection of our revenue projections after taking into account the impact on our revenue recognition following our early adoption of ASC 606. Our ability to amend the 2018 LSA in the future is subject to the approval of Oxford and SVB. Accordingly, should we seek to further amend the 2018 LSA, there can be no assurance that any such amendment would be available on terms acceptable to us, if at all.

The 2018 LSA also requires us to comply with a number of other covenants (affirmative and negative), including restrictive covenants that limit our ability to: incur additional indebtedness; encumber the collateral securing the loan; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; transfer a material portion of our assets; acquire other businesses; and merge or consolidate with or into any other organization or otherwise suffer a change in control, in each case subject to exceptions.

In addition to other specified events of default, and subject to limited exceptions, the lenders could declare an event of default upon the occurrence of any event that they interpret as having a material impairment in their lien on the collateral under the agreement, a material adverse change in our business, operations or condition (financial or otherwise) or a material impairment in the prospect of repayment of our obligations under the agreement. If we default under the credit facility, the lenders may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, the lenders could take control of our pledged assets and we would have to immediately cease operations. During the continuance of an event of default, the then-applicable interest rate on the then-outstanding principal balance will increase by 5.0%. Upon an event of default, the lenders could also require us to repay the loan immediately, together with a prepayment charge of up to 2.5% of the then-outstanding principal balance, together with other fees. If we were to renegotiate the agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, the lenders' right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by the lenders of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our securities to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

The audit report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern.

The audit report from our independent registered public accounting firm expresses substantial doubt that we can continue as an ongoing business due to uncertainties about our ability to comply with certain debt covenants under our long-term debt that is required to finance operations and our future financial statements may include a similar qualification about our ability to continue as a going concern. Our audited financial statements were prepared assuming that we will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

If we are unable to meet the applicable debt covenants, the lenders could accelerate all of our repayment obligations under the 2018 LSA and we would need to seek additional or alternate financing or modify our operational plans. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We have identified material weaknesses in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.*

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audits of our financial statements for the years ended December 31, 2017 and 2018, we concluded that there were material weaknesses in our internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

These material weaknesses related to a lack of (i) appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations, (ii) personnel with appropriate knowledge, experience and training commensurate with accounting and reporting requirements and (iii) appropriately designed and implemented controls to evaluate variable consideration and the related constraint in accordance with ASC 606, and resulted in certain material corrections to the financial statements.

In an attempt to remediate these weaknesses, we have hired a full-time director of SEC reporting and technical accounting and another full-time accounting resource, both certified public accountants with active licenses, to augment our accounting staff and to provide more resources for complex accounting matters and financial reporting. We also have commenced development of a new information technology tool designed to improve the efficiency of our processes with respect to revenue recognition under ASC 606 and have begun an evaluation of third parties to assist us with formalizing our internal control documentation and implementation of enhancements to our internal control over financial reporting. However, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all.

If we are unable to successfully remediate our material weaknesses or identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, a material misstatement in our financial statements could occur, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, which may adversely affect our business and our stock price may decline as a result.

In addition, even if we remediate our material weaknesses, we will be required to expend significant time and resources to further improve our internal controls over financial reporting, including by further expanding our finance and accounting staff to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley. If we fail to adequately staff our accounting and finance function to remediate our material weaknesses, or fail to maintain adequate internal control over financial reporting, any new or recurring material weaknesses could prevent our management from concluding our internal control over financial reporting is effective and impair our ability to prevent material misstatements in our financial statements, which could cause our business to suffer.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.*

Accounting principles generally accepted in the United States of America are subject to interpretation by the Financial Accounting Standards Board, the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. For example, as described in Note 2 to our audited financial statements included in the Prospectus, we adopted the revenue recognition standard under ASC 606 which superseded previous revenue recognition guidance applicable to us. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

Our quarterly and annual operating results and cash flows may fluctuate in the future, which could cause the market price of our stock to decline substantially.

Numerous factors, many of which are outside our control, may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting uncertain. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, comparing our operating results on a period-to-period basis may be difficult to understand and may not be meaningful. You should not rely on our past results as indicative of our future performance.

In addition, a significant portion of our operating expense is relatively fixed in nature, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls could decrease our gross margins and cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our stock could fall substantially.

This variability and unpredictability caused by factors such as those described above could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We may need to raise additional capital to fund our existing operations, commercialize new products or expand our operations.*

We believe our existing cash and cash equivalents and anticipated cash generated from sales of our products will be sufficient to fund our operating expenses through at least the next 24 months. If our available cash balances and anticipated cash generated from sales of our products are insufficient to satisfy our liquidity requirements including because of lower demand for our products, lower than currently expected rates of reimbursement from third-party payors or other risks described in this Quarterly Report on Form 10-Q, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts for DecisionDx-Melanoma and address competitive developments;
- fund ongoing development of our pipeline products, including for SCC and suspicious pigmented lesions, in addition to other programs in development;
- expand our laboratory testing facility and related testing capacity;
- expand our technologies into other types of skin cancer management and detection products;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements with third-party payors;
- our rate of progress in, and cost of the sales, marketing, coverage and reimbursement activities associated with, establishing adoption of DecisionDx-Melanoma, among our other products;
- the cost of expanding our laboratory operations and offerings, including our sales, marketing, coverage and reimbursement efforts;
- our rate of progress in, and cost of research and development activities associated with, diagnostic products in research and early development;
- the potential cost of, and delays in, the development of new products as a result of changes in regulatory oversight applicable to our products; and
- the effect of competing technological and market developments.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or products, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our commercialization, research and development efforts or grant rights to third parties to market and/or develop products that we would otherwise prefer to market and develop ourselves.

Risks Related to Our Business

Our revenue currently depends primarily on sales of DecisionDx-Melanoma, and we will need to generate sufficient revenue from this and other products to grow our business.

Most of our revenue in 2017 and 2018 was derived from the sale of our lead product, DecisionDx-Melanoma. While we also derive revenue from DecisionDx-UM, we expect that the majority of our revenue for the foreseeable future will be derived from sales of DecisionDx-Melanoma. Further, we believe that our long-term commercial success will depend on our ability to develop and market additional products, such as our pipeline products for SCC and suspicious pigmented lesions. Our ability to derive revenue from DecisionDx-Melanoma, DecisionDx-UM and any future products that we commercialize is uncertain and depends on favorable coverage and reimbursement policies from government payors, like Medicare, and from private payors, like insurance companies. Without positive coverage policies, our products may not be reimbursed and we may not be able to recognize revenue. If we are unable to increase sales and expand coverage and reimbursement for

DecisionDx-Melanoma, develop and commercialize other products, and successfully obtain coverage and adequate reimbursement for such products, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our stock could decline substantially.

Billing for our products is complex and requires substantial time and resources to collect payment.

Billing for clinical laboratory testing services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, including Medicare, Medicaid, private insurance companies, private healthcare institutions, and patients, all of which have different billing requirements. We generally bill third-party payors for products 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 accounts receivable 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 billing rates and reimbursement rates for our products;

compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare, Medicaid and TRICARE;

- risk of government audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical studies, including our registry studies, which can affect eligibility for payment;
- ongoing monitoring provisions of LCDs for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- 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 CPT codes, to bill for our products. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment we receive.

As we introduce new products, we may 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, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, we may challenge the reason, low payment amount or payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received.

Additionally, the Patient Protection and Affordable Care Act requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our products, 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 parties for tumor sample collection, preparation and delivery. Any defects in sample collection or preparation by such third parties and any delays in delivery of such samples could cause errors in our test reports and delay our ability to deliver test reports in a timely manner, which could significantly harm our business.

The tumor tissue samples that we test are biopsied, preserved, prepared and delivered to us by third parties, including dermatopathologists and laboratory facilities. As such, we rely on these third parties to prepare, label and deliver the tissue

samples that we test in compliance with applicable laws and guidelines, and in a timely manner. Therefore, the accuracy and correctness of the test reports that we deliver are dependent on proper chain of custody and appropriate methods of sample collection or preparation utilized by these third parties, and our ability to timely deliver reports is dependent upon the ability of these third parties to provide these samples to us in a timely manner. Any errors in any part of the sample collection or preparation process could cause us to deliver incorrect test reports, potentially resulting in harm to patients whose physicians implement a change in treatment decisions based upon our test report. If we are unable to timely deliver test reports, physicians may be less likely to recommend and order our products. The occurrence of any of the foregoing could significantly harm our reputation and our results of operations, causing significant harm to our business.

We rely on our database of tumor samples for the development and improvement of our products. Depletion or loss of our tumor samples could significantly harm our business.

The development and validation of accurate products is a complex process that requires access to tumor tissue specimens and long-term outcomes data. Our research and development efforts to improve our existing products and develop new products may require the depletion of our existing database of tumor samples. If our tumor samples are lost or destroyed, or substantially depleted before we are able to generate meaningful data, we may be unable to improve our existing products, continue the development of pipeline products or validate product candidates. While we have historically been able to create and maintain a large sample bank to expand the clinical use of our products and develop new products, we may be unable to do so in the future. If we were unable to maintain or replenish our sample bank, we may be unable to improve our products or develop new products.

If our sole laboratory facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to conduct our laboratory analysis and pursue our research and development efforts may be jeopardized.

We currently perform all of our testing and store our database of tumor samples at a single laboratory facility in Phoenix, Arizona. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, terrorism, burglary or other events, which may make it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform tests or to reduce the backlog of sample analysis that could develop if our facility becomes inoperable, for even a short period of time, may result in the loss of revenue, loss of customers or harm to our reputation, and we may be unable to regain that revenue, those customers or repair our reputation in the future. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events.

In addition, the loss of our tumor samples due to such events could limit or prevent our ability to conduct research and development analysis on existing tests as well as tests in active pipeline development.

While we have a business continuity plan in place, our facility and the equipment we use to perform our testing and research and development could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility, to locate and qualify a new facility, replace certain pieces of equipment or license or transfer our proprietary technology to a third-party, particularly in light of licensure and accreditation requirements. Even in the unlikely event that we are able to find a third party with such qualifications to enable us to resume our operations, we may be unable to negotiate commercially reasonable terms.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

Our current or future products may not achieve or maintain significant commercial market acceptance.

We believe our commercial success is dependent upon our ability to continue to successfully market and sell our products, to continue to expand our current relationships and develop new relationships with healthcare providers, to expand and maintain coverage for our products, and to develop and commercialize new products. Our ability to achieve and maintain commercial market acceptance of our existing and future products will depend on a number of factors, including:

- our ability to increase awareness of our products through successful clinical utility and validity studies;
- the rate of adoption of our products by physicians and other healthcare providers;
- our ability to achieve guideline inclusion for our products;
- the timeliness with which we can provide our clinical reports to the ordering physician;

- the timing and scope of any regulatory approval for our products, if such approvals become required, and maintaining ongoing compliance with regulatory requirements;
- our ability to obtain and maintain positive coverage decisions for our products from government and commercial payors;
- our ability to obtain and maintain adequate reimbursement from third-party payors, including Medicare, Medicare Advantage plans, United Healthcare and BlueCross BlueShield plans, which accounted for an aggregate of approximately 73% and 83% of our total revenue for the years ended December 31, 2017 and 2018, respectively;
- the impact of our investments in research and development and commercial growth;
- negative publicity regarding our or our competitors' products resulting from scientific publications, or defects or errors in the products; and
- our ability to further validate our products through clinical research and accompanying publications.

We cannot assure you that we will be successful in addressing each of these factors or other factors that might affect the market acceptance of our products. If we are unsuccessful in achieving and maintaining market acceptance of our products, our business and results of operations will suffer.

New product development involves a lengthy and complex process, and we may be unable to develop and commercialize, or receive reimbursement for, on a timely basis, or at all, new products.

We continually seek to develop new product offerings, which requires us to devote considerable resources to research and development. For example, before we can commercialize our pipeline products for SCC and suspicious pigmented lesions, we will need to expend significant resources in order to conduct substantial research and development, including clinical utility and validity studies, and further develop and scale our laboratory processes and infrastructure to accommodate additional products.

Our product development process takes time and involves a high degree of risk, and such development efforts may fail for many reasons, including failure of the product to perform as expected, failure to successfully complete analytic and clinical validation, or failure to demonstrate the clinical utility of the product.

As we develop new products, we will have to make significant investments in research and development, marketing, selling, coverage and reimbursement activities. Typically, few research and development projects result in a commercialized product, and there can be no assurance that we will be able to successfully develop new products that can be commercialized. At any point, we may abandon development of a product or we may be required to expend considerable resources conducting research, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity or clinical utility, we might choose to abandon the development of the product, which could harm our business. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

We may experience limits on our revenue if we are unable to increase and support adoption of our products by physicians and other healthcare providers.

Physicians and other healthcare providers may be unwilling to adopt our products due to their reliance on existing traditional clinical and pathology staging criteria and our ability to generate revenue from our products would be significantly impaired if we were unable to educate physicians, healthcare providers, patients and third-party payors about the benefits and advantages of our products. We will need to continue to educate physicians and pathologists about the benefits and cost-effectiveness of our products through published papers, presentations at scientific conferences, one-on-one marketing efforts by our sales force and one-on-one education by our medical affairs team. However, physicians and other healthcare providers may be reluctant to adopt our products in circumstances where our products are not incorporated into the current standard of care or practice guidelines. For example, while clinical utility of DecisionDx-Melanoma has been demonstrated in peer reviewed publications, the SLNB surgery is the most widely used staging tool for determining a cutaneous melanoma patient's metastatic risk. Whether healthcare providers adopt DecisionDx-Melanoma as a complementary or triage diagnostic method relative to the SLNB surgery will depend on our ability to increase awareness of DecisionDx-Melanoma and its clinical validation.

In addition, our testing services are performed by our certified laboratory located in Phoenix, Arizona, under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, rather than by local laboratory or pathology practices. Accordingly, it may be difficult for us to collect samples from pathologists, and pathologists may be reluctant to support our testing services.

We rely on limited or sole suppliers for some of the reagents, equipment, chips and other materials used by our products, and we may not be able to find replacements or transition to alternative suppliers.

We rely on limited or sole suppliers for certain reagents and other materials and components that we use for our products. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in laboratory operations could occur, we may not be able to deliver patient reports on a timely basis, or at all, and we may incur higher one-time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available. If our testing volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new products, we may experience supply issues as we ramp test volume. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents or other materials we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

If our products do not meet the expectations of physicians and patients, our operating results, reputation and business could suffer.

Our success depends on physician and patient confidence that we can provide reliable, high-quality information that will improve treatment outcomes, lower healthcare costs and enable better patient care. We believe that patients, physicians and other healthcare providers are likely to be particularly sensitive to defects and errors in our products, including if our products fail to accurately predict risk of metastasis with high accuracy from samples, and there can be no guarantee that our products will meet their expectations. As a result, the failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or reports.

If we are unable to compete successfully, our business will suffer and we may be unable to increase or sustain our revenue or achieve profitability.

We face competition from companies and academic institutions that have either developed or may seek to develop products intended to compete with our products. Potential competitors within the broader genomics profiling space based on tissue sample collection include laboratory companies such as Laboratory Corporation of America and Myriad Genetics, and other companies which have strong infrastructures capable of supporting the commercialization of diagnostic services.

In addition, competitors may develop their own versions of our solutions in countries where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their solutions by physicians in other countries.

Some potential competitors may have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their products than we do or sell their products at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. Certain potential competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to test development than we can. In addition, companies or governments that control access to testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, our business will suffer and we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline. As we add new tests and services, we will face many of these same competitive risks for these new tests.

The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate.

Our estimates of the total addressable markets for DecisionDx-Melanoma, DecisionDx-UM and our products in development are based on a number of internal and third-party estimates, including, without limitation, the annual rate of patients with the applicable form of skin cancer, the list price of our products relative to the reimbursement we expect to receive from third-party payors and the assumed prices at which we can sell our products in markets that have not been established. For example, we estimate that the total addressable market for DecisionDx-Melanoma is approximately $540 million, which is based, in part, on our review of multiple recent publications which show that diagnosis of melanoma is underreported by 30% to 40%. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

The diagnostic testing industry is subject to rapid change, which could make our current or future products obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current products and the other products we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of physicians and patients on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our existing products and develop new products to keep pace with evolving standards of care. If we do not update our products to reflect new scientific knowledge about cancer biology, information about new cancer therapies or relevant clinical trials, our products could become obsolete and sales of our current products and any new products we develop could decline or fail to grow as expected.

Risks Related to Government Regulation and Reimbursement

We currently have limited reimbursement coverage for our lead product, DecisionDx-Melanoma, and if third-party payors, including government and commercial payors, do not provide sufficient coverage of, or adequate reimbursement for, our products, our commercial success will be negatively affected.

Our revenue depends on achieving broad coverage and adequate reimbursement for our products from third-party payors, including both government and commercial third-party payors. If third-party payors do not provide coverage of, or do not provide adequate reimbursement for, a substantial portion of the list price of our products, we may need to seek additional payment from the patient beyond any co-payments and deductibles, which may adversely affect demand for our products. Coverage determinations by a third-party payor may depend on a number of factors, including, but not limited to, a third-party payor's determination of whether our products are appropriate, medically necessary or cost-effective. If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our products, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenues and our ability to succeed. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our products may decrease as we encounter pricing pressure from these competitors.

Since each third-party payor makes its own decision as to whether to establish a policy to cover our products, enter into a contract with us and set the amount it will reimburse for a product, these negotiations are a time-consuming and costly process, and they do not guarantee that the third-party payor will provide coverage or adequate reimbursement for our products. In addition, the determinations by a third-party payor whether to cover our products and the amount it will reimburse for them are often made on an indication-by-indication basis.

In cases where there is no coverage policy or we do not have a contracted rate for reimbursement as a participating provider, the patient is typically responsible for a greater share of the cost of the product, which may result in further delay of our revenue, increase our collection costs or decrease the likelihood of collection.

Our claims for reimbursement from third-party payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming and expensive, and may not result in payment. Third-party payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the third-party payors believe the funds were paid in error or determine that our

products were medically unnecessary. If a third-party payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial third-party payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the third-party payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on current claims. We cannot predict when, or how often, a third-party payor might engage in these reviews and we may not be able to dispute these retroactive adjustments. We adopted the new revenue recognition guidance under ASC 606 on January 1, 2018 using the full retrospective method and adjusted the comparative reporting period for the year ended December 31, 2017.

Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating physician. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved. We consider variable consideration to be fully constrained (and therefore not recognized) for Medicare claims when the payment of such claims is subject to approval by an ALJ at an appeal hearing, due to the level of uncertainty and timing of the outcome.

Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Due to the outcome of ALJ hearings, potential future changes in insurance coverage policies, contractual rates and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period.

Although we are an in-network participating provider with some commercial third-party payors, including several Blue Cross Blue Shield plans, and certain large, national commercial third-party payors, including Aetna, other commercial third-party payors have issued non-coverage policies that currently categorize DecisionDx-UM and DecisionDx-Melanoma as experimental or investigational. If we are not successful in obtaining coverage from third-party payors, in reversing existing non-coverage policies, or if other third-party payors issue similar non-coverage policies, this could have a material adverse effect on our business and operations.

Palmetto, the MAC responsible for administering MolDX, the program that assesses molecular diagnostic technologies, issued a final LCD for DecisionDx-Melanoma, which became effective on December 3, 2018. This LCD provides for coverage of DecisionDx-Melanoma for certain sentinel lymph node biopsy, or SLNB, eligible patients with cutaneous melanoma tumors with clinically negative sentinel node basins who are being considered for SLNB to determine eligibility for adjuvant therapy. Similarly, Palmetto issued a final LCD for DecisionDx-UM effective July 10, 2017. This LCD provides for coverage of DecisionDx-UM to determine metastatic risk in connection with the management of a patient's newly diagnosed uveal melanoma and to guide surveillance and referral to medical oncology for those patients. We worked with Palmetto to obtain these positive coverage decisions through the submission of a detailed dossier of analytical and clinical data to substantiate that the tests meet Medicare's medical necessity requirements. Per their joint operating agreement, Noridian, the MAC responsible for administering claims for laboratory services performed in Arizona, has adopted the same coverage policy as Palmetto for DecisionDx-UM and DecisionDx-Melanoma. This coverage process is lengthy, time-consuming, has changed over time, may change in the future and requires significant dedication of resources, and as we develop new products, we may be unsuccessful in receiving LCD determinations for those products or in maintaining our current LCDs. On a periodic basis, the Centers for Medicare & Medicaid Services, or CMS, requests bids for its MAC services, and MAC jurisdictions have changed in the past. A change in our MAC, or future changes in the MolDx program, the elimination of the program, or a change in the administrator of that program, may affect our ability to obtain Medicare coverage and reimbursement for products for which we have coverage, for products for which we do not yet have coverage, or for any products we may launch in the future, or delay payments for our tests.

Under Medicare, payment for products like ours is generally made under the Clinical Laboratory Fee Schedule, or CLFS, with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, certain laboratories were required to report to CMS, beginning in 2017 and every three years thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), commercial third-party payor payment rates and volumes for each test they perform. CMS uses this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We bill Medicare for our products, and therefore we are subject to reporting requirements under PAMA.

On May 17, 2019, CMS determined that DecisionDx-UM meets the criteria for ‘‘existing ADLT’’ status. This means that beginning in 2021, the DecisionDx-UM Medicare rate will be set annually based upon the median private payor rate for the first half of the second preceding calendar year. Specifically, the median private payor rate from January 1 to June 30, 2019 will be used to set the Medicare rate for the calendar year 2021. From May 17, 2019 through December 31, 2020, our rate will be set by Noridian, our local MAC. Also, on May 17, 2019, CMS determined that DecisionDx-Melanoma meets the criteria for ‘‘new ADLT’’ status. This means that from July 1, 2019 through March 31, 2020 the Medicare reimbursement rate will equal the initial list price of $7,193.00. The rate for April 1, 2020 through December 31, 2021 will be calculated based upon the median private payor rate from July 1, 2019 to November 30, 2019. Accordingly, beginning in 2022, the rate will be set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2022 will be set using median private payor rate data from January 1, 2020 to June 30, 2020. If CMS determines the list charge amount for DecisionDx-Melanoma was greater than 130% of the weighted median of private payor rates, CMS will recoup from us the difference between the actual list charge and 130% of the weighted median. If we are unable to obtain and maintain adequate reimbursement rates from commercial third-party payors, this may adversely affect our Medicare rate. It is unclear what impact new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations or cash flows.

The U.S. federal government continues to show significant interest in pursuing health care reform and reducing health care costs. Similarly, commercial third-party payors may seek to reduce costs by limiting coverage or reducing reimbursement for our products. Any government-adopted reform measures or changes to commercial third-party payor coverage and reimbursement policies could cause significant pressure on the pricing of, and reimbursement for, health care products and services, including our products, which could decrease demand for our products, and adversely affect our sales and revenue.

In addition, some third-party payors have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it could have a negative impact on our revenue in the short term. It is possible that third-party payors will resist reimbursement for the products that we offer, in favor of less expensive products, may require pre-approval for our products or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our products.

We expect to continue to focus substantial resources on increasing coverage and reimbursement for our current products and any future products we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of third-party payors for our products.

However, we cannot predict whether, under what circumstances, or at what payment levels third-party payors will cover and reimburse our products. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our products, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

Our products are currently marketed as laboratory developed tests, and any changes in regulations or the U.S. Food and Drug Administration’s enforcement discretion for laboratory developed tests, or violations of regulations by us, could adversely affect our business, prospects, results of operations or financial condition.

The diagnostics industry is highly regulated, and we cannot assure you that the regulatory environment in which we operate will not change significantly and adversely in the future. In many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Although the U.S. Food and Drug Administration, or FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics that are designed, manufactured and used within a single laboratory. These tests are referred to as laboratory developed tests, or LDTs. We currently market our products as LDTs.

The FDA has adopted a policy of enforcement discretion with respect to LDTs whereby the FDA does not actively require premarket review of LDTs or otherwise impose its requirements applicable to other medical devices on LDTs. However, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. The FDA could ultimately modify its current approach to LDTs in a way that would subject our products marketed as LDTs to the enforcement of additional regulatory requirements. Moreover, legislative measures have recently been proposed in Congress that, if ultimately enacted, could provide the FDA with additional authority to require premarket review of and regulate LDTs. If and when such changes to the regulatory framework occur, we could for the first time be subject to enforcement of regulatory requirements as a device manufacturer such as registration and listing requirements, medical device reporting requirements and the requirements of the FDA’s Quality System Regulation. We may be required to conduct clinical trials prior to continuing to sell

our existing products or launching any other products we may develop. This may increase the cost of conducting, or otherwise harm, our business.

Moreover, even if the FDA does not modify its policy of enforcement discretion, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements. While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, we cannot assure you that the FDA will agree with our determination. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

If the FDA begins to actively regulate our diagnostic products, we may be required to obtain premarket clearance under Section 510(k) of the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, or a premarket approval, or PMA. The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer, and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all. Moreover, there can be no assurance that any cleared or approved labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our products. If premarket review is required for some or all of our products, the FDA may require that we stop selling our products pending clearance or approval, which would negatively impact our business. Even if our products are allowed to remain on the market prior to clearance or approval, demand or reimbursement for our products may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our products, or from other products now in development.

If the FDA imposes significant changes to the regulation of LDTs it could reduce our revenues or increase our costs and adversely affect our business, prospects, results of operations or financial condition.

We conduct business in a heavily regulated industry, and failure to comply with federal, state and foreign laboratory licensing requirements and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.

The diagnostics industry is highly regulated, and the laws and regulations governing the marketing of diagnostic tests are extremely complex. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal and state laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and/or regulatory agencies enforcing those laws and regulations;
- federal and state fraud and abuse laws;
- federal and state laboratory anti-mark-up laws;
- coverage and reimbursement levels by Medicare, Medicaid, other governmental payors and private insurers;
- restrictions on coverage of and reimbursement for tests;
- federal and state laws governing laboratory testing, including CLIA, and state licensing laws;
- federal and state laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including LDTs;
- federal, state and local laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations; and
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar state data privacy laws.

In particular, the FDCA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.

Our products are considered by the FDA to be subject to regulation as medical devices, and marketed under FDA's policy of enforcement discretion for LDTs. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices manufactured between the United States and international markets.

We are also subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. Any testing subject to CLIA regulation must be performed in a CLIA certified or accredited lab. CLIA certification or accreditation is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial third-party payors, for our products. We have a current CLIA accreditation under the College of American Pathologists, or CAP, program to conduct our tests at our clinical reference laboratory in Phoenix, Arizona.

To maintain our CLIA accreditation, we have elected to be subject to survey and inspection every two years by CAP. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time.

In addition, certain states require our laboratory to be licensed in such states in order to test specimens from those states. Accordingly, our laboratory is also licensed by California, Maryland, New York, Pennsylvania and Rhode Island. Other states may have similar requirements or may adopt similar requirements in the future.

Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future.

In order to test specimens from New York, LDTs must be approved by the New York State Department of Health, or NYSDOH, on a test-by-test basis before they are offered. Our laboratory director must also be separately qualified to be a laboratory director in New York. DecisionDx-UM, DecisionDx-PRAME and DecisionDx-Melanoma have each been approved and our laboratory director has been qualified by NYSDOH. We are subject to periodic inspection by the NYSDOH and are required to demonstrate ongoing compliance with NYSDOH regulations and standards. To the extent NYSDOH identified any non-compliance and we are unable to remedy such non-compliance, the State of New York could withdraw approval for our products. We will need to seek NYSDOH approval of any future LDTs we develop and want to offer for clinical testing to New York residents, and there can be no assurance that we will be able to obtain such approval.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our products or such jurisdictions adopt new licensure requirements, which may require review of our products in order to offer them or may have other limitations such as restrictions on the transport of human tissue samples necessary for us to perform our tests that may limit our ability to make our products available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays.

CAP maintains a clinical laboratory accreditation program. While not required for the operation of a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. CAP accredited laboratories are surveyed for compliance with CAP standards every two years in order to maintain accreditation. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our products and the results of our operations. Our most recent CAP inspection occurred in the fourth quarter of 2018 and our CLIA accreditation certificate expires on December 20, 2020.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA accreditation and/or state licenses, imposition of a directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA accreditation, or a state or foreign license, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The FDA may modify its enforcement discretion policy with respect to LDTs in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

If the FDA changes or ends its policy of enforcement discretion with respect to LDTs, and our products become subject to the FDA's requirements for premarket review of medical devices, we may be required to cease commercial sales of our products and conduct clinical trials prior to making submissions to the FDA to obtain premarket clearance or approval. If we are required to conduct such clinical trials, delays in the commencement or completion of clinical trials could significantly increase our product development costs and delay commercialization of any currently marketed testing that we may be required to cease selling or the commercialization of any future tests that we may develop. 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.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or ''off-label'' uses; and the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health.

Even if we were able to obtain FDA clearance or approval for one or more of our products, if required, a diagnostic test may be subject to limitations on the indications for which it may be marketed or to other regulatory conditions. In addition, such clearance or approval may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the test.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approvals. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline or data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and marketing efforts.

Further, others, including healthcare providers or payors, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed

significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the topline or interim data that we report differ from actual results, or if others, including healthcare providers or payors, disagree with the conclusions reached, our ability to commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in health care policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our products.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the ACA, became law. This law substantially changed the way health care is financed by both government and commercial third-party payors, and significantly impacted our industry. The ACA contains a number of provisions that are expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in state and federal health care programs, reimbursement changes and fraud and abuse, which impact existing state and federal health care programs and will result in the development of new programs. Among other things, the ACA requires medical device manufacturers to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, and began to apply to sales of taxable medical devices after December 31, 2012. FDA officials have indicated that a laboratory will not have to pay the tax under the proposed ‘‘notification’’ procedure in the Notification draft guidance. However, the laboratory would have to pay the tax at the time that it lists a test with FDA. In FDA’s Notification draft guidance, listing occurs at the time a laboratory submits either a PMA or 510(k) for the test. While it is possible that this tax will apply to some or all of our products or products that are in development, for the time being, Congress has enacted a two-year moratorium on the medical device tax until January 1, 2020.

Since 2016 there have been efforts to repeal all or part of the ACA, and the current administration and the U.S. Congress have taken action to roll back certain provisions of the ACA. The current administration and the U.S. Congress may take further action regarding the ACA, including, but not limited to, repeal or replacement.

Additionally, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the tax penalty on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the ‘‘individual mandate,’’ was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or the TCJA. While the Texas District Court Judge, as well as the current administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027, unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our products, the coverage of or the amounts of reimbursement available for our products from third-party payors, including government and commercial payors.

We are subject to numerous federal and state healthcare statutes and regulations, and complying with laws pertaining to our business is an expensive and time-consuming process. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties and a material adverse effect to our business and operations.

Physicians, other healthcare providers and third-party payors play a primary role in the recommendation of our products. Our arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that affect the business and financial arrangements and relationships through which we market and sell our products. The laws that affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, or the AKS, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value, such as specimen collection materials or test kits. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, however these are drawn narrowly. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have

committed a violation. Violations are subject to civil and criminal fines and monetary penalties of up to $100,000 for each violation, plus up to three times the remuneration involved, imprisonment of up to ten years and exclusion from government healthcare programs. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or the FCA;

- the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties and exclusion from the federal health care programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA;

- federal civil and criminal false claims laws and civil monetary penalty laws, such as the FCA, which can be enforced by private citizens through civil qui tam actions, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented through distribution of template medical necessity language or other coverage and reimbursement information, false, fictitious or fraudulent claims for payment or approval by the federal government, including federal health care programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Private individuals can bring False Claims Act ‘‘qui tam’’ actions, on behalf of the government and such individuals, commonly known as ‘‘whistleblowers,’’ may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions;

- state laws that prohibit other specified practices, such as billing physicians for tests that they order or providing tests at no or discounted cost to induce physician or patient adoption; insurance fraud laws; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other third-party payors employing, exercising control over or splitting professional fees with licensed professionals in violation of state laws prohibiting fee splitting or the corporate practice of medicine and other professions; and

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed

under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians, certain other healthcare professionals, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations. We believe that we are exempt from these reporting requirements. We cannot assure you, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business;

- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other part;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from patients. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories.

We have entered into consulting and scientific advisory board arrangements, speaking arrangements and clinical research agreements with physicians and other healthcare providers, including some who could influence the use of our products. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with physicians, as well as our financial assistance programs, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. Responding to investigations can be time and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations is costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance

with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to certain U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations and may become subject to their similar foreign equivalents. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively, Trade Laws, prohibit, among other things, companies and their employees, agents, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect that we may engage in non-U.S. activities over time. We expect to rely on third-party suppliers and/or third parties to obtain necessary permits, licenses, and patent registrations. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Our collection, use and disclosure of individually identifiable information, including health and/or employee information, is subject to state, federal and foreign privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

We and any potential collaborators are subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

In the ordinary course of our business, we collect and store sensitive data, including protected health information, or PHI, personally identifiable information, or PII, credit card and other financial information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payors and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data centers, and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as HIPAA, as amended by HITECH, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payers or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business. In addition, we may obtain health information from third parties that are also subject to privacy and security requirements under HIPAA, as amended by HITECH.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such PHI or PII along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our services, decrease demand for our services, reduce our revenue and/or subject us to additional liabilities.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our products.

Genetic testing has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities have, through the Genetic Information Nondisclosure Act of 2008, and could further, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Ethical and social concerns may also influence governmental authorities to deny or delay the issuance of patents for technology relevant to our business. While we do not currently perform genetic tests for genetic predisposition to certain conditions, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, our genomic tests or genetic tests for somatic mutations even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our products or reduce the potential markets for our products, either of which could have an adverse effect on our business, financial condition, or results of operations.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize diagnostic tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.*

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection as well as nondisclosure, confidentiality and other contractual restrictions to protect our brands and proprietary tests and technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

As is the case with other life science companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely or jointly with others or in-license from others, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing life sciences patents is costly, time-consuming and complex, and we may fail to apply for patents on important tests, services and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We have four licensed U.S. patents and two pending U.S. patent applications, with foreign counterparts. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable tests or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our future patented technologies. We may not be successful in defending any such challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. Even if our patents are held valid and enforceable, they may still be found insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may have to challenge the patents or patent applications of third parties, such as to counter infringement or unauthorized use. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to enjoin the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Even if we prevail against an infringer in a U.S. district court or foreign trial-level court, there is always the risk that the infringer will file an appeal and the initial court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. The outcome of patent litigation or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the life sciences field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA sequences.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to life science technologies, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition, and our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time-consuming and expensive. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive tests for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other life sciences companies, our success is heavily dependent on intellectual property, particularly patents relating to our research programs and products. Obtaining and enforcing patents in the life sciences industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or the United States Patent and Trademark Office, or the USPTO, rules and regulations could increase these uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the AIA, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent in USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. For applications filed after March 15, 2013 that do not claim the benefit of applications filed before that date, the AIA transitioned the United States from a first to invent system to a first-inventor-to-file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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.

Our in-licensed intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as ''march-in'' rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Intellectual property rights that have been in-licensed pursuant to our license agreement, or the License Agreement, with The Washington University in St. Louis, Missouri, or WUSTL, have been generated through the use of U.S. government funding, and are therefore subject to certain federal regulations. As a result, the United States federal government may retain certain rights to intellectual property embodied in our current or future product candidates under the Bayh-Dole Act. These federal government rights include a ''nonexclusive, nontransferable, irrevocable, paid-up license'' to use inventions for any governmental purpose. The Bayh-Dole Act also provides federal agencies with ''march-in rights.'' March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a ''nonexclusive, partially exclusive, or exclusive license'' to a ''responsible applicant or applicants'' if it determines that (1) adequate steps have

not been taken to commercialize the invention, (2) government action is necessary to meet public health or safety needs or (3) government action is necessary to meet requirements for public use under federal regulations. If the patent owner refuses to do so, the government may grant the license itself.

The U.S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States, and the License Agreement requires that we comply with this requirement. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or future in-licensed intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Issued patents covering our products and related technologies could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications (including licensed patents) have been, are being or may be challenged at a future point in time in an opposition, nullification, derivation, reexamination, *inter partes* review, post-grant review or interference action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could harm our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future diagnostic tests.

We may not be aware of all third-party intellectual property rights potentially relating to our products. 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 approximately 18 months after filing or, in some cases (*e.g.*, U.S. applications for which a request not to publish has been filed), not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we have and may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Therefore, the validity, enforceability and scope of our patents in the United States and other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The life sciences industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our potential competitors in both the United States and abroad, may have substantially greater resources and are likely to make substantial investments in patent portfolios and competing technologies, and may apply for or obtain patents that could prevent, limit or otherwise interfere with our ability to make, use and sell our products. Numerous third-party patents exist in fields relating to our products and technologies, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products and technologies. Moreover, because some patent

applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products and technologies.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our products, components of our products, and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or technologies do not infringe those third parties' patents;
- we may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products or technologies;
- if a competitor files patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our products or technologies infringe their patent or other intellectual property rights, we will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products and technologies; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our products or technologies infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force us to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the diagnostic test or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party's attorneys' fees;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the diagnostic test or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such test or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our products and technologies so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with applicable third party, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing technologies, which could be costly and create significant delay; or

- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Third parties may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact our business, cause delays, or prohibit us from marketing or otherwise commercializing our products and technologies. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

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, which could have a material adverse effect on the price of our common stock. 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. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

We depend on information technology systems that we license from third parties. Any failure of such systems or loss of licenses to the software that comprises an essential element of such systems could significantly harm our business.

We depend on information technology systems for significant elements of our operations, such as our laboratory information management systems, including test validation, specimen tracking and quality control, our bioinformatics analytical software systems and our test report generating systems. Essential elements of these systems depend on software that we license from third parties. If we are unable to maintain the licenses to this software or our software providers discontinue or alter the programs on which we rely, it could render our test reports unreliable or hinder our ability to generate accurate test reports, among other things. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We rely on licenses from third parties, and if we lose these licenses or are not able to obtain licenses to third-party technology on reasonable grounds or at all, then we may not be able to continue to commercialize existing diagnostic tests, be subjected to future litigation and may not be able to commercialize new diagnostic tests in the future.

We are party to certain royalty-bearing license agreements that grant us rights to use certain intellectual property, including patents and patent applications, in certain specified fields of use. Although we intend to develop products and technologies through our own internal research, we may need to obtain additional licenses from others to advance our research, development and commercialization activities. Our license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us.

In the future, we may identify third-party technology we may need, including to develop or commercialize new diagnostic tests or services. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of the cost of our products or services and affect our margins. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercialized test. The in-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 in-license or acquire third-party intellectual property rights for technologies that we may consider attractive or necessary.

These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may not be able to obtain necessary or strategic licenses to patents or patent applications, and our business may suffer if we are unable to enter into these licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize tests and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, tests identical to ours and we may be required to cease our development and

commercialization activities. For example, we license certain intellectual property from WUSTL that is incorporated into DecisionDx-UM. In 2018, we provided more than 1,400 test reports for DecisionDx-UM. If this license agreement were terminated, we would be unable to continue to issue test reports and thus sales of DecisionDx-UM. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may arise with respect to any one of our licensing agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our products, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any of such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected diagnostic tests, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our failure to maintain such licenses could have a material adverse effect on our business, financial condition and results of operations. Any of these licenses could be terminated, such as if either party fails to abide by the terms of the license, or if the licensor fails to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable. Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products or services, including DecisionDx-UM and DecisionDx-Melanoma, which could adversely affect our ability to offer our products or services, our ability to continue operations and our financial condition.

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. 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 tests or products and may also export infringing tests or products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products. 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 many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to life science technologies, which could make it difficult for us to stop the infringement of our patents in such countries. We do not have patent rights in certain

foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce our patent rights could result in substantial cost 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. We may not be able to stop a competitor from marketing and selling in foreign countries tests, products and services that are the same as or similar to our products and technologies, in which case our competitive position in the international market would be harmed.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to pursuing patents on our technology, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We take steps to protect our trade secrets, in part, by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain 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. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and, once disclosed, we are likely to lose trade secret protection and may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

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

We do and may employ individuals who previously worked with universities or other companies, including potential competitors. We could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer or competitor. Although, we are currently not subject to any such claims.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Therefore, we could be required to obtain a license from such third-party employer to commercialize our products or technology. Such a license may not be available on commercially reasonable terms or at all.

Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

We have not yet registered certain of our trademarks in all of our potential markets, although we have registered DecisionDx, DecisionDx-UM and DecisionDx-Melanoma in the United States. Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions, and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, right to use, or right to exclude others from using, intellectual property that is important to our products. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications must be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, such as failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we, or our licensors, fail to maintain the patents and patent applications covering our products and technologies, potential competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent term has expired, we may be open to competition from competitive tests or products. Given the amount of time required for the development, testing and regulatory review of potential new tests or products, patents protecting such tests or products might expire before or shortly after such tests or products are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing tests or other products similar or identical to ours.

Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business

We are highly dependent on the services of our key personnel.

We are highly dependent on the services of our key personnel, including Derek J. Maetzold, our President and Chief Executive Officer. Although we have entered into agreements with them regarding their employment, they are not for a specific term and each of may terminate their employment with us at any time, though we are not aware of any present intention of any of these individuals to leave us.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our sole laboratory facility located in Phoenix, Arizona. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified sales people. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

Our employees, clinical investigators, consultants, speakers, vendors and any current or potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.*

We are exposed to the risk of fraud or other misconduct by our employees, clinical study investigators, consultants, speakers, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: federal laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information; manufacturing standards; federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad; sexual harassment and other workplace misconduct; or laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, laboratory operations, customer support and sales administration systems, processes and controls. Failure to effectively manage our anticipated growth could lead us to over-invest or under-invest in development, operational and administrative infrastructure, result in weaknesses in our infrastructure, systems, or internal controls, give rise to operational mistakes, losses,

loss of customers, productivity or business opportunities, and result in loss of employees and reduced productivity of remaining employees.

We also anticipate further growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to increase headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, and sales and marketing staff and improve and maintain our technology to properly manage our growth. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed.

In addition, our anticipated growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new diagnostic tests and services. As we commercialize additional diagnostic tests, we may need to incorporate new equipment, implement new technology systems, or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher costs, declining quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products, and could damage our reputation and the prospects for our business.

We may not be able to maintain the quality or expected turnaround times of our products, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations. If our management is unable to effectively manage our anticipated growth, our expenses may increase more than expected, our revenue could decline or grow more slowly than expected and we may be unable to implement our business strategy. The quality of our products and services may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, the U.S. government enacted the TCJA that significantly revises the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. We do not expect the TCJA to have a material impact to our current projection of minimal cash taxes for the near future.

However, we continue to examine the impact that the TCJA may have on our business in the longer term. Accordingly, notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the TCJA. The impact of the TCJA on holders of our common stock is also uncertain and could be adverse. We urge prospective investors to consult with their legal and tax advisors with respect to the TCJA and the potential tax consequences of investing in or holding our common stock.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had federal net operating loss carryforwards of approximately $62.2 million. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under the TCJA, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the TCJA. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an ‘‘ownership change’’ (which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced an ownership change in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss

carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Our business could be negatively impacted by cyber security threats.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage and the further development and commercialization of our products could be delayed.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, we maintain a tumor specimen database comprised of over 38,000 samples some of which were used to develop and validate DecisionDx-Melanoma, some of which are currently being used to improve on the test and some of which will be used in the future. If we were to lose this database, our ability to further validate, improve and therefore maintain and grow sales of DecisionDx-Melanoma could be significant impaired.

Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information related to our patient samples or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Product or professional liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of our products.

We face an inherent risk of product and professional liability exposure related to our products. The marketing, sale and use of our products could lead to the filing of product liability claims were someone to allege that our products identified or reported inaccurate or incomplete information, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities.

If we cannot successfully defend ourselves against claims that our products caused injury or otherwise failed to function properly, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our current tests any tests that we may develop, and the inability to commercialize such tests;
- injury to our reputation and significant negative media attention;
- reluctance of experts willing to conduct our clinical studies;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management’s time and our resources;
- substantial monetary awards to study subjects or patients;

- product recalls, withdrawals or labeling, or marketing or promotional restrictions; and
- loss of revenue.

We currently carry product liability insurance. However, the amount of this insurance may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

We currently do not accept orders from customers outside of the United States, but our long term business strategy incorporates potential international expansion. Doing business internationally involves a number of risks, including:

multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- limits in our ability to penetrate international markets if we are not able to perform tests locally;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- difficulties in staffing and managing foreign operations;
- failure to obtain regulatory approvals for the commercialization of our products in various countries;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.*

We are subject to the reporting requirements of the Exchange Act or the other rules and regulations of the SEC or any securities exchange relating to public companies. Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory ''say on pay'' voting requirements that will apply to us when we cease to be an emerging growth company. 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. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial

condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products. In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Ownership of Our Common Stock

The stock price of our common stock may be volatile or may decline regardless of our operating performance, and you may lose all or part of your investment.*

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our operating performance and the performance of other similar companies;
- our success in marketing and selling our products;
- reimbursement determinations by third-party payors and reimbursement rates for our products;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to product development and clinical studies for our products;
- our ability to achieve product development goals in the timeframe we announce;
- announcements of clinical study results, regulatory developments, acquisitions, strategic alliances or significant agreements by us or by our competitors;
- the success or failure of our efforts to acquire, license or develop additional tests;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a significant percentage of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our market float; and
- any other factors discussed in this Quarterly Report on Form 10-Q.

In addition, the stock market in general, and diagnostic and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.*

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of August 30, 2019, we had 17,069,094 shares of common stock outstanding. Of these shares, only the 4,600,000 shares sold in the IPO are currently freely tradable, without restriction, in the public market. All of our other outstanding shares of common stock are currently restricted from resale as a result of market standoff and lock-up agreements and will become available to be sold on January 21, 2020, which is 181 days after the date of the underwriting agreement we entered into in connection with the IPO. Shares held by directors, executive officers and other affiliates are subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

Certain of our stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders, subject to market standoff and lockup agreements. We have registered shares of common stock that we have issued and may issue under our employee equity incentive plans. As a result, these shares will be able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements. SVB Leerink LLC and Robert W. Baird & Co. Incorporated, as the representatives of the underwriters in the IPO may, in their discretion, permit our stockholders to sell shares prior to the expiration of the restrictive provisions contained in those lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

We have broad discretion in the use of working capital and may not use it effectively or in ways that increase our share price.*

We cannot specify with any certainty the particular uses of working capital, but we currently expect such uses will include: funding selling and marketing activities, including expansion of our sales force to support the ongoing commercialization of current and future products; research and development related to the continued support of our current products as well as the development of our product pipeline; and other general corporate purposes, including the additional costs associated with being a public company. The failure by our management to apply our working capital effectively could adversely affect our business and financial condition. Pending its use, we may invest working capital in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

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

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

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.*

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new

relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

We are an emerging growth company and a smaller reporting company and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.*

We are an emerging growth company as defined in the JOBS ACT, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced ‘‘Management’s Discussion and Analysis of Financial Condition and Results of Operations’’ disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, or July 29, 2024, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. In addition, the terms of the 2018 LSA precludes us from paying dividends without prior consent. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.*

Based upon shares outstanding as of August 30, 2019, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 37% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.*

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to

suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and

- provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

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

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation and amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

Recent Sales of Unregistered Equity Securities

During the six months ended June 30, 2019, we granted stock options to purchase an aggregate of 510,355 shares of our common stock at a weighted-average exercise price of $3.46 per share, to certain of our employees, consultants and directors in connection with services provided to us by such persons. During the six months ended June 30, 2019, options to purchase 276,237 shares have been exercised for aggregate consideration of approximately $418,000 and options to purchase 10,698 shares have been canceled. The offers, sales and issuances of the foregoing stock options were deemed to be exempt from registration under the Securities Act in reliance on either Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2008 Stock Plan and our 2018 Equity Incentive Plan.

Use of Proceeds from IPO of Common Stock

On July 29, 2019, we completed the IPO pursuant to which we issued and sold 4,600,000 shares of our common stock, including 600,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statements on Form S-1, as amended (File Nos. 333-232369 and 333-232796), which were declared or became effective on July 24, 2019. SVB Leerink LLC and Robert W. Baird & Co. Incorporated acted as joint book-running managers for the IPO and as representatives of the underwriters. Canaccord Genuity LLC and BTIG, LLC acted as co-managers for the IPO.

We received gross proceeds from the IPO of $73.6 million, or net proceeds of $66.0 million after deducting $5.2 million in underwriting discounts and commissions and $2.4 million of offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in the Prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description of document
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2019.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2019.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.1#	First Amendment to Loan and Security Agreement, dated June 13, 2019, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank, incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
32.1**	Certification of Principal Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.
32.2**	Certification of Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.
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.

_____
*Filed herewith.
**Furnished herewith.
#Certain portions of this exhibit (indicated by "[***]") have been omitted as we have determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to us if publicly disclosed.

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.

CASTLE BIOSCIENCES, INC.

Date: September 3, 2019

By: /s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

Date: September 3, 2019

By: /s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Derek J. Maetzold, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Castle Biosciences, 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(s) 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)) [omitted pursuant to Rules 13a-14(a) and 15d-14(a)] for the registrant and have:

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

   (b) [omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

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

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

5. The registrant's other certifying officer(s) 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: September 3, 2019

/s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Frank Stokes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Castle Biosciences, 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(s) 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)) [omitted pursuant to Rules 13a-14(a) and 15d-14(a)] for the registrant and have:

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

   (b) [omitted pursuant to Rules 13a-14(a) and 15d-14(a)];

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

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

5. The registrant's other certifying officer(s) 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: September 3, 2019

/s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER
UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002, 18 U.S.C. § 1350

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 of Castle Biosciences, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Derek J. Maetzold, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: September 3, 2019

/s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF
PRINCIPAL FINANCIAL OFFICER
UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002, 18 U.S.C. § 1350

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 of Castle Biosciences, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Frank Stokes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: September 3, 2019

/s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)