

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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 March 31, 2020

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 001-38118

**DERMTECH, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**84-2870849**  
(I.R.S. Employer  
Identification No.)

**11099 N. Torrey Pines Road, Suite 100**  
**La Jolla, CA**  
(Address of principal executive offices)

**92037**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 450-4222**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	DMTK	The Nasdaq Capital Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

As of May 7, 2020, the registrant had 14,907,305 shares of common stock, \$0.0001 par value per share, outstanding.

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## Item 1. Financial Statements.

**DERMTECH, INC.**  
**Condensed Consolidated Balance Sheets**  
(in thousands, except share and per share data)  
(Unaudited)

Assets	March 31, 2020	December 31, 2019
<b>Current assets:</b>		
Cash and cash equivalents	\$ 67,922	\$ 15,374
Accounts receivable	1,175	680
Inventory	75	35
Prepaid expenses and other current assets	892	1,061
Total current assets	70,064	17,150
Property and equipment, net	1,736	977
Other assets	167	84
Total assets	\$ 71,967	\$ 18,211
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,561	\$ 1,609
Accrued compensation	1,120	1,142
Accrued liabilities	200	218
Deferred revenue	1,093	1,390
Deferred underwriting fees	1,363	1,363
Total current and total liabilities	5,337	5,722
<b>Commitments and contingencies</b>		
Series A convertible preferred stock, \$0.0001 par value per share; 1,250 Series A shares authorized as of March 31, 2020 and December 31, 2019; 1,231 shares issued and outstanding at March 31, 2020 and December 31, 2019; \$6.9 million and \$7.6 million liquidation preference at March 31, 2020 and December 31, 2019	—	—
Series B-1 convertible preferred stock, \$0.0001 par value per share; 3,200 and zero Series B-1 shares authorized as of March 31, 2020 and December 31, 2019; 3,199 and zero shares issued and outstanding at March 31, 2020 and December 31, 2019; \$36.0 million and zero liquidation preference at March 31, 2020 and December 31, 2019	—	—
Series B-2 convertible preferred stock, \$0.0001 par value per share; 525 and zero Series B-2 shares authorized as of March 31, 2020 and December 31, 2019; 524 and zero shares issued and outstanding at March 31, 2020 and December 31, 2019; \$5.9 million and zero liquidation preference at March 31, 2020 and December 31, 2019	—	—
<b>Stockholders' equity:</b>		
Common stock, \$0.0001 par value per share; 50,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 14,899,701 and 12,344,818 shares issued and outstanding at March 31, 2020 and December 31, 2019	1	1
Additional paid-in capital	164,741	103,599
Accumulated deficit	(98,112)	(91,111)
Total stockholders' equity	66,630	12,489
Total liabilities, convertible preferred stock and stockholders' equity	\$ 71,967	\$ 18,211

See accompanying notes to unaudited condensed consolidated financial statements.

**DERMTECH, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share data)  
(Unaudited)

	Three Months Ended March 31,	
	2020	2019
<b>Revenues:</b>		
Assay revenue	\$ 796	\$ 235
Contract revenue	761	361
Total revenues	1,557	596
<b>Cost of revenues</b>		
Gross profit/(loss)	354	(39)
<b>Operating expenses:</b>		
Sales and marketing	2,944	864
Research and development	897	572
General and administrative	3,514	1,528
Total operating expenses	7,355	2,964
Loss from operations	(7,001)	(3,003)
<b>Other expense:</b>		
Interest expense, net	—	(1,968)
Other expense	—	(185)
Total other expense	—	(2,153)
Net loss and comprehensive loss	<u>\$ (7,001)</u>	<u>\$ (5,156)</u>
Weighted average shares outstanding used in computing net loss		
per share, basic and diluted	13,100,642	4,411,279
Net loss per common share outstanding, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (1.17)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**DERMTECH, INC.**  
**Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Three Months Ended March 31, 2020 & March 31, 2019**  
**(in thousands, except share and per share data)**  
**(Unaudited)**

	Series C convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount			
Balance, December 31, 2018	1,524,122	\$ —	4,411,567	\$ 1	\$ 66,021	\$ (71,377)	\$ (5,355)
Cumulative effect adjustment of accounting method change	—	—	—	—	—	(45)	(45)
Stock-based compensation	—	—	—	—	258	—	258
Net loss	—	—	—	—	—	(5,156)	(5,156)
Balance, March 31, 2019	<u>1,524,122</u>	<u>\$ —</u>	<u>4,411,567</u>	<u>\$ 1</u>	<u>\$ 66,279</u>	<u>\$ (76,578)</u>	<u>\$ (10,298)</u>

	Series A convertible preferred stock		Series B-1 convertible preferred stock		Series B-2 convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2019	1,231	\$ —	—	\$ —	—	\$ —	12,344,818	\$ 1	\$ 103,599	\$ (91,111)	\$ 12,489
Issuance of common stock at \$10.50 per share, net of \$2.0 million in issuance costs	—	—	—	—	—	—	2,467,724	—	23,891	—	23,891
Issuance of Series B-1 preferred stock at \$10,500 per share, net of \$2.6 million in issuance costs	—	—	3,199	—	—	—	—	—	30,971	—	30,971
Issuance of Series B-2 preferred stock at \$10,500 per share, net of \$0.4 million in issuance costs	—	—	—	—	524	—	—	—	5,071	—	5,071
Issuance of common stock from option exercises	—	—	—	—	—	—	85,061	—	253	—	253
Issuance of common stock from warrant exercises	—	—	—	—	—	—	2,098	—	11	—	11
Issuance costs in connection with Form S-1 registration statement	—	—	—	—	—	—	—	—	(77)	—	(77)
Stock-based compensation	—	—	—	—	—	—	—	—	1,022	—	1,022
Net loss	—	—	—	—	—	—	—	—	—	(7,001)	\$ (7,001)
Balance, March 31, 2020	<u>1,231</u>	<u>\$ —</u>	<u>3,199</u>	<u>\$ —</u>	<u>524</u>	<u>\$ —</u>	<u>14,899,701</u>	<u>\$ 1</u>	<u>\$ 164,741</u>	<u>\$ (98,112)</u>	<u>\$ 66,630</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**DERMTECH, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
(in thousands)  
(Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,001)	\$ (5,156)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	60	19
Stock-based compensation	1,022	258
Amortization of debt discount and issuance costs	—	1,781
Change in fair value of derivative liability	—	185
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(495)	302
Inventory	(40)	1
Prepaid expenses and other current assets	86	(72)
Accounts payable and accrued compensation	(714)	49
Accrued liabilities and deferred revenue	(315)	(73)
Net cash used in operating activities	<u>(7,397)</u>	<u>(2,706)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(175)	(6)
Net cash used in investing activities	<u>(175)</u>	<u>(6)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock in connection with private placement offering, net	23,891	—
Proceeds from issuance of Series B-1 Convertible Preferred Stock, net	30,971	—
Proceeds from issuance of Series B-2 Convertible Preferred Stock, net	5,071	—
Payments of issuance costs in connection with Form S-1 registration statement	(77)	—
Proceeds from exercise of common stock warrants	11	—
Proceeds from exercise of stock options	253	—
Net cash provided by financing activities	<u>60,120</u>	<u>—</u>
Net increase/(decrease) in cash and cash equivalents	52,548	(2,712)
Cash and cash equivalents, beginning of period	15,374	4,753
Cash and cash equivalents, end of period	<u>\$ 67,922</u>	<u>\$ 2,041</u>
<b>Supplemental cash flow information:</b>		
Purchases of property and equipment recorded in accounts payable	\$ 644	\$ 4

See accompanying notes to unaudited condensed consolidated financial statements.

**DERMTECH, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. The Company and a Summary of its Significant Accounting Policies**

**(a) Nature of Operations**

On August 29, 2019, DermTech, Inc., formerly known as Constellation Alpha Capital Corp, (the “Company”), and DermTech Operations, Inc., formerly known as DermTech, Inc., (“DermTech Operations”), consummated the transactions contemplated by the Agreement and Plan of Merger, dated as of May 29, 2019, by and among the Company, DT Merger Sub, Inc., a wholly owned subsidiary of the Company (“Merger Sub”), and DermTech Operations. The Company refers to this agreement, as amended by that certain First Amendment to Agreement and Plan of Merger dated as of August 1, 2019, as the Merger Agreement. Pursuant to the Merger Agreement, Merger Sub merged with and into DermTech Operations, with DermTech Operations surviving as a wholly-owned subsidiary of the Company. The Company refers to this transaction as the Business Combination. In connection with and two days prior to the completion of the Business Combination, the Company domesticated from the British Virgin Islands to Delaware. DermTech Operations changed its name from DermTech, Inc. to DermTech Operations, Inc. shortly before the completion of the Business Combination. On August 29, 2019, immediately following the completion of the Business Combination, the Company changed its name from Constellation Alpha Capital Corp. to DermTech, Inc., and then effected a one-for-two reverse stock split of its common stock (“Reverse Stock Split”).

The Company is an emerging growth molecular diagnostic company developing and marketing its Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) laboratory services including molecular pathology tests to facilitate the diagnosis of dermatologic conditions including melanoma. The Company has developed a proprietary, non-invasive technique for sampling the surface layers of the skin using an adhesive patch in order to collect individual biological information for commercial applications in the medical diagnostic field.

During and following the first quarter of 2020, there has been a widespread worldwide impact from the COVID-19 pandemic. The Company is considered an essential business due to the importance for early melanoma detection, which has allowed the Company’s CLIA laboratory to remain fully operational. The Company has implemented additional safety measures and social distancing with its CLIA laboratory operations and has transitioned administrative functions to working remotely. Beginning in March 2020, the ongoing COVID-19 pandemic has reduced patient access to clinician offices for in-person testing, which has resulted in a reduced volume of billable samples received. Additionally, the Company expects that the ongoing COVID-19 pandemic will have an effect on its pharmaceutical customers’ clinical trials. The extent of such effect on the Company’s future revenue is uncertain and will depend on the duration and extent of the effects of the ongoing COVID-19 pandemic.

**(b) Basis of Presentation**

These condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included.

**(c) Use of Estimates**

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the amounts of revenues and expenses reported during the period. On an ongoing basis, management evaluates these estimates and judgments, including those related to assay revenue, stock-based compensation, accounts receivable and the realization of deferred tax assets. Actual results may differ from those estimates.

**(d) Cash and Cash Equivalents**

The Company considers all highly liquid investments with remaining maturities of three months or less when purchased to be cash equivalents. The Company maintains its cash balances at banks and financial institutions. The balances are insured up to the legal limit. The Company maintains cash balances that may, at times, exceed this insured limit.

**(e) Property and Equipment**

Property and equipment is recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from two to five years. Leasehold improvements are depreciated over the shorter of the remaining term of the lease or the useful life of the asset. The Company recorded depreciation expense of \$0.1 million and \$19,000 for the three months ended March 31, 2020 and 2019, respectively. No property or equipment was disposed of during the three months ended March 31, 2020 and 2019. The Company assesses its long-lived assets, consisting primarily of property and equipment, for impairment when material events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses for the three months ended March 31, 2020 and 2019.

**(f) Research and Development**

Costs incurred in connection with research and development (“R&D”) activities are expensed as incurred. R&D expenses consist of (i) employee-related expenses, including salaries, benefits, travel and stock compensation expense; (ii) and facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies.

The Company expenses all costs as incurred in connection with patent applications (including direct application fees and the legal and consulting expenses related to making such applications), and such costs are included in general and administrative expenses.

**(g) Concentration of Credit Risk**

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. As of March 31, 2020, the Company maintained \$67.9 million in a bank deposit account, which is in excess of the \$250,000 insurance provided by the Federal Deposit Insurance Corporation in one federally insured financial institution. The Company has not experienced any losses in such accounts.

**(h) Income Taxes**

The Company provides for federal and state income taxes on the asset and liability approach which requires deferred tax assets and liabilities to be recognized based on temporary differences between the condensed consolidated financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the temporary differences are expected to reverse.

Deferred tax assets are reduced by a valuation allowance when, in management’s opinion, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. The Company’s valuation allowance is based on available evidence, including its current year and prior year operating losses, evaluation of positive and negative evidence with respect to certain specific deferred tax assets including evaluation sources of future taxable income to support the realization of the deferred tax assets. The Company has established a full valuation allowance on the deferred tax assets as of March 31, 2020.

Current and deferred tax assets and liabilities are recognized based on the tax positions taken or expected to be taken in the Company’s income tax returns. U.S. GAAP requires that the tax benefits of an uncertain tax position can only be recognized when it is more likely than not that the tax position will be sustained upon examination by the relevant taxing authority. Tax benefits related to tax positions that do not meet this criterion are not recognized in the condensed consolidated financial statements, of which there are none.

The Company recognizes interest and penalties related to income tax matters in income tax expense.

**(i) Revenue Recognition**

The Company’s revenue is generated from two revenue streams: contract revenue and assay revenue. The Company accounts for revenue in accordance with Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as amended, and accounts for revenue in accordance with Accounting Standards Codification Topic 606 (“ASC 606”). The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The ASC 606 revenue recognition model consists of the following five steps: (1) identify the contracts with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation.



The Company recognizes revenue from its contract and assay goods and service in accordance with the core principles and key aspects considered by the Company. These considerations are described below, first for Contract Revenue and then for Assay Revenue.

### **Contract Revenue**

Contract revenue is generated from the sale of laboratory services and adhesive sample collection kits to third party companies through contract research agreements. Revenues are generated from providing gene expression tests to facilitate the development of drugs designed to treat dermatologic conditions. The provision of gene expression services may include sample collection using the Company’s patented adhesive patch biopsy devices, assay development for research partners, ribonucleic acid (“RNA”) isolation, expression, amplification and detection, including data analysis and reporting.

### **Assay Revenue**

The Company generates revenues from its Pigmented Lesion Assay (“PLA”) and Nevome services it provides to healthcare physicians in various states throughout the United States to assist in a clinician’s diagnosis of melanoma. The Company provides prescribing clinicians with its adhesive sample collection kits to perform non-invasive skin biopsies of clinically ambiguous pigmented skin lesions on patients. Once the sample is collected by the healthcare clinician, it is returned to the Company’s CLIA laboratory for analysis. The patient RNA and deoxyribonucleic acid (“DNA”) is extracted from the adhesive patch collection kit and analyzed using gene expression technology to determine if the pigmented skin lesion contains certain genomic features indicative of melanoma. Upon completion of the gene expression analysis, a final report is drafted and provided to the dermatologists detailing the test results for the pigmented skin lesion indicating whether the sample collected is indicative of melanoma or not.

#### *(a) Disaggregation of Revenue*

The following table presents the Company’s revenues disaggregated by revenue source during the three months ended March 31, 2020 and 2019, respectively, (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Assay Revenue</b>		
PLA Test	\$ 796	\$ 235
<b>Contract Revenue</b>		
Adhesive Patch kits	14	167
RNA Extractions	671	115
Project Management Fees	76	78
Other	—	1
<b>Total Revenue</b>	<b>\$ 1,557</b>	<b>\$ 596</b>

#### *(b) Contract Balances and Deferred Revenue*

The timing of revenue recognition, billings and cash collections results in billed accounts receivable and deferred revenue on the condensed consolidated balance sheets.

Generally, contract revenue has a majority of agreements in which the Company receives a substantial up-front payment upon various milestones over the life of the agreement. This results in deferred revenue and is relieved upon delivery of the applicable adhesive patch kits or RNA extraction results. Changes in accounts receivable and deferred revenue were not materially impacted by any other factors.

The Company records a deferred revenue liability if a customer pays consideration before the Company transfers a good or service to the customer. Deferred revenue primarily represents upfront milestone payments, for which consideration is received prior to when goods/services are completed or delivered. Deferred revenue at March 31, 2020 and December 31, 2019 was \$1.1 million and \$1.4 million, respectively.

**(j) Accounts Receivable**

*Contract Accounts Receivable*

Contract accounts receivable are recorded at the net invoice value and are not interest bearing. The Company reserves specific receivables if collectability is no longer reasonably assured, and as of March 31, 2020, the Company did not maintain any reserve over contract receivables as they deal with large established credit worthy customers. The Company re-evaluates such reserves on a regular basis and adjusts its reserves as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve. The Company recorded \$0.4 million and \$0.3 million of contract accounts receivable as of March 31, 2020 and December 31, 2019, respectively.

*Assay Accounts Receivable*

Due to the nature of the Company's assay revenue, it can take a significant amount of time to collect upon billed PLA services. The Company prepares an analysis on reimbursement collections and data obtained for each financial reporting period to determine the amount of receivables to be recorded relating to PLA services performed in the applicable period. 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. Adjustments for implicit price concessions attributable to variable consideration are incorporated into the measurement of the accounts receivable balances. The Company recorded \$0.8 million and \$0.5 million of gross assay accounts receivable as of March 31, 2020 and December 31, 2019, respectively.

**(k) Freight and Shipping Costs**

The Company records outbound freight and shipping costs for its contract and assay revenues in cost of revenues.

**(l) Comprehensive Income / (Loss)**

Comprehensive income / (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.

**(m) Segment Reporting**

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.

**(n) Net Loss Per Share**

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average common shares outstanding during the period. Because there is a net loss attributable to common shareholders during the three months ended March 31, 2020 and 2019, the outstanding common stock warrants, stock options, restricted stock units and preferred stock have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted loss per share are the same. Diluted net loss per common share for the three months ended March 31, 2020 excludes the effect of anti-dilutive equity instruments including 4,338,136 shares of common stock issuable upon conversion of the Company's preferred stock, 4,212,349 shares of common stock issuable upon the exercise of outstanding common stock warrants and 1,342,625 shares of common stock issuable upon the exercise stock options and release of restricted stock units. Diluted net loss per common share for the three months ended March 31, 2019 excludes the effect of anti-dilutive equity instruments including 1,524,122 shares of common stock issuable upon conversion of the Company's preferred stock, 685,761 shares of common stock issuable upon the exercise of outstanding warrants and 1,574,655 shares of common stock issuable upon the exercise stock options and release of restricted stock units. The Company did not consider a two-class method of loss per share given that the Company's convertible participating securities do not participate in losses.

(o) **Stock-Based Compensation**

Effective January 1, 2020, the Company elected an accounting policy change to no longer estimate forfeitures in connection with expense recognition of stock options and RSUs. All stock options and RSUs granted on or subsequent to January 1, 2020 will recognize forfeitures when they occur in accordance with Accounting Standards Update (“ASU”) 2016-09, *Compensation - Stock Compensation (Topic 718)*. In addition, effective January 1, 2020, the Company has elected to recognize stock-based compensation expense over the requisite service period of options and awards on a ratable basis. The Company believes that the recognition of stock-based compensation on a ratable basis is more in line with their business practices of granting options and awards.

Compensation costs associated with stock option awards and other forms of equity compensation are measured at the grant-date fair value of the awards and recognized over the requisite service period of the awards on a ratable basis.

The Company grants stock options to purchase common stock to employees with exercise prices equal to the fair market value of the underlying stock, as determined by the board of directors, management and outside valuation experts prior to the Business Combination. The board of directors and outside valuation experts determined the fair value of the underlying stock by considering a number of factors, including historical and projected financial results, the risks the Company faced at the time, the preferences of the Company’s debt holders and preferred stockholders, and the lack of liquidity of the Company’s common stock. Subsequent to the close of the Business Combination, the fair market value of stock options is based on the closing stock price on the grant date.

The fair value of each stock option award is estimated using the Black-Scholes-Merton valuation model. Such value is recognized as expense over the requisite service period using the ratable method. The expected term of options is based on the simplified method which defines the expected term as the average of the contractual term of the options and the weighted average vesting period for all option tranches. The expected volatility of stock options is based upon the historical volatility of a number of related publicly traded companies in similar stages of development as well as the volatility of the Company’s common stock. The risk-free interest rate is based on the average yield of U.S. Treasury securities with remaining terms similar to the expected term of the share-based awards. The assumed dividend yield was based on the Company’s expectation of not paying dividends in the foreseeable future.

The Company accounts for stock options to non-employees using the fair value approach. The fair value of these options is measured using the Black-Scholes-Merton option pricing model, reflecting the same assumptions applied to employee options, other than expected life, which is assumed to be the remaining contractual life of the award. Options that are granted to employees generally have a requisite service period of three to four years. Equity instruments awarded to non-employees are periodically re-measured as the underlying awards vest unless the instruments are fully vested, immediately exercisable, and non-forfeitable on the date of grant.

Restricted stock units (“RSUs”), are considered restricted stock. The fair value of restricted stock is equal to the fair market value of the underlying stock, as determined by the board of directors, management and input from outside valuation experts prior to the Business Combination. Subsequent to the close of the Business Combination, the fair market value of RSUs is based on the closing stock price on the grant date. The Company recognizes stock-based compensation expense based on the fair value on a ratable basis over the requisite service periods of the awards. RSUs that are granted to employees have a requisite service period between two and four years.

All stock options and RSUs granted prior to January 1, 2020 will maintain the estimated forfeiture approach and will be recognized over the requisite service period using the straight line method.

The fair value of each option for employees was estimated on the date of grant using the following assumptions:

	Three Months Ended March 31,	
	2020	2019
Assumed risk-free interest rate	0.79% - 1.69%	2.51%
Assumed volatility	64.03% - 65.92%	72.30%
Expected option term	5.04 - 6.08	6.04
Expected dividend yield	—	—

The Company recorded stock-based compensation expense for employee options, RSUs, common stock warrants, and consultant options of \$1.0 million and \$0.3 million for the three months ended March 31, 2020 and 2019, respectively. The total compensation cost related to non-vested awards not yet recognized at March 31, 2020 was \$7.8 million, which is expected to be recognized over a weighted average term of 2.96 years.

**(p) Fair Value Measurements**

The Company uses a three-tier fair value hierarchy to prioritize the inputs used in the Company's fair value measurements. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets for identical assets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. There were no other assets or liabilities that were measured at fair value on a recurring basis as of March 31, 2020 or December 31, 2019. The Company believes the carrying amount of cash and cash equivalents, accounts payable and accrued expenses approximate their estimated fair values due to the short-term nature of these accounts.

**(q) Accounting Pronouncement Recently Adopted**

In June 2019, the Financial Accounting Standards Board ("FASB") issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies accounting for nonemployee share-based payment transactions to now include share-based payment transactions for acquiring goods and services from nonemployees. This new standard is effective for interim and annual periods beginning December 15, 2019 and early adoption is permitted. The Company adopted this guidance on January 1, 2020, and it did not have a material impact on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which modified the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. This new standard is effective for interim and annual periods beginning December 15, 2019 and early adoption is permitted. The Company adopted this guidance on January 1, 2020, and it did not have a material impact on our condensed consolidated financial statements.

**(r) Accounting Pronouncements Issued But Not Yet Effective**

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires lessees to generally recognize on the balance sheet operating and financing lease liabilities and corresponding right-of-use assets, and to recognize on the income statement the expenses in a manner similar to current practice. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which improves the clarity of the new lease standard and corrects unintended application of the guidance. In December 2018, the FASB issued ASU 2018-20, *Narrow-Scope Improvements for Lessors*, which increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing transactions. In March 2019, the FASB issued ASU 2019-01, *Lease (Topic 842): Codification Improvements*, which increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing essential information about leasing transactions. Per ASU 2019-10, this new standard is effective for interim and annual periods of smaller reporting companies beginning January 1, 2021 and early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which helps reduce the complexity and costs associated with Topic 740 while maintaining and/or improving the usefulness of the information provided to users of financial statements. Per ASU 2019-12, this new standard is effective for interim and annual periods of public reporting companies beginning January 1, 2021 and early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

## 2. Balance Sheet Details

Condensed consolidated balance sheet details are as follows (in thousands):

	March 31, 2020	December 31, 2019
Prepaid expenses and other current assets:		
Prepaid insurance	\$ 678	\$ 951
Prepaid trade shows	87	85
Other current assets	127	25
Total prepaid expenses and other current assets	<u>\$ 892</u>	<u>\$ 1,061</u>
Property and equipment, gross:		
Laboratory equipment	\$ 1,586	\$ 1,135
Computer equipment	41	15
Furniture and fixtures	34	34
Leasehold improvements	32	32
Construction in progress	343	—
Total property and equipment, gross	2,036	1,216
Less accumulated depreciation	(300)	(239)
Total property and equipment, net	<u>\$ 1,736</u>	<u>\$ 977</u>
	March 31, 2020	December 31, 2019
Accrued compensation:		
Accrued paid time off	\$ 357	\$ 309
Accrued bonus and deferred compensation	452	465
Accrued severance	311	368
Total accrued compensation	<u>\$ 1,120</u>	<u>\$ 1,142</u>
Accrued liabilities:		
Accrued consulting services	\$ 98	\$ 37
Accrued printing fees	—	55
Deferred rent	83	88
Other accrued expenses	19	38
Total accrued liabilities	<u>\$ 200</u>	<u>\$ 218</u>

## 3. Debt

### 2018 Convertible Bridge Notes

From August to November 2018, DermTech Operations issued \$6.8 million aggregate principal amount of convertible bridge notes (“2018 Bridge Notes”), resulting in \$6.6 million in net proceeds. The 2018 Bridge Notes carried a 10% interest rate and matured on March 31, 2019. Since the 2018 Bridge Notes were not paid or converted by March 31, 2019, the interest rate increased to 15%.

The 2018 Bridge Notes were subject to automatic conversion into equity securities of DermTech Operations at the closing of a single capital raising transaction or series of related capital raising transactions in which DermTech Operations issued equity securities with aggregate gross proceeds to DermTech Operations of at least \$20 million (“Qualified Financing”) that occurred on or prior to the maturity date. Upon automatic conversion of these 2018 Bridge Notes, the note holders were entitled to receive shares of DermTech Operations’ equity securities equal to the quotient obtained by dividing the unpaid principal amount of these 2018 Bridge Notes plus interest accrued but unpaid by the lesser of:

- 1) the lowest price per share of the new stock paid in the Qualified Financing by investors multiplied by 70%.

2) the price per share obtained by dividing \$45 million by DermTech Operations' fully-diluted capitalization immediately prior to such Qualified Financing assuming exercise or conversion of all outstanding options and issuance of all outstanding restricted stock unit awards, including all shares of common stock reserved and available for future grant under any equity incentive plan of the Company, and/or any equity incentive or similar plan to be created or increased in connection with the Qualified Financing, but excluding any shares issuable upon exercise of the DermTech Operations' outstanding common stock warrants or conversion of the 2018 Bridge Notes.

Several of the embedded features of the 2018 Bridge Notes were identified as meeting the criteria of a derivative and ultimately bifurcated from the host contract. DermTech Operations accounted for this by separating the derivative component of the 2018 Bridge Notes as a derivative liability on the condensed consolidated balance sheet. DermTech Operations assigned a value to the debt component of the 2018 Bridge Notes equal to the difference between the estimated fair value of the 2018 Bridge Notes with and without the conversion features, which resulted in DermTech Operations recording the 2018 Bridge Notes at a discount. The total debt discount amount as of the respective date of issuance of the 2018 Bridge Notes was determined to be \$2.5 million. DermTech Operations amortized the debt discount over the contractual life (i.e., March 31, 2019) of the 2018 Bridge Notes as additional non-cash interest expense utilizing the effective interest method. At each financial reporting period, DermTech Operations remeasured the fair value of the embedded features bifurcated from the 2018 Bridge Notes (i.e., the derivative liability) and changes in the fair value are recognized in earnings. Losses relating to the change in fair value of the derivative liability recognized as other expense on the Statement of Operations were zero and \$0.2 million for the three months ended March 31, 2020 and 2019, respectively.

On May 23, 2019, DermTech Operations and the various convertible 2018 Bridge Note holders agreed to amend the outstanding convertible notes that were issued in the last half of 2018. As part of the amendment, the maturity dates of the notes were extended to the earliest of (i) September 24, 2019; (ii) the occurrence of an Event of Default (as defined in the 2018 Bridge Notes); (iii) the consummation of a liquidation or dissolution of DermTech Operations; (iv) a Liquidation Transaction (as defined in the 2018 Bridge Notes); or (v) the consummation of a merger with or into the Company or any of its subsidiaries.

In addition, immediately prior to the consummation of a DermTech Operations merger with or into the Company or any of its subsidiaries substantially on the terms contemplated as of the date of the amendment to the outstanding convertible notes on or before September 24, 2019 ("Qualifying Merger"), the outstanding principal amount of and all accrued but unpaid interest on each of the convertible notes would automatically be converted into shares of the DermTech Operations' common stock at a price per share equal to 70% of the Merger Consideration. For purposes of the preceding sentence, the "Merger Consideration" means (i) the lesser of \$6.46 and (ii) the offering price per share of the private investment in public equity ("PIPE") transaction to be consummated concurrently with the consummation of the Qualifying Merger multiplied by the Conversion Ratio. For the purposes of the preceding sentence, the "Conversion Ratio" means the quotient resulting from dividing 8,000,000 by the number of fully diluted shares of the Company as of immediately after the conversion of the notes.

This new embedded Qualifying Merger feature of the 2018 Bridge Notes was identified as meeting the criteria of a derivative and ultimately bifurcated from the host contract with the previously identified embedded features that met the criteria of being a derivative. In addition, this amendment was accounted for as a debt modification of the existing 2018 Bridge Notes.

#### *2019 Convertible Bridge Notes*

Between June 5<sup>th</sup> and June 10<sup>th</sup>, 2019, DermTech Operations issued additional convertible bridge notes (the "2019 Bridge Notes") to existing investors for aggregate gross proceeds of \$2.6 million. These convertible bridge notes carried an interest rate of 10% and matured after the earliest to occur of: (i) September 25, 2019; (ii) the occurrence of an Event of Default (as defined in the 2019 Bridge Notes); (iii) the consummation of a liquidation or dissolution of DermTech Operations; (iv) a Liquidation Transaction (as defined in the 2019 Bridge Notes); or (v) the consummation of a merger of DermTech Operations with DT Merger Sub, Inc., a previous subsidiary of the Company, in accordance with the Merger Agreement.

The unpaid principal amount of these convertible bridge notes together with any interest accrued but unpaid thereon, would automatically be converted into shares of DermTech Operations' common stock immediately prior to the consummation of a Qualifying Merger. Upon the conversion of these notes, the note holders were entitled to receive a number of shares of DermTech Operations' common stock equal to the quotient obtained by dividing (i) the unpaid principal amount of these notes plus interest accrued but unpaid thereon, by (1) if the Qualifying Merger consummates prior to the maturity date, the lesser of (x) \$5.80 and (y) 90% of the Merger Consideration (as defined below), or (2) if the Qualifying Merger consummates on or after the maturity date, the lesser of (x) \$4.51 and (y) 70% of the Merger Consideration. For purposes of the preceding sentence, the "Merger Consideration" means the offering price per share of the PIPE transaction between Constellation and the investors thereto, consummated substantially concurrently with the consummation of the Qualifying Merger, multiplied by the Conversion Ratio (as defined below). For purposes of the preceding sentence, the "Conversion Ratio" means the quotient

resulting from dividing 8,000,000 by the number of the Company's fully diluted shares immediately prior to the consummation of the Qualifying Merger, assuming exercise of all outstanding options, issuance of all common stock underlying outstanding restricted stock unit awards, exercise of all outstanding warrants, and conversion of all outstanding convertible promissory notes, including these notes and any other note of substantially the same form, but excluding all shares of DermTech Operations' common stock reserved and available for future grant under any equity incentive or similar plan of DermTech Operations, and in each case as adjusted for stock splits, combinations and similar transactions, all calculated in accordance with the final allocation schedule delivered in connection with the Qualifying Merger.

Several of the embedded features of the 2019 Bridge Notes were identified as meeting the criteria of a derivative and ultimately bifurcated from the host contract. DermTech Operations accounted for this by separating the derivative component of the 2019 Bridge Notes as a derivative liability on the condensed consolidated balance sheet. The Company assigned a value to the debt component of the 2019 Bridge Notes equal to the difference between the estimated fair value of the 2019 Bridge Notes with and without the conversion features, which resulted in DermTech Operations recording the 2019 Bridge Notes at a discount. The total debt discount amount as of the respective date of issuance of the 2019 Bridge Notes was determined to be \$0.3 million. DermTech Operations amortized the debt discount over the contractual life (i.e., September 25, 2019) of the 2019 Bridge Notes as additional non-cash interest expense utilizing the effective interest method. At each financial reporting period, DermTech Operations remeasured the fair value of the embedded features bifurcated from the 2019 Bridge Notes (i.e., the derivative liability) and changes in the fair value were recognized in earnings. For the three months ended March 31, 2020 and 2019, the Company did not record any gains or losses on the change in fair value of the derivative liability pertaining to the 2019 Bridge Notes.

#### *Exchange of Convertible Debt for Common Shares*

On August 29, 2019, immediately prior to the completion of the Business Combination, all unpaid principal and interest on the 2019 Bridge Notes and the 2018 Bridge Notes (collectively, "the Bridge Notes") was converted into 2,267,042 common shares of DermTech Operations.

The conversion of the Bridge Notes debt for common shares of DermTech Operations was accounted for as an extinguishment of the Bridge Notes. The conversion resulted in DermTech Operations having legally settled the debt obligations. DermTech Operations' equity was increased by the settlement-date fair value of the common shares issued. Certain bifurcated embedded derivative instruments also were settled as part of the transaction.

The net carrying amounts of the Bridge Notes, including remaining unamortized debt discount and issuance costs, and the bifurcated embedded derivative liability were extinguished on the date of the Business Combination. A gain on debt extinguishment of \$0.9 million was recognized, which represented the unamortized debt discounts and issuance costs remaining at the time of the debt extinguishment.

There was no liability balance for the Company's 2019 Bridge Notes or 2018 Bridge Notes as of March 31, 2020 and December 31, 2019.

## **4. Convertible Preferred Stock and Stockholders' Equity**

### **(a) Classes of Stock**

The Company's amended and restated certificate of incorporation authorizes it to issue 50,000,000 shares of common stock and 5,000,000 shares of preferred stock. Both classes of stock have a par value of \$0.0001 per share.

Pursuant to the Business Combination, the Company issued shares of its common stock to DermTech Operations common stockholders at an exchange ratio of approximately 1.16 shares of the Company's common stock for each share of DermTech Operations common stock. In connection with and immediately following the Business Combination, the Company filed a certificate of amendment to its amended and restated certificate of incorporation to affect a one-for-two reverse stock split of its common stock. All stock information presented throughout this document have been adjusted to reflect these capital structure changes.

**(b) Series C Convertible Preferred Stock Financing**

DermTech Operations conducted a Series C Convertible Preferred Stock private offering in August of 2016 for a total offering amount of \$15 million at a price per share of \$9.54. During 2017, 559,849 shares of Series C Convertible Preferred Stock were issued for gross cash proceeds of \$5.3 million, reduced by issuance costs of \$0.4 million. In addition, 102,740 common stock warrants were issued in connection with this offering, exclusive of compensatory warrants issued to the placement agent. During 2018, 506,539 shares of Series C Convertible Preferred Stock were issued for gross cash proceeds of \$4.8 million, reduced by issuance costs of \$0.3 million.

On May 23, 2019, DermTech Operations agreed to an amendment with the Series C Convertible Preferred Stockholders that immediately prior to the consummation of a merger with or into the Company or any of its subsidiaries on or before September 24, 2019, the outstanding Series C Convertible Preferred Stock would convert into common stock at a one to one ratio in accordance with DermTech Operations' amended and restated certificate of incorporation. Immediately prior to the completion of the Business Combination, each share of Series C Convertible Preferred Stock of DermTech Operations outstanding as of such time was automatically converted into one share of common stock of DermTech Operations.

**(c) Series A Convertible Preferred Stock Financing**

In connection with the PIPE transaction and on August 29, 2019, immediately following the completion of the Business Combination, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for the Company's Series A Convertible Preferred Stock (the "Series A Certificate of Designation"). An aggregate of 1,231 shares of Series A Convertible Preferred Stock for an aggregate purchase price of \$4.0 million were issued to certain accredited investors.

*Preferred Dividends*

Holders of the Company's Series A Convertible Preferred Stock (the "Series A Convertible Preferred Stock") are entitled to receive dividends on an as-converted basis equal to and in the same form as dividends paid on shares of the Company's common stock when, as and if these dividends are paid on the Company's common stock.

*Preferred Liquidation Preference*

Holders of the Series A Convertible Preferred Stock will participate pari passu with the holders of the Company's common stock on an as-converted basis in the event of dissolution, liquidation or winding up of the Company.

*Redemption*

The Series A Convertible Preferred Stock does not contain any mandatory redemption features. The Series A Convertible Preferred Stock has been classified as temporary equity in the accompanying condensed consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in beneficial ownership events outside of the Company's control. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

*Conversion*

Each share of the Company's Series A Convertible Preferred Stock is convertible into 500 shares of the Company's common stock at a conversion price, as adjusted for the Reverse Stock Split, of \$6.50 per share, subject to adjustment as set forth in the Series A Certificate of Designation, and provided that in no event may any shares of the Series A Convertible Preferred Stock be convertible if the conversion would result in the holder beneficially owning more than 9.99% of the Company's then-outstanding shares of common stock.

*Voting Rights*

The shares of the Series A Convertible Preferred Stock have no voting rights, except with respect to certain protective provisions set forth in the Series A Certificate of Designation relating to the powers, preferences and rights of such shares.



**(d) 2020 PIPE Financing**

On February 28, 2020, the Company, entered into a securities purchase agreement with certain institutional investors for a private placement of the Company's equity securities (the "2020 PIPE Financing"). Cowen and Company, LLC served as lead placement agent for the 2020 PIPE Financing, with William Blair & Company, L.L.C. acting as joint placement agent. Lake Street Capital Markets, LLC acted as co-placement agent. The 2020 PIPE Financing closed on March 4, 2020.

The 2020 PIPE Financing consisted of 2,467,724 shares of common stock at a price of \$10.50 per share, 3,199 shares of Series B-1 Convertible Preferred Stock (the "Series B-1 Shares") at a price of \$10,500 per share, and 524 shares of Series B-2 Convertible Preferred Stock (the "Series B-2 Shares") at a price of \$10,500 per share, for aggregate gross proceeds of approximately \$65.0 million, reduced by \$5.1 million in issuance costs.

Prior to the closing of the 2020 PIPE Financing, the Company designated (i) 3,200 shares of its authorized and unissued preferred stock as Series B-1 Convertible Preferred Stock by filing the Series B-1 Certificate of Designation with the Delaware Secretary of State and (ii) 525 shares of its authorized and unissued preferred stock as Series B-2 Convertible Preferred Stock by filing the Series B-2 Certificate of Designation with the Delaware Secretary of State.

**(e) Series B-1 Convertible Preferred Stock Issued in Connection with 2020 PIPE Financing**

In connection with the 2020 PIPE Financing transaction and on March 2, 2020, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for the Company's Series B-1 Convertible Preferred Stock (the "Series B-1 Certificate of Designation"). An aggregate of 3,199 shares of Series B-1 Convertible Preferred Stock for an aggregate purchase price of \$33.6 million were issued to certain accredited investors.

*Preferred Dividends*

Holders of the Company's Series B-1 Convertible Preferred Stock (the "Series B-1 Convertible Preferred Stock") are entitled to receive dividends on an as-converted basis equal to and in the same form as dividends paid on shares of the Company's common stock when, as and if these dividends are paid on the Company's common stock.

*Preferred Liquidation Preference*

Holders of the Series B-1 Convertible Preferred Stock will participate pari passu with the holders of the Company's common stock on an as-converted basis in the event of dissolution, liquidation or winding up of the Company.

*Redemption*

The Series B-1 Convertible Preferred Stock does not contain any mandatory redemption features. The Series B-1 Convertible Preferred Stock has been classified as temporary equity in the accompanying condensed consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in beneficial ownership events outside of the Company's control. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

*Conversion*

Each Series B-1 Share will be convertible into 1,000 shares of the Company's common stock at a conversion price of \$10.50, subject to adjustment as provided in the Series B-1 Certificate of Designation. Each Series B-1 Share will automatically convert into Company common stock on the first trading day after the approval of the 2020 PIPE Financing by the stockholders of the Company (the "Stockholder Approval") which the Company has agreed to seek at a stockholder meeting to be held on or before June 30, 2020, and which is currently scheduled for May 26, 2020. The Company will not undertake any conversion of the Series B-1 Convertible Preferred Stock, and no stockholder will have the right to convert any portion of its Series B-1 Convertible Preferred Stock, until after the Company obtains the Stockholder Approval.

*Voting Rights*

The Series B-1 Shares have no voting rights, except with respect to certain protective provisions set forth in the Series B-1 Certificate of Designation relating to the powers, preferences and rights of such shares.

**(f) Series B-2 Convertible Preferred Stock Issued in Connection with 2020 PIPE Financing**

In connection with the 2020 PIPE Financing transaction and on March 2, 2020, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for the Company's Series B-2 Convertible Preferred Stock (the "Series B-2 Certificate of Designation"). An aggregate of 524 shares of Series B-2 Convertible Preferred Stock for an aggregate purchase price of \$5.5 million were issued to certain accredited investors.

*Preferred Dividends*

Holders of the Company's Series B-2 Convertible Preferred Stock (the "Series B-2 Convertible Preferred Stock") are entitled to receive dividends on an as-converted basis equal to and in the same form as dividends paid on shares of the Company's common stock when, as and if these dividends are paid on the Company's common stock.

*Preferred Liquidation Preference*

Holders of the Series B-2 Convertible Preferred Stock will participate pari passu with the holders of the Company's common stock on an as-converted basis in the event of dissolution, liquidation or winding up of the Company.

*Redemption*

The Series B-2 Convertible Preferred Stock does not contain any mandatory redemption features. The Company's Series B-2 Convertible Preferred Stock has been classified as temporary equity in the accompanying condensed consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in beneficial ownership events outside of the Company's control. The Company has determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

*Conversion*

Each Series B-2 Share will be convertible into 1,000 shares of the Company's common stock at a conversion price equal to \$10.50, subject to adjustment as provided in the Series B-2 Certificate of Designation. Each Series B-2 Share will be convertible into Company common stock at the option of the holder, provided that conversion will be prohibited (i) until the first trading day after the Stockholder Approval and (ii) following the Stockholder Approval, if, as a result of any such conversion, the holder would beneficially own in excess of 9.99% of the total number of shares of Company common stock outstanding immediately after giving effect to such conversion. The Company refers to the conversion limitation described in clause (ii) of the preceding sentence as the Beneficial Ownership Limitation. A holder of Series B-2 Shares may reset the Beneficial Ownership Limitation to a higher or lower number upon providing written notice to the Company. Any such notice providing for an increase to such Holder's Beneficial Ownership Limitation will be effective on the 61st day after its delivery to the Company.

*Voting Rights*

The Series B-2 Shares have no voting rights, except with respect to certain protective provisions set forth in the Series B-2 Certificate of Designation relating to the powers, preferences and rights of such shares.

**(g) Accelerated Vesting in Association with Business Combination**

On January 4, 2019, in contemplation of the Business Combination (refer to Note 8), DermTech Operations modified certain provisions of its stock-based compensation awards to all employees and certain non-employees to accelerate the vesting period for various outstanding stock awards.

In connection with the modifications, the incremental fair value of certain unvested stock option grants was measured at the date of the modification. For any options in which the fair value immediately after the modification was lower than the fair value immediately prior to the modification, no additional compensation expense was or will be recognized. For options in which the fair value increased as a result of the modification and the award was not fully vested, the incremental fair value will be recognized as an expense over the remaining service period. For options that were modified and became fully vested as a result of the accelerated vesting, the Company recognized an expense for the remaining unrecognized grant date fair value. As a result of the accelerated vesting, the Company recognized stock-based compensation expense of \$0.4 million related to this modification.

**(h) Warrants**

*Public Warrants*

The Company previously issued 14,936,250 warrants to purchase common stock in public and private placement offerings which were consummated on June 23, 2017 (the “Public Warrants”). The Public Warrants have a five year life from the date the Business Combination was consummated and every four Public Warrants entitle the holder to purchase one share at an exercise price of \$23.00 per whole share (as adjusted for the Reverse Stock Split). Outstanding Public Warrants totaled 14,936,250 at March 31, 2020 and December 31, 2019.

*Series C Warrants*

In connection with DermTech Operations’ Series C Preferred Stock financing that took place between 2016 and 2018, investors that purchased at least \$1 million of Series C Convertible Preferred Stock in a single closing received a three-year warrant to purchase common shares at an exercise price of \$9.54 in the amount equal to 20% of shares of Series C Preferred Stock purchased. Outstanding Series C warrants totaled 201,708 and 202,897 at March 31, 2020 and December 31, 2019, respectively.

*Placement Agent Warrants*

In connection with several of DermTech Operations’ financings that took place between 2015 and 2018, DermTech Operations engaged a registered placement agent to assist in marketing and selling of common and preferred units. From 2015 to 2016, 168,522 seven-year warrants were issued to purchase one common share at an exercise price of \$8.68. From 2016 to 2018, 72,658 seven-year warrants were issued to purchase one common share at an exercise price of \$9.54. In 2020, the Company issued 15,724 seven-year warrants to purchase one common share at an exercise price of \$9.54 in connection with the Company’s 2018 Bridge Note financing. Outstanding placement agent warrants totaled 254,258 and 241,217 at March 31, 2020 and December 31, 2019, respectively.

**(i) Stock-Based Compensation**

In connection with the Business Combination, the Company adopted DermTech Operations’ Amended and Restated 2010 Stock Option Plan (the “Plan”), which provides for the granting of incentive and non-statutory stock options and restricted stock purchase rights and bonus awards. Under the Plan, incentive and non-statutory stock options may be granted at not less than 100% of the fair market value of the Company’s common stock on the date of grant. For incentive stock options granted to a ten percent shareholder under the Plan, the exercise price shall not be less than 110% of the fair market value of a share of stock on the effective date of grant. DermTech Operations initially reserved 1.0 million shares of common stock for issuance to its employees, non-employee directors and consultants. The Plan includes a provision which annually increases the amount of common stock reserved for issuance under the Plan. The contractual term of options granted under the Plan is ten years. Vesting provisions vary based on the specific terms of the individual option awards. 39,354 and 0.1 million options remain available for future grant under the Plan as of March 31, 2020 and December 31, 2019, respectively.

*Management Warrants*

Warrants to purchase DermTech Operations common stock were issued to executive officers of DermTech Operations in lieu of issuing certain stock options (the “Management Warrants”). The Management Warrants were assumed by the Company in connection with the Business Combination. The Management Warrants have a ten year life and are exercisable for Company common stock at \$1.08 per common share. The Management Warrants vested monthly over a four-year period. Outstanding Management Warrants totaled 22,320 at March 31, 2020 and December 31, 2019.

*Common Stock Reserved for Future Issuance*

Common stock reserved for future issuance consists of the following at March 31, 2020 and December, 31 2019 (in thousands):

	March 31, 2020	December 31, 2019
Warrants to purchase common stock	478	466
Public Warrants to purchase common stock*	3,734	3,734
Stock options issued and outstanding	858	444
Restricted stock units issued and outstanding	485	—
Authorized for future option grants	39	143
Total common stock reserved for future issuance	<u>5,594</u>	<u>4,787</u>

\* Public Warrants are presented as four Public Warrants are needed to purchase one share of common stock.

## 5. Income Taxes

The Company has reported net losses since inception and therefore, the minimum provision for state income taxes has been recorded. The federal statutory rate was 21% at March 31, 2020 and December 31, 2019, respectively, and the effective income tax rate for the Company's provision for income taxes was 0% at March 31, 2020 and December 31, 2019, respectively.

The utilization of NOL and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, ("IRC"), a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred. If an ownership change has occurred, the Company's ability to use its NOL or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

The Company conducts intensive research and experimentation activities, generating research tax credits for federal and state purposes under IRC Section 41. The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D, tax credits available could vary from what was originally claimed on the tax returns.

Due to the net operating loss carryforwards, the U.S. federal and state returns are open to examination for all years since inception.

### *Business Combination Tax Implications*

In connection with the Business Combination, the Company changed its jurisdiction of incorporation from the British Virgin Islands to the State of Delaware. This reincorporation constituted a tax-free reorganization within the meaning of Section 368(a)(1)(F) of the IRC. The IRC provides that corporations and shareholders do not recognize gain with respect to certain qualifying reorganizations. To satisfy the requirements for this nonrecognition benefit, a transaction must meet one of the statutory definitions of a "reorganization" set forth in IRC Section 368(a)(1). IRC Section 368(a)(1)(F) provides that a reorganization includes a mere change in identity, form, or place of organization. As a result of the reincorporation, the Company will be treated as a U.S. corporation for federal income tax purposes.

For federal income tax purposes, the Business Combination qualified as a reverse triangular merger within the meaning IRC Sections 368(a) and 368(a)(2)(E). Additionally, the Company, Merger Sub, and DermTech Operations were all parties to the reorganization under IRC Section 368(b). As the transaction qualified as reorganization under IRC Section 368(a), there were no tax consequences to either DermTech Operations or the Company and all tax attributes retained carryover basis.

## 6. Commitments and Contingencies

### *Operating Leases*

In January 2013, DermTech Operations entered into a non-cancelable lease agreement for its operating facilities. In January 2014, DermTech Operations signed an amendment to the lease to extend the term through January 2017. In November 2016, DermTech Operations signed a second amendment to the lease to extend the term through March 2022. In August 2019, DermTech Operations signed a third amendment to the lease to add additional space, and in September 2019, the Company signed a fourth amendment to the lease to add additional space. In February 2020, the Company signed a fifth amendment to the lease to add additional space. In connection with the Business Combination, the Company assumed all obligations under the lease, as amended, from DermTech Operations. As part of the fifth amendment, the Company is entitled to a tenant improvement allowance for certain costs incurred while performing these improvements in the amount of \$0.3 million, which amount may be increased by up to \$0.1 million at the Company's election and subject to a corresponding increase in rent. The Company records rent expense on a straight line basis over the life of the lease and the difference between the average rent expense and cash payments for rent is recorded as deferred rent and is included in accrued liabilities on the condensed consolidated balance sheet.

Rent and associated common area maintenance expense totaled \$0.3 million and \$0.2 million for the three months ended March 31, 2020 and 2019, respectively.

Future minimum operating lease payments for the operating facilities as of March 31, 2020 were (in thousands):

Remainder of 2020	\$	992
2021		1,371
2022		1,412
2023		478
Total future minimum lease payments	\$	<u>4,253</u>

### *Deferred Underwriting Fees*

In connection with the execution of the Merger Agreement, the Company, DermTech Operations and Cowen and Company, LLC ("Cowen") entered into a letter agreement, dated May 29, 2019, (the "Deferred Underwriting Fee Assignment Agreement"), pursuant to which the Company agreed to assign to DermTech Operations, and DermTech Operations agreed to assume, the Company's obligations under the Underwriting Agreement, dated as of June 19, 2017 (the "Underwriting Agreement"), by and among the Company and Cowen. On September 4, 2019, the Company, DermTech Operations and Cowen amended the Deferred Underwriting Fee Assignment Agreement, pursuant to which the Company paid Cowen \$0.8 million for the reduction of the balance owed by the Company to Cowen under the Underwriting Agreement to \$1.4 million.

Pursuant to the terms of the Deferred Underwriting Fee Assignment Agreement, as amended, if the Company raises at least \$15.0 million in proceeds received from equity financings consummated prior to the one-year anniversary of the Business Combination, excluding the proceeds received from any financing consummated prior to or simultaneous with the Business Combination, then the Company will pay to the underwriters \$1.4 million within one week of the one-year anniversary of the Business Combination. In connection with the Company's 2020 PIPE Financing, the Company raised \$65.0 million in gross proceeds, which satisfied this condition of the Deferred Underwriting Fee Assignment Agreement. The Company's payment to the Underwriters of \$1.4 million by September 5, 2020 will satisfy the Company's obligation to pay Cowen the deferred underwriting fees in full, and no further payment will be required of the Company in connection with the deferred underwriting fees.

### *Legal Proceedings*

The Company is not currently party to any material legal proceedings.

## 7. Retirement Plan

The Company has an IRC Section 401(k) retirement plan, covering all employees. The Company does not offer a contribution percentage match.

## **8. Business Combination with DermTech Operations**

On August 29, 2019, the Company completed the Business Combination with DermTech Operations. Upon the closing of the Business Combination, DermTech Operations became a wholly-owned subsidiary of the Company.

The Business Combination was accounted for as a reverse acquisition in accordance with ASC 805-40, Business Combinations, Reverse Acquisitions, as the stockholders of DermTech Operations obtained effective control of the Company through (1) a majority of the voting common stock of the post-merger company, (2) appointment of a majority of the board of directors, (3) continued business operations of DermTech Operations, including certain directors and management, and (4) the ability to appoint the executive officers of the combined company. Accordingly, the assets, liabilities and results of operations prior periods presented before the Business Combination reflect those of DermTech Operations. Since the Business Combination, the assets, liabilities, and results of operations have been presented on a consolidated basis. Historical stockholders' (deficit) equity of the Company prior to the Business Combination has been retroactively adjusted for the equivalent number of shares received by the stockholders of DermTech Operations after giving effect to any difference in par value of the Company and the DermTech Operations' stock, with any such difference recognized as additional paid-in capital. Retained earnings and other equity balances of the Company/DermTech Operations have been carried forward after the Business Combination. Certain direct costs incurred in connection with the Business Combination were expensed in the period that such costs were incurred and services were received. Approximately \$0.3 million in printer fees related to the Business Combination were treated as a reduction of the total amount of equity raised as an offset to additional paid in capital.

## **9. Related Party Transactions**

During 2019 and 2020, the Company engaged EVERSANA Life Science Services, LLC ("EVERSANA") to provide certain marketing services to the Company. Leana Wood, the spouse of Todd Wood, the Company's Chief Commercial Officer, is an employee of EVERSANA. The Company incurred \$0.3 million and zero in costs for the three months ended March 31, 2020 and 2019, respectively.

On October 1, 2019, the Company entered into a consulting agreement with Michael Dobak pursuant to which the Company will compensate Michael Dobak, in an amount not to exceed \$100,000, for certain public relations and marketing services. Michael Dobak is the brother of Dr. John Dobak, the Company's Chief Executive Officer. The Company incurred \$32,000 and zero in costs for the three months ended March 31, 2020 and 2019, respectively.

There were no other related party transactions identified in 2020 and 2019.

## **10. Subsequent Events**

The Company considered subsequent events through May 13, 2020, the date the condensed consolidated financial statements were available to be issued.

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

The following Discussion and Analysis of Financial Condition and Results of Operations of DermTech, Inc. (together with its subsidiaries, “DermTech,” “we,” “us,” “our” or the “Company”) should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited condensed consolidated financial statements and notes thereto and Management’s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2019 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC, on March 11, 2020.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This report, including the following Management’s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are intended to be covered by the “safe harbor” created by those sections. All statements, other than statements of historical facts, contained in this report, including statements regarding DermTech’s or its management’s intentions, beliefs, expectations and strategies for the future, are forward looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “intend,” “potential” or “continue” or the negative of these terms or other comparable terminology. Forward-looking statements are made as of the date of this report, deal with future events, are subject to various risks and uncertainties, and actual results could differ materially from those anticipated in those forward-looking statements. The risks and uncertainties that could cause actual results to differ materially are more fully described under “Risk Factors” elsewhere in this Quarterly Report on Form 10-Q, and in our other reports filed with the SEC. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results.*

### Overview

We are an emerging growth molecular diagnostic company developing and marketing novel non-invasive genomics tests that seek to transform the practice of dermatology and related fields. Our platform may change the diagnostic paradigm in dermatology from one that is subjective, invasive, less accurate and higher-cost, to one that is objective, non-invasive, more accurate and lower-cost. Our initial focus is skin cancer. We currently have two clinical commercial tests, with a third in development, that enhance the early detection of skin cancer and related conditions. Our scalable genomics platform has been designed to work with a proprietary adhesive patch sample collection kit that provides a skin sample collected non-invasively. We process our tests in a Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified and College of American Pathologists accredited commercial laboratory located in La Jolla, California that is licensed by the State of California and all states requiring out-of-state licensure. We also provide our technology platform on a contract basis to large pharmaceutical companies who use the technology in their clinical trials to test for the existence of genetic targets of various diseases and to measure the response of new drugs under development. We have a history of net losses since our inception.

### Events, Trends and Uncertainties

We filed an application for a technology assessment for our Pigmented Lesion Assay, or PLA, with MolDX, or Medicare, in April 2018, and the comment period for the accompanying Medicare Draft Local Coverage Decision, or Draft LCD, closed in August 2018. In March 2019, a Draft LCD proposed favorable coverage for the PLA. In late October 2019, the American Medical Association, or AMA, provided us with a Proprietary Laboratory Analyses Code, or PLA Code. Pricing of \$760 for the PLA Code was published on December 24, 2019 as part of the Centers for Medicare and Medicaid Services Laboratory Fee Schedule, or CLFS, for 2020. The Medicare Final Coverage Decision, or Final LCD, first made available on December 26, 2019, expanded the coverage proposal in the Draft LCD from one to two tests per date of service and it allows clinicians to order our PLA if they have sufficient skill and experience to decide whether a pigmented lesion should be biopsied. The PLA became eligible for Medicare reimbursement on February 10, 2020. Our local Medicare Administrative Contractor, Noridian Healthcare Solutions, LLC, or Noridian, has issued its own Local Coverage Decision, or LCD, announcing coverage of our PLA. Even though the effective date of Noridian’s LCD is June 7, 2020, Noridian began reimbursing us for our PLA as of February 10, 2020. With Medicare coverage granted, we have the opportunity to approach commercial payors and as a result, we believe that the PLA may generate significant revenues in 2021 and 2022.

Despite the grant of Medicare coverage for the PLA, uncertainty surrounds third-party payor reimbursement, including governmental and commercial payors, of any test incorporating new technology, including tests developed using our technologies. For example, technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current tests and our planned future tests will be provided in the future by additional third-party payors or that existing policy decisions, or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain or maintain coverage and reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our business financial condition, results of operation, and cash flows.

### *Revenue Effects Related to COVID-19 Pandemic*

#### *Assay Revenue*

As much of our assay revenue is driven by the samples that are sent by physicians and physician assistants to our central lab for testing, a key performance measure for us is samples that are received and processed by our central lab successfully, also known as billable samples. Sample volume is dependent on two major factors; the number of physicians or physician assistants who order an assay in any given quarter and the number of assays ordered by each physician during the period. The number of ordering physicians and the utilization per physician can vary based on a number of factors including the types of patients presenting skin cancer conditions, physician reimbursement, office workflow, market awareness, physician education and other factors.

Beginning in March 2020, the ongoing COVID-19 pandemic has reduced patient access to clinician offices for in person testing, which has resulted in a reduced volume of billable samples received. We estimate that the various stay-at-home orders issued throughout the country have reduced our first quarter billable sample volume by approximately 200-300 tests. April 2020 billable sample volume is down by approximately 80%, commensurate with the closure of dermatology offices, compared to the average monthly billable sample volume for January and February of 2020 prior to the beginning of the stay-at-home orders. April 2020 billable sample volume decreased 56% compared to April 2019. While we are providing this additional information regarding April and current quarter volume impacts due to the pandemic in this report, we do not intend to continue to provide this type of data for any period following the date of this report.

We have made available beginning in late April 2020 a telemedicine option for the PLA, but the telemedicine market is relatively new and unproven, and it is uncertain whether it will achieve and sustain high levels of demand, consumer acceptance and market adoption. While the COVID-19 pandemic is ongoing, we expect that our revenues will depend to a substantial extent on the willingness of clinicians and their patients to use our telemedicine option for the PLA, as well as on our ability to demonstrate the value of our telemedicine option to health plans and other purchasers of healthcare for beneficiaries. Accordingly, we also expect that the duration and extent of the effects of the ongoing COVID-19 pandemic in reducing patient access to clinician offices for in person testing will affect our revenues.

#### *Contract Revenue*

Contract revenues with major pharmaceutical companies relate to ongoing clinical trial contracts and new contracts. Contract revenue can be highly variable as it is dependent on the pharmaceutical customers' clinical trial progress which can be difficult to forecast due to variability of patient enrollment, drug safety and efficacy and other factors. Many of our contracts with third parties are structured to contain milestone billing payments, which typically are advance payments on work yet to be performed. These advanced payments are structured to help fund operations and are included in deferred revenue as the work has not yet been performed. These advance payments will remain in deferred revenue until we process the laboratory portion of the contracts allowing us to recognize the revenue.

We expect that the ongoing COVID-19 pandemic will have an effect on our pharmaceutical customers' clinical trials. The extent of the effect on our future revenue is uncertain and will depend on the duration and extent of the effects of the ongoing COVID-19 pandemic on our pharmaceutical customers' clinical trials.

## **Financial Overview**

### **Revenue**

We generate revenue through laboratory services that are billed to Medicare, private medical insurance companies and to pharmaceutical companies who order our laboratory services, which can include sample collection kits, assay development, gene expression analysis, data analysis and reporting. Our revenue is generated from two revenue streams, contract revenue and assay revenue. Assay revenue can be highly variable as it is based on payments received by private insurance payors that are not under contract and can vary based on patient insurance coverage, deductibles and co-pays. Contract revenue is ordered by customers on projects that may span over several years. Segments of these contracts may be increased, delayed or eliminated based on the success of each customers' clinical trials or other factors. We account for revenue in accordance with Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, or ASC 606. The core principle of ASC 606 is that the Company recognizes



revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The ASC 606 revenue recognition model consists of the following five steps: (1) identify the contracts with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. We adopted ASC 606 on January 1, 2019, using the modified retrospective method and elected to utilize Practical Expedient 1 to apply the modified retrospective method to only contracts which were open as of January 1, 2019.

## **Operating Expenses**

### *Sales and Marketing Expenses*

Sales and marketing expenses are primarily related to our specialty field sales force, market research, reimbursement efforts, trade show attendance, public relations, and general marketing.

### *Research and Development Expenses*

Our research and development, or R&D, expenses consist primarily of salaries and fringe benefits, clinical trials, consulting costs, facilities costs, laboratory costs, equipment expense, and depreciation. We also conduct clinical trials to validate the performance characteristics of our tests and to show medical cost benefit in support of our reimbursement efforts. We expect these expenses to increase significantly as we continue to develop new products and expand the use of our existing products.

### *General and Administrative Expenses*

Our general and administrative expenses consist of senior management compensation, consulting, legal, billing and collections, human resources, information technology, accounting, insurance, and general business expenses. We expect our general and administrative expenses, especially insurance, accounting, and legal fees, to increase due to operating as a publicly traded company.

## **Financing Activities**

### *Convertible Bridge Notes*

On May 23, 2019, DermTech Operations, Inc. (formerly known as DermTech, Inc.), or DermTech Operations, and various holders of its convertible bridge notes agreed to amend DermTech Operations' then outstanding convertible notes that were issued prior to June 5, 2019. As part of the amendment, the maturity dates of the notes were extended to the earliest of (i) September 24, 2019; (ii) the occurrence of an Event of Default (as defined in such notes); (iii) the consummation of a liquidation or dissolution of DermTech Operations (iv) a Liquidation Transaction (as defined in such notes); or (v) the consummation of a merger with or into the Company or any of its subsidiaries.

Between June 5, 2019 and June 10, 2019, DermTech Operations issued additional convertible bridge notes to its existing investors for aggregate gross proceeds of \$2.6 million. These convertible bridge notes carried an interest rate of 10% and matured after the earliest to occur of: (i) September 25, 2019; (ii) the occurrence of an Event of Default (as defined in such notes); (iii) the consummation of a liquidation or dissolution of DermTech Operations; (iv) a Liquidation Transaction (as defined in such notes); or (v) the consummation of a merger of DermTech Operations with DT Merger Sub, Inc., a previous subsidiary of the Company, in accordance with the Merger Agreement (as defined below).

On August 29, 2019, in connection with the completion of the Business Combination (as defined below), all of the outstanding convertible bridge notes of DermTech Operations converted into Company common stock, in accordance with their respective terms.

### *Business Combination*

On August 29, 2019, the Company and DermTech Operations consummated the transactions contemplated by the Agreement and Plan of Merger, dated as of May 29, 2019, by and among the Company, DT Merger Sub, Inc., or Merger Sub, and DermTech Operations. We refer to this agreement, as amended by that certain First Amendment to Agreement and Plan of Merger dated as of August 1, 2019, as the Merger Agreement. Pursuant to the Merger Agreement, Merger Sub merged with and into DermTech Operations, with DermTech Operations surviving as a wholly-owned subsidiary of the Company. We refer to this transaction as the Business Combination.

Immediately following the completion of the Business Combination, the Company changed its name from Constellation Alpha Capital Corp. to DermTech, Inc. and effected a one-for-two reverse stock split of its common stock, or the Reverse Stock Split. Prior to the closing of the Business Combination, the Company's stock was listed on the Nasdaq Capital Market under the ticker symbol "CNAC." On August 30, 2019, the Company's common stock commenced trading on the Nasdaq Capital Market under the ticker symbol "DMTK."

#### *2019 PIPE Financing*

On August 29, 2019, immediately prior to the completion of the Business Combination, the Company issued, in a private placement transaction, or the 2019 PIPE Financing, an aggregate of 3,076,925 shares of common stock at a purchase price, as adjusted for the Reverse Stock Split, of \$6.50 per share and 1,231 shares of Series A Convertible Preferred Stock at a purchase price, as adjusted for the Reverse Stock Split, of \$6.50 per share of common stock issuable upon conversion thereof, which, are convertible into an aggregate of up to 615,385 shares of common stock, for an aggregate purchase price of \$24.0 million, to certain accredited investors pursuant to the terms of separate Subscription Agreements and Amended and Restated Subscription Agreements, dated between May 22, 2019 and August 1, 2019, entered into by the Company and such investors. Each share of Series A Convertible Preferred Stock is convertible into 500 shares of the Company's common stock, subject to conditions and adjustment as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.

#### *2020 PIPE Financing*

On February 28, 2020, the Company entered into a securities purchase agreement with certain institutional investors for a private placement of the Company's equity securities, or the 2020 PIPE Financing. Cowen and Company, LLC served as lead placement agent for the 2020 PIPE Financing, with William Blair & Company, L.L.C. acting as joint placement agent. Lake Street Capital Markets, LLC acted as co-placement agent. The 2020 PIPE Financing closed on March 4, 2020.

Pursuant to the 2020 PIPE Financing, on March 4, 2020 the Company issued an aggregate of 2,467,724 shares of common stock at a purchase price of \$10.50 per share, 3,199 shares of Series B-1 Convertible Preferred Stock, or the Series B-1 Shares, at a purchase price of \$10.50 per share of common stock issuable upon conversion thereof, which will be convertible into an aggregate of up to 3,198,942 shares of common stock, and 524 shares of Series B-2 Convertible Preferred Stock, or the Series B-2 Shares, at a purchase price of \$10.50 per share of common stock issuable upon conversion thereof, which will be convertible into an aggregate of up to 523,809 shares of common stock, for aggregate gross proceeds of approximately \$65.0 million. Each Series B-1 Share and Series B-2 Share will be convertible into 1,000 shares of the Company's common stock, subject to conditions and adjustment as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock and the Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Convertible Preferred Stock, respectively.

### **Results of Operations**

#### **Three Months Ended March 31, 2020 and March 31, 2019**

##### *Assay Revenue*

Assay revenues grew \$0.6 million, or 239%, to \$0.8 million for the three months ended March 31, 2020 compared to \$0.2 million for the three months ended March 31, 2019. As much of our assay revenue is driven by the samples that are sent by physicians and physician assistants to our central lab for testing, a key performance measure for us is samples that are received and processed by our central lab successfully, also known as billable samples. Billable samples increased to 5,811 for the three months ended March 31, 2020 compared to 2,338 for the three months ended March 31, 2019. Sample volume is dependent on two major factors; the number of physicians or physician assistants who order an assay in any given quarter and the number of assays ordered by each physician during the period. The number of ordering physicians and the utilization per physician can vary based on a number of factors including the types of patients presenting skin cancer conditions, physician reimbursement, office workflow, market awareness, physician education and other factors.

##### *Contract Revenue*

Contract revenues with major pharmaceutical companies increased \$0.4 million, or 111%, to \$0.8 million for the three months ended March 31, 2020, compared to \$0.4 million for the three months ended March 31, 2019, due to accelerating activity with ongoing contracts and new contracts. Contract revenue can be highly variable as it is dependent on the pharmaceutical customers' clinical trial progress, which can be difficult to forecast due to variability of patient enrollment, drug safety and efficacy and other factors. Many of our contracts with third parties are structured to contain milestone billing payments, which typically are advanced payments on work yet to be performed. These advanced payments are structured to help fund operations and are included in deferred revenue as the work has not yet been performed. At March 31, 2020, the deferred revenue amount for these contracts, which is the advanced payments minus the value of work performed, was \$1.1 million. These advanced payments will remain in deferred revenue until we process the laboratory portion of the contracts allowing us to recognize the revenue.

### *Cost of Revenue*

Cost of revenues increased \$0.6 million, or 89%, to \$1.2 million for the three months ended March 31, 2020 compared to \$0.6 million for the three months ended March 31, 2019. The increase was largely attributable to a higher billable sample volume in 2020. We have been focused on automating more processes within our central laboratory in order to reduce costs and improve efficiency. At current capacity, a majority of the costs of revenue are fixed, and these costs include the CLIA facility, quality assurance, management and supervision and equipment calibration and depreciation. Much of the cost of revenue expenses incurred primarily relate to salaries and benefits, laboratory supplies, shipping costs, equipment maintenance and calibration, utilities and depreciation. In the near- and long-term future, we remain committed to continuing the automation of our laboratory processes in order to become more cost efficient and productive.

### *Operating Expenses*

#### *Sales and Marketing*

Sales and marketing expenses increased \$2.1 million, or 241%, to \$2.9 million for the three months ended March 31, 2020 compared to \$0.9 million for the three months ended March 31, 2019. The increase was primarily attributable to higher compensation-related costs, including from the hiring of a new Chief Commercial Officer, expansion of the existing sales force and increased spending on advertising activities to increase market exposure. We expect to significantly add to our specialty sales force and payor access teams throughout 2020 and 2021, which would significantly increase our sales and marketing expenses.

#### *Research and Development*

R&D expenses increased \$0.3 million or 57% to \$0.9 million for the three months ended March 31, 2020 compared to \$0.6 million for the three months ended March 31, 2019. The increase was due to higher compensation and recruiting costs of expanding the R&D team as well as an increased spend on laboratory supplies to conduct research and development activities. We expect these expenses to increase as we continue to grow the R&D team and focus on the development of our basal and squamous cell skin cancer assays and other products.

#### *General and Administrative*

General and administrative expenses increased \$2.0 million, or 130%, to \$3.5 million for the three months ended March 31, 2020 compared to \$1.5 million for the three months ended March 31, 2019. The increase was due to \$0.8 million of additional legal fees, \$0.1 million of additional accounting fees, \$0.5 million in additional headcount-related costs and \$0.3 million of additional insurance costs. The increase was primarily due to significant costs required to operate as a publicly traded company, including making filings with the SEC. We expect these expenses to continue to increase as we add additional infrastructure such as human resources, information technology and legal resources. Ongoing expenses include salaries and benefits, facility costs, billing and collections, auditing and legal expenses.

#### *Interest Expense, net*

Interest expense decreased \$2.0 million or 100% to \$0 for the three months ended March 31, 2020 compared to interest expense of \$2.0 million for the three months ended March 31, 2019. The significant decrease was due to the extinguishment of the convertible bridge notes that occurred in August 2019 in connection with the Business Combination. We do not expect to incur significant interest expense for future reporting periods in 2020.

#### *Other Expense*

Other expense decreased \$0.2 million or 100% to \$0 for the three months ended March 31, 2020 compared to other expense of \$0.2 million for the three months ended March 31, 2019. The significant decrease was due to the extinguishment of the convertible bridge notes that occurred in August 2019 in connection with the Business Combination.

### **Liquidity and Capital Resources**

We have never been profitable and have historically incurred substantial net losses, including net losses of \$10.0 million for the twelve months ended December 31, 2018, \$19.7 million for the twelve months ended December 31, 2019, and \$7.0 million for the three months ended March 31, 2020. As of March 31, 2020, our accumulated deficit was \$98.1 million, and we had negative operating cash flow of \$7.4 million. In connection with the Business Combination, we completed the 2019 PIPE Financing that raised a total of \$24.0 million in gross proceeds in addition to the \$1.8 million in cash the Company had on hand at the close of the Business Combination. In addition, we completed the 2020 PIPE Financing in March 2020 that raised a total of \$65.0 million in gross proceeds. We have historically financed operations through private placement equity offerings and convertible debt offerings.

We expect our losses to continue as a result of costs relating to ongoing R&D expenses and increased sales and marketing costs for existing and planned products. These losses have had, and will continue to have, an adverse effect on our working capital. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, we are unable to predict when we will become profitable, and we may never become profitable. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operation and cash flows.

As of March 31, 2020, our cash and cash equivalents totaled approximately \$67.9 million. Based on our current business operations and the additional financing completed in March 2020, we believe our current cash and cash equivalents will be sufficient to meet our anticipated cash requirements for at least the next twelve months. While we believe we have enough capital to fund anticipated operating costs for at least the next 12 months, we expect to incur significant additional operating losses over at least the next several years. We anticipate that we will raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements in order to support our planned operations and to continue developing and commercializing gene expression tests. We may also consider raising additional capital in the future to expand our business, to pursue strategic investments or to take advantage of financing opportunities. Our present and future funding requirements will depend on many factors, including:

- our revenue growth rate and ability to generate cash flows from operating activities;
- the willingness of clinicians and their patients to use our telemedicine option for the PLA and the duration and extent of the effects of the ongoing COVID-19 pandemic in reducing patient access to clinician offices for in person testing;
- the duration and extent of the effects of the ongoing COVID-19 pandemic on our pharmaceutical customers' clinical trials;
- our sales and marketing and R&D activities;
- effects of competing technological and market developments;
- costs of and potential delays in product development;
- changes in regulatory oversight applicable to our tests; and
- timing of and costs related to future international expansion.

There can be no assurances as to the availability of additional financing or the terms upon which additional financing may be available to us. If we are unable to obtain sufficient funding at acceptable terms, we may be forced to significantly curtail our operations, and the lack of sufficient funding may have a material adverse impact on our ability to continue as a going concern.

#### *Cash Flow Analysis*

##### *Three Months Ended March 31, 2020*

Net cash used in operating activities for the three months ended March 31, 2020 totaled \$7.4 million, primarily driven by the \$7.0 million net loss offset by non-cash related items, including \$1.0 million in stock-based compensation and \$0.1 million in depreciation. This was offset by cash outflows of \$0.7 million through payments of accounts payables and accrued compensation, \$0.5 million in the buildup of accounts receivable and \$0.3 million related to the recognition of deferred revenue.

Net cash used in investing activities for the three months ended March 31, 2020 totaled \$0.2 million, which related predominantly to purchases of laboratory equipment. As we scale our sales force and the resulting expected increase to assay volume, the timing of which increase in volume is uncertain as the ongoing COVID-19 pandemic has resulted in a reduced volume of billable samples received, additional laboratory equipment investment will be needed to install complex automation systems and other genomic testing equipment.

Net cash provided by financing activities for the three months ended March 31, 2020 totaled \$60.1 million, which was driven by the \$59.9 million in net proceeds raised from the 2020 PIPE Financing.

#### **Off-Balance Sheet Arrangements**

As of March 31, 2020 and March 31, 2019, we did not have any off-balance sheet arrangements, as such term is defined under Item 303 of Regulation S-K, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Critical accounting policies, significant judgments, and estimates are those that we believe are most important for the portrayal of the Company's financial condition and results, and that require management's most subjective and complex judgments. Judgments and uncertainties regarding the application of these policies may result in materially different amounts being reported under various conditions or using different assumptions. There have been no material changes to the critical accounting estimates previously disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and disclosed in Note 1(i) and Note 1(o) of the condensed consolidated financial statement herein.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

### **Item 4. Controls and Procedures.**

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act. Based upon that evaluation, our principal executive officer and our principal financial officer concluded that, as of March 31, 2020, our disclosure controls and procedures were effective. Disclosure controls and procedures enable us to record, process, summarize and report information required to be included in our Exchange Act filings within the required time period. Our disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting, despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their operating effectiveness.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

**Item 1. Legal Proceedings.**

We are not currently a party to any material legal proceedings.

**Item 1A. Risk Factors.**

*We are in a market environment that cannot be predicted and that involves significant risks, many of which are beyond our control. Before making a decision to invest in, hold or sell our common stock, stockholders and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in or incorporated by reference into this report, as well as the other information we file with the SEC. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the value of our common stock could decline, and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business, financial condition or results of operations. Refer to our disclaimer regarding forward-looking statements at the beginning of our Management's Discussion and Analysis of Financial Condition and Results of Operations.*

In addition to the risk factors set forth below, you should review the discussion under the heading "Cautionary Statements Regarding Forward-Looking Statements" in Part I, Item 2 of this Quarterly Report on Form 10-Q. You should also refer to the other information set forth in this Quarterly Report and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, including our financial statements and the related notes. These risks and uncertainties are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. If any of the risks or uncertainties actually occurs, our business and financial results could be harmed. In that case, the market price of our common stock could decline.

**Risks Relating to Our Financial Condition and Capital Requirements**

*We are an emerging growth company with a history of net losses; we expect to incur net losses in the future and may never achieve profitability.*

We have historically incurred substantial net losses in each year since our inception, including net losses of \$7.0 million for the three months ended March 31, 2020. As of March 31, 2020, we had an accumulated deficit of \$98.1 million.

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

*We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make our future performance difficult to predict.*

We are an emerging molecular diagnostics company with a limited operating history. Our operations to date have been primarily focused on developing and market testing our technology. We have not obtained regulatory approvals from the Food and Drug Administration, or FDA, for any of our tests as we operate a clinical laboratory under the CLIA guidelines and believe our tests are laboratory developed tests, or LDTs, that are not currently being regulated by the FDA. Consequently, if regulatory approval is determined to be necessary, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or more commercialized products. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere in this report and also include:

- our ability to obtain additional funding to develop and market our products and tests;
- the market adoption and demand for our tests;
- the existence of favorable or unfavorable clinical guidelines for our tests;
- the reimbursement of our tests by Medicare and commercial payors;

- our ability to obtain and maintain any necessary regulatory approval for any of our tests in the United States and foreign jurisdictions, if required;
- potential side effects of our tests that could delay or prevent commercialization, limit the use of any of our tests, or cause any of our commercialized tests to be taken off the market;
- our dependence on third-party suppliers and manufacturers, to supply or manufacture our specimen collection products;
- our ability to establish or maintain collaboration, licensing, or other arrangements;
- our ability to maintain and grow an effective sales and marketing infrastructure, either through the expansion of our commercial infrastructure or through strategic collaborations;
- competition from existing tests or new tests that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our tests;
- our ability to leverage our proprietary technology platform to discover and develop additional test candidates;
- our ability to successfully obtain, maintain, defend, and enforce intellectual property rights important to our business;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

***Our financial condition, commercialization efforts and results of operations could be adversely affected by the ongoing COVID-19 pandemic.***

Any outbreak of a contagious disease, such as the current COVID-19 pandemic, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers, including our sole laboratory.

As COVID-19 continues to affect individuals and businesses around the globe, we will likely experience disruptions that could severely impact our business, including:

- closure of or reduced access to physician offices, which would limit our ability to market our tests to physicians and limit physicians' ability to offer our tests to patients;
- patient concerns about going to physicians' offices to have our tests administered in person, even if offices are open;
- difficulties in transitioning to marketing our telemedicine option for the PLA or processing test results for our telemedicine option, which we recently initiated on an accelerated basis due to the COVID-19 environment;
- dependence to a substantial extent on the willingness of clinicians and their patients to use our telemedicine option, as well as on our ability to demonstrate the value of our telemedicine option to payors;
- limitations on reimbursement of or difficulties in obtaining regulatory approvals for our telemedicine option, which could impede its adoption by physicians and patients;
- limitations on employee resources that would otherwise be focused on our commercialization and sales efforts, including because of sickness of employees or their families or requirements imposed on employees to avoid contact with large groups of people;
- delays in our third-party suppliers' ability to manufacture our tests, including because of interruptions in shipping that may affect the transport of required materials;
- delays or difficulties marketing our tests to new commercial payors, including due to layoffs, furloughs or diversion of attention of payor employees responsible for negotiating coverage contracts for our PLA;

- interruptions in our laboratory operations, including because of the inability of our suppliers to timely obtain laboratory reagents, equipment or other materials due to increased global demand;
- loss of patient insurance coverage due to unemployment caused by COVID-19, which would likely result in a decline in our sales growth if and as we secure additional insurance contracts; and
- interruption of our clinical studies due to quarantines or other limitations on travel or access to facilities imposed or recommended by federal, state or local governments, employers or others.

In addition, the continued spread of COVID-19 globally and implementation of mitigation measures could adversely affect our manufacturing and supply chain. Parts of our direct and indirect supply chain are located overseas and may accordingly be subject to restrictions on export to the U.S. or other disruptions. Additionally, our results of operations have been adversely affected by COVID-19 and such effects could be expected to worsen to the extent that the COVID-19 pandemic persists and continues to harm the U.S. economy in general. The extent to which COVID-19 affects our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional information that may emerge concerning the severity of COVID-19 and ongoing actions to contain COVID-19 or mitigate its impact, among others, which could have a further adverse effect on our business, financial condition, results of operations, and cash flows.

***We expect to continue to incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.***

As a public company, we incur and expect to continue to incur additional significant legal, accounting and other expenses in relation to our status as a public reporting company. We expect that these expenses will further increase after we are no longer an “emerging growth company.” We may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal controls over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an “emerging growth company,” we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, this could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

***Our commercial success could be compromised if customers do not pay our invoices or if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind, or modify their contracts or reimbursement policies, reimburse at a low rate, or delay payments for our current tests and our planned future tests.***

Physicians, including dermatologists, may not order our PLA, our Nevome test, or our planned tests unless third-party payors, such as managed care organizations and government payors (e.g., Medicare and Medicaid), pay a substantial portion of the test price. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor’s determination that tests using our technologies are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;



- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Uncertainty surrounds third-party payor reimbursement of any test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation. In March 2019, the Draft LCD proposed coverage for the PLA. In late October 2019, the AMA provided us with a Current Procedural Technology Proprietary Laboratory Analysis code for our PLA of 0089U, or the PLA Code. Pricing of \$760 for the PLA Code was published on December 24, 2019 as part of the CLFS for 2020. The Final LCD was made available on December 26, 2019 and our PLA became eligible for Medicare reimbursement on February 10, 2020. Medicare does not currently cover our Nevome test.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current tests and our planned future tests will be provided in the future by additional third-party payors or that existing policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. In addition, the coding procedure used by all third-party payors with respect to establishing payment rates for various procedures, including our tests, is complex, does not currently adapt well to the genetic tests we perform and may not enable coverage or adequate reimbursement rates for our tests. If we cannot obtain or maintain coverage and reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations, and cash flows. Measures have been undertaken to reduce payment rates for and decrease utilization of the clinical laboratory testing generally, including the Protecting Access to Medicare Act of 2014, or PAMA, which has resulted in reduced rates on the CLFS. These reductions may also impact our PLA and Nevome test and may also impact tests we develop in the future. Because of the cost-trimming trends, third-party payors that cover and provide reimbursement for our tests and our planned tests may suspend, revoke, or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations, and cash flows. Additionally, if we are not able to obtain sufficient clinical information in support of our tests, third-party payors could designate our tests as experimental or investigational and decline to cover and reimburse our tests because of this designation. As a result of these factors, obtaining approvals from third-party payors to cover our tests and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may never be successful. Further, we have experienced in the past, and will likely experience in the future, delays and interruptions in the receipt of payments from third-party payors due to missing documentation and/or other issues, which could cause delay in recognizing our revenue.

Additionally, we are currently considered a “non-contracted provider” or “out of network” by most private third-party payors because we have not entered into a specific contract to provide tests to their insured patients at specified rates of reimbursement. If we were to become a contracted provider with one or more payors in the future, the amount of overall reimbursement we receive would likely decrease because we could be reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we pursue payment of patient co-payments, co-insurance and deductibles, but we typically do not collect substantial payments from patients and therefore experience overall loss to revenue as a result.

***Billing and collections processing for our tests is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on our revenue.***

Billing for our tests is complex, time-consuming, and expensive. Depending on the billing arrangement and applicable law, we bill, or plan to bill, various different parties for our tests, including Medicare, Medicaid, insurance companies, and patients, all of which may have different billing requirements. We may face increased risk in our collection efforts due to the complexities of these billing requirements, including long collection cycles and lower collection rates, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing government health care programs, including Medicare and Medicaid;
- disputes among payors as to which party is responsible for payment;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;

- differences in information and billing requirements among payors;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We are developing internal systems and procedures to handle these billing and collections functions and have engaged third parties to assist with some of these functions, but we will need to make significant efforts and expend substantial resources to further develop our systems and procedures to handle these aspects of our business. As a result, these billing complexities, along with the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve or sustain profitability, and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payors on a timely basis, or if we are required to switch to a different provider to handle our processing and collections functions, our revenue and business could be adversely affected.

***We will need to raise additional capital to fund our existing operations, commercialize our products, and expand our operations.***

As of March 31, 2020, our cash and cash equivalents totaled approximately \$67.9 million. On February 28, 2020, we entered into a securities purchase agreement with certain institutional investors for a private placement, which closed on March 4, 2020, of our equity securities for aggregate gross proceeds of approximately \$65.0 million, and net proceeds to the Company of approximately \$60.0 million, after deducting estimated offering expenses payable by the Company. Based on our current business operations and the additional financing completed in March 2020, we believe our current cash and cash equivalents, will be sufficient to meet our anticipated cash requirements for at least the next twelve months. We anticipate that we will need to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements in the future in order to satisfy our anticipated liquidity requirements. We may also 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 efforts to drive market adoption of our tests and address competitive developments;
- fund research and development activities and efforts of commercializing future 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 revenue growth rate and ability to generate cash flows from operating activities;
- our sales and marketing and R&D activities;
- effects of competing technological and market developments;
- costs of and potential delays in product development;
- changes in regulatory oversight applicable to our tests; and
- timing of and costs related to future international expansion.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also could provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products, or grant licenses on terms that are not favorable to us. Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more R&D programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us. We will also need to raise additional capital to expand our business to meet our long-term business objectives. Additional financing may be from the sale of equity or convertible or other debt securities in a public or private offering, from a credit facility or strategic partnership coupled with an investment in us, or a combination of both. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations –Liquidity and Capital Resources.*”

***If physicians, including dermatologists, decide not to order the PLA, the Nevome test, or our future tests, we may be unable to generate sufficient revenue to sustain our business.***

To generate demand for our current tests and our planned tests, we will need to educate dermatologists and other health care professionals on the clinical utility, benefits, and value of the tests we provide through published papers, presentations at scientific conferences, educational programs, and one-on-one education sessions by members of our sales force. In addition, we need to assure dermatologists of their ability to obtain and maintain adequate reimbursement coverage from third-party payors for the adhesive patch sample collection method. Medical professionals are influenced by standard-setting bodies that influence and/or dictate the standard of care. If we are not successful in changing current guidelines from legacy standards to new molecular-based approaches our market adoption will suffer. If we cannot convince medical practitioners to order our current tests and our planned tests, we will likely be unable to create demand in sufficient volume for us to achieve profitability or meet our anticipated revenue projections.

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

In recent years, we have incurred significant costs in connection with the development of our tests. For the three months ended March 31, 2020, our R&D expenses were \$0.9 million, our sales and marketing expenses were \$2.9 million and our general and administrative expenses were \$3.5 million. For the three months ended March 31, 2019, our R&D expenses were \$0.6 million, our sales and marketing expenses were \$0.9 million and our general and administrative expenses were \$1.5 million. We expect our expenses to continue to increase for the foreseeable future as we conduct studies of our current tests and our planned other tests, grow our sales and marketing organization, drive adoption of and reimbursement for our tests, and develop new tests. As a result, we need to generate significant revenues in order to achieve profitability.

***We may not be able to generate sufficient revenue from the commercialization of PLA and the Nevome test, or successfully develop and commercialize other tests to achieve or sustain profitability.***

We launched the PLA assay during the first half of 2016. We launched the Nevome test in 2018. We are in varying stages of R&D for other tests that we may offer in the future. We believe that our commercialization success is dependent upon our ability to significantly increase the number of customers who are using our tests. In addition, demand for our tests may not increase as quickly as planned and we may be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of PLA and the Nevome test by dermatologists, in maintaining and creating relationships with our existing and new customers, and developing and commercializing additional molecular diagnostic testing products, we may not be able to generate sufficient revenue to achieve or sustain profitability.

***If we are unable to execute our marketing strategy for PLA and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.***

Although we believe that our current tests and planned future tests represent a promising commercial opportunity, our tests may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our tests and build that market through physician education, awareness programs, and the publication of clinical trial results. Gaining acceptance in medical communities requires publication in leading peer-reviewed journals of results from studies using our current tests and/or our planned future tests. The process of publication in leading medical journals is subject to a peer-review process and peer-reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our current tests and our planned tests.

Our ability to successfully market the tests that we develop will depend on numerous factors, including:

- conducting clinical utility studies of such tests in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- the success of our sales force;
- whether health care providers believe such tests provide clinical utility;
- whether the medical community accepts that such tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and
- whether health insurers, government health care programs, and other third-party payors will cover and pay for such tests and, if so, whether they will adequately reimburse us.

Failure to achieve widespread market acceptance of our current tests and our planned future tests would materially harm our business, financial condition, and results of operations.

***The telemedicine market is immature and unpredictable, and if it does not develop, if it develops more slowly than we expect, if it encounters negative publicity or if limitations on reimbursement or difficulties in obtaining regulatory approvals impede our ability to adopt telemedicine, the growth of our business will be harmed.***

With respect to our telemedicine solution, the telemedicine market is relatively new and unproven, and it is uncertain whether it will achieve and sustain high levels of demand, consumer acceptance and market adoption. Our success will depend to a substantial extent on the willingness of clinicians and their patients to use our telemedicine solution, as well as on our ability to demonstrate the value of our telemedicine solution to health plans and other purchasers of healthcare for beneficiaries. Negative publicity concerning our telemedicine solution or the telemedicine market as a whole could limit market acceptance of our solution. If clinicians or their patients do not believe that our telemedicine solution can provide melanoma testing as accurate as our clinical studies have already proven, or if clinicians or their patients are not willing to utilize the clinician-supervised remote collection process then a market for our solution may be slow to develop, or may not develop at all. Changes by state professional licensing boards to the standards of care or other requirements governing the practice of telemedicine, including any such requirements from federal regulatory bodies, could impact the success of our telemedicine solution. Additionally, reimbursement may not be available from government and third party payors for the teledermatology services or remote collection supervision services that are provided by clinicians as part of our telemedicine solution. Similarly, individual and healthcare industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telemedicine could limit market acceptance of our solution. If any of these events occurs, it could have a material adverse effect on our business, financial condition or results of operations, especially given the ongoing COVID-19 pandemic and patients' reduced access to physician offices for testing.

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

In recent years, there have been numerous advances in technologies relating to the molecular diagnosis for cancer and other medical conditions. Several new cancer drugs have been approved, including several for melanoma, and a number of new drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new tests and enhance any existing tests to keep pace with evolving standards of care. Our current tests and our planned tests could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring, or prognosis of patients with cancer and other dermatologic conditions. If we cannot adequately demonstrate the applicability of our current tests and our planned future tests to new diagnostic and treatment developments, sales of our tests could decline, which would have a material adverse effect on our business, financial condition, results of operations and cash flows.

***Our future success will depend in part upon our ability to enhance PLA, and to develop, introduce, and commercialize other novel innovative and non-invasive diagnostics tests and services. New test development involves a lengthy and complex process and we may be unable to commercialize new or improved tests or any other products we may develop on a timely basis, or at all.***

Our future success will depend in part upon our ability to enhance PLA, and to develop new innovative products. Our failure to successfully develop new products on a timely basis could have a material adverse effect on our revenue, results of operations, and business.

The development of new or enhanced tests is a complex and uncertain process requiring precise technological execution. In addition, the successful development of new products may depend on the development of new technologies. We may be required to undertake time-consuming and costly development activities. We may experience difficulties that could delay or prevent the successful development, commercialization, and marketing of these new products. Before we can commercialize any new products, we will need to expend significant funds in order to conduct substantial R&D, including validation studies.

Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including a failure to demonstrate the performance of the product or an inability to obtain any required certification or regulatory approval, if required.

As we develop new tests and other products, we will have to make significant investments in product development, as well as sales and marketing resources. In addition, competitors may develop and commercialize competing products faster than we are able to do so, which could have a material adverse effect on our revenue, results of operations and business.

***We rely on a limited number of suppliers and, in some cases, a single supplier, for certain of our laboratory substances, equipment and other materials, and any delays or difficulties securing these materials could disrupt our laboratory operations and materially harm our business.***

We rely on a limited number of suppliers for certain of our laboratory substances, including reagents, as well as for the sequencers and various other equipment and materials we use in our laboratory operations. In particular, we rely on Fisher Scientific and VWR for supplies and Adhesive Research for our adhesive tape material. We do not have long-term agreements with any of our suppliers and, as a result, they could cease supplying these materials and equipment to us at any time due to an inability to reach agreement with us on supply terms, disruptions in their operations, a determination to pursue other activities or lines of business, or for other reasons, or they could fail to provide us with sufficient quantities of materials that meet our specifications. Transitioning to a new supplier or locating a temporary substitute, if any are available, would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations, or could require that we revalidate our tests. In addition, the use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and procedures. Moreover, we believe there are currently only a few manufacturers that are capable of supplying and servicing some of the equipment and other materials necessary for our laboratory operations, including sequencers and various associated reagents. As a result, replacement equipment and materials that meet our quality control and performance requirements may not be available on reasonable terms, in a timely manner or at all. If we encounter delays or difficulties securing, reconfiguring or revalidating the equipment, reagents and other materials we require for our tests, our operations could be materially disrupted and our business, financial condition, results of operations, and reputation could be adversely affected.

***Our tests employ a novel diagnostic platform and may never be accepted by their intended markets.***

Our future success depends on our ability to successfully commercialize PLA, as well as our ability to develop and market other tests that use our proprietary technology platform. The scientific discoveries that form the basis of our proprietary technology platform and our tests are relatively new. We are not aware of any other gene expression tests such as ours and there can be no assurance that physicians will be willing to use them. If we do not successfully develop and commercialize our tests based upon our technological approach, we may not become profitable and the value of our common stock may decline.

The novel nature of our tests also means that fewer people are trained in or experienced with products of this type, which may make it difficult to find, hire, and retain capable personnel for research, development, and clinical laboratory positions.

Further, our focus solely on gene expression tests, as opposed to multiple, more proven technologies for patient diagnosis, increases the risks associated with the ownership of our common stock. If we do not achieve market acceptance for our tests, we may be required to change the scope and direction of our product development activities. In that case, we may not be able to identify and implement successfully an alternative product development strategy.

***If our current tests and our planned tests do not to perform as expected, as a result of human error or otherwise, it could have a material adverse effect on our operating results, reputation, and business.***

Our success depends on the market's confidence that we can provide reliable, high-quality diagnostic results. There is no guarantee that any accuracy we have demonstrated to date will continue, particularly as the number of tests using our assays increases and as the number of different tests that we develop and commercialize expands. We believe that our customers are likely to be particularly sensitive to test defects and errors. As a result, the failure of our current or planned tests to perform as expected could significantly impair our reputation and the public image of our tests. As a result, the failure or perceived failure of our products to perform as expected could have a material adverse effect on our business, financial condition, results of operation and cash flows.

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

As part of our strategy, we expect to increase our number of employees as our business grows. This future growth could create strain on our organizational, administrative, and operational infrastructure, including laboratory operations, quality control, customer service, and sales and marketing. 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. If our current infrastructure is unable to handle our growth, we may need to further expand our infrastructure and staff and implement new reporting systems. The time and resources required to implement such expansion and systems could adversely affect our operations. Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage this potential future growth effectively, without compromising quality.

***If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide molecular tests and pursue our R&D efforts may be jeopardized.***

We do not have any clinical reference laboratory facilities outside of our facility in La Jolla, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding, and power outages, which may render it difficult or impossible for us to perform our diagnostic tests for some period of time. The inability to perform our current tests, our planned tests, or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our R&D work could be costly and time-consuming to repair or replace.

The San Diego area has recently experienced serious fires and power outages, and is considered to lie in an area with earthquake risk.

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

Further, if our CLIA certified laboratory became inoperable we may not be able to license or transfer our technology to another facility with the necessary state licensure and CLIA certification under which our current tests and our planned future tests could be performed. Even if we find a facility with such qualifications to perform our tests, it may not be available to us on commercially reasonable terms. In addition, the use of a third-party laboratory to perform our tests could affect their classification as LDTs and require us to seek FDA market authorization for the tests prior to the completion of such a transfer.

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

Our principal competition comes from mainstream clinical diagnostic methods, used by dermatologists for many years, which focus on visual tumor tissue analysis. It may be difficult to change the methods or behavior of dermatologists to incorporate our PLA, Nevome test, and Adhesive Skin Sample Collection Kits into their practices in conjunction with, or instead of, tissue biopsies and analysis. In addition, companies offering capital equipment and kits or reagents to local dermatologists represent another source of potential competition. These tests are used directly by the dermatologists, which can facilitate adoption. We plan to focus our marketing and sales efforts on medical dermatologists rather than pathologists.

We also face competition from companies that offer device products or are conducting research to develop device products for analysis of pigmented lesions. In particular, MELA Sciences, Inc., used to market its MelaFind® device to dermatologists, but we believe they no longer actively market this product. Scibase AB and Verisante Technology, Inc. have devices under development and may market their medical products directly to dermatologists if and when they obtain FDA approval. In addition to these companies, our competitors also include other device companies selling photographic technologies, whole body photography services, dermatoscopes, or confocal microscopy, such as Fotofinder, Molemate, Canfield Scientific, MedX, and Caliber I.D. Many of these groups, in addition to operating R&D laboratories, are selling equipment and devices.

In addition to these device companies, Myriad Genetics, Inc. offers an expression test for melanoma that is used on surgical biopsy specimens. Myriad Genetics, Inc. could also try and market their test as a biopsy aid at the point-of-care. Gene expression testing is a relatively new area of science, especially in dermatology and we cannot predict what tests others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the tests we develop. There are a number of companies that are focused on the oncology diagnostic market and expression tests including Exact Sciences Corporation, Veracyte, Inc., Genomic Health, Inc. and others.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at analyzing pigmented lesions and identifying melanoma may be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current or planned tests in countries where we did not apply for patents or where our patents have not issued or have expired and may compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries. In addition, one or more competitors may seek to invalidate or render unenforceable any of our patents in a court of competent jurisdiction or at the United States Patent and Trademark Office, or USPTO. If any such proceeding were to be successful and result in the invalidation or unenforceability of one or more patents in our intellectual property portfolio, we may be unable to prevent unlicensed third-party competition in the marketplace with respect to our current and planned future tests.

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

Our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and distribution strategies and as new companies enter the market with new technologies and distribution strategies. We may not be able to compete effectively against these organizations. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional, and high-quality products and services and achieving strong customer satisfaction. Increased competition in the future could adversely affect our revenue, revenue growth rate, if any, margins and market share.

***If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that a test provides clinically meaningful information and value, commercial adoption of our tests may be slow, which would negatively impact our business.***

We believe clinical utility studies will show how the PLA changes the decision-making of the dermatologist when making a surgical biopsy decision, particularly to avoid performing a surgical biopsy when the test is negative. Clinical utility studies also show the impact of the test results on patient care and management. Clinical utility studies are typically performed with collaborating dermatologists at medical centers and hospitals, analogous to a clinical trial, and generally result in peer-reviewed publications.

We are currently conducting a variety of clinical trials for the PLA and other non-melanoma tests with investigators at multiple sites in the U.S. We will need to conduct additional studies for these tests, as well as other tests we may offer in the future, to drive test adoption in the marketplace and reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for physicians, including dermatologists and oncologists, adoption of our tests could be impaired and we may not be able to obtain reimbursement for them.

***We are undergoing a management transition.***

We have recently added new executives including a Chief Commercial Officer, Chief Financial Officer, Chief Operating Officer and Senior Vice President of Payor Access. Our management reporting structure may continue to change. Such a management transition subjects us to a number of risks, including risks pertaining to coordination of responsibilities and tasks, creation of new management systems and processes, differences in management style, effects on corporate culture, and the need for transfer of historical knowledge. In addition, our operations will be adversely affected if our management does not work together harmoniously, efficiently allocate responsibilities between themselves, or implement and abide by effective controls.

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

Our success in implementing our business strategy depends largely on the skills, experience, and performance of key members of our executive management team and others in key management positions, including John Dobak, M.D., the Company's Chief Executive Officer. The collective efforts of our executive management team are critical to us as we continue to develop our technologies, tests, and R&D and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies, and implementing our business strategy. Our Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Chief Commercial Officer, Chief Medical Officer, and Chief Scientific Officer have employment agreements; however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain "key person" life insurance on any of our employees.

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

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

***Most of our management has limited experience in operating a public company.***

Most of our management team has limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage our transition to operating as a public company that is subject to significant regulatory oversight and reporting obligations under federal securities laws. Our limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of our time may be devoted to these activities which will result in less time being devoted to the management and growth of the Company. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company which will increase our operating costs in future periods.

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

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

***Our inability to attract, hire, and retain a sufficient number of qualified sales professionals would hamper our ability to launch and increase demand for our PLA, to expand geographically, and to successfully commercialize any other tests or products we may develop.***

To succeed in selling our PLA, and any other tests or products that we are able to develop, we must expand our sales force in the United States and/or internationally by recruiting sales representatives with extensive experience in dermatology and close relationships with medical dermatologists, dermatopathologists, and other hospital personnel. To achieve our marketing and sales goals, we will need to substantially build our sales and commercial infrastructure, with which to date we have had little experience. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire, and retain the number of sales professionals with the right qualifications, scientific backgrounds, and relationships with decision-makers and potential customers needed to achieve our sales goals. We expect to face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer.

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

The Adhesive Skin Sample Collection Kits we distribute are manufactured by a third party supplier. This manufacturer assembles several components, including the key adhesive patch trifold, into a finished product, then labels, stores, and ships this finished product. The adhesive tape subcomponent of the adhesive patches is provided by a single-source third party. This tape is assembled into the individual adhesive patches by another third-party supplier.

We believe we have arranged for adequate manufacturing capacity for the Adhesive Skin Sample Collection Kits through our third-party manufacturer. If demand for our current tests and our planned future tests increases significantly, we will need to either expand manufacturing capabilities through our third-party manufacturer or outsource to other manufacturers. If our third-party or other manufacturers engaged by us fail to manufacture and deliver the Adhesive Skin Sample Collection Kits or certain reagents in a timely manner, or they are unable to fulfil our orders due to regulatory non-compliance or other quality-related issues, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing or quality control problems will not arise as we attempt to increase the production of the Adhesive Skin Sample Collection Kit or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot have the Adhesive Skin Sample Collection Kits manufactured consistently on a timely basis because of these or other factors, it could have a significant negative impact on our ability to perform tests and generate revenues.



***If we cannot support demand for our current tests and our planned future tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.***

As our test volume grows, we will need to increase our testing capacity, implement automation, increase our scale and related processing, customer service, billing, collection, and systems process improvements, and expand our internal quality assurance program and technology to support testing on a larger scale. We will also need additional technicians, certified laboratory scientists, and other scientific and technical personnel to process these additional tests. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional tests are commercialized, we may need to implement new equipment, systems, technology, controls and procedures, and hire personnel with different qualifications. Failure to implement necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our test results or that we will respond successfully to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our current tests and our planned future tests, our reputation could be harmed and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations, and cash flows.

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

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

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

***If we use biological and hazardous materials in a manner that causes injury or violates laws or regulations, we could be liable for damages or subject to enforcement actions.***

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

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

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

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

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

Our business strategy contemplates possible international expansion, including partnering with academic and commercial testing laboratories, and introducing the PLA or other future products outside the United States and exporting the Adhesive Skin Sample Collection Kit. We are currently testing samples through a distributor in Canada. Doing business internationally involves a number of risks, including:

- multiple, conflicting, and changing laws and regulations such as tax laws, export and import restrictions, privacy, data security and data transfer laws, employment laws, intellectual property laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our current tests and our planned future tests in various countries, if required;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes, or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our current tests and our planned future diagnostic tests cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on any trade secrets we may have, if such protection is available;
- natural or man-made disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease (such as the ongoing COVID-19 pandemic), boycotts, curtailment of trade, and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities, as well as similar foreign anti-bribery and anti-corruption laws that may become applicable to our business.

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

***Declining general economic and business conditions as a result of the COVID-19 pandemic have had a negative impact on our business, and the extent and duration of the effects of the COVID-19 pandemic and economic downturn are difficult to predict, which makes our future performance more difficult to predict.***

Economic and business prospects in the United States and other countries have declined rapidly due to the COVID-19 pandemic and resulting restrictions on individual and business activity to mitigate the pandemic. These factors, coupled with decreased business and consumer confidence and substantial unemployment resulting from the declared global pandemic of COVID-19 and restrictions on activity, have precipitated a sharp economic slowdown and recession, and the economic climate may deteriorate further. The extent and duration of the effects of the COVID-19 pandemic and economic downturn are difficult to predict, which makes our future performance more difficult to predict. If the COVID-19 pandemic and economic downturn persist, or if they worsen, we expect that our business, including our access to patient samples and the addressable market for our tests will continue to be adversely affected, resulting in a further negative impact on our business, financial condition, results of operations and cash flows.

***Intrusions into our computer systems could result in compromise of confidential information and our ability to continue operations (in event of a cyber-attack).***

Despite the implementation of security measures, our technology or systems that we interface with, including the Internet and related systems, may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business, or payment information, including as may be disclosed as part of a credit card transaction, or other information of other persons or of us, including employees, being revealed to unauthorized persons. Additional use of remote working technology as a result of the COVID-19 pandemic may increase these vulnerabilities.

***We may have to comply with laws governing the use and disclosure of genetic testing information.***

Many states have adopted laws governing genetic testing and the use and disclosure of genetic test results. These laws impose specific testing consent requirements, patient authorization requirements for the use and disclosure of test results and some impose limits on the retention and secondary use of patient samples. Many of these laws are vaguely written and some are overly broad. We must analyze and ensure compliance with the genetic testing laws in the jurisdictions from which we obtain samples and may be required to expend significant capital and other resources to ensure ongoing compliance. Our failure to comply could interfere with our ability to operate and/or lead to sanctions, fines, or other regulatory actions as well as civil claims.

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

We depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, R&D activities, and our general and administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems, or those used by our third-party service providers could prevent us from processing tests, providing test results to oncologists, pathologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting R&D activities, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have a material effect on our business, financial condition, results of operation and cash flows.

***We rely on Federal Express Corporation, or FedEx, and United Parcel Service of America, Inc., or UPS, for the distribution of our Adhesive Skin Sample Collection Kits to customers and to transport specimens back to our laboratory facility and, if FedEx or UPS incurs any damage to their facilities or is unable to deliver our products as needed, it could have a material adverse effect on our results of operations and business.***

We rely on FedEx and UPS for the distribution of our Adhesive Skin Sample Collection Kits to customers, as well as to transport patient specimens back to our laboratory facility for processing. The FedEx or UPS facilities involved in such distribution may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, power outages, communications failure, infectious disease outbreaks, or terrorism. Any material destruction to their facilities could adversely affect the ability of FedEx or UPS to meet the needs of our customers. In addition, a disruption or slowdown in the operations of FedEx or UPS, including as a result of the COVID-19 pandemic and restrictions on business activity, damage to the facilities of FedEx or UPS or a strike by FedEx or UPS employees, could cause delays in our ability to fulfill customer orders and may cause orders to be cancelled, lost, or delivered late, our shipments to be returned, or receipt of shipments to be refused, any of which could adversely affect our business and our results of operations. If our shipping costs were to increase as a result of an increase by FedEx or UPS or as a result of obtaining a new third-party logistics company and if we are unable to pass on these higher costs to our customers, it could have a material adverse effect on our results of operations and business, financial condition, results of operation and cash flows.

## Regulatory Risks Related to Our Business

### ***Changes in health care law and policy may have a material adverse effect on our financial condition, results of operations, and cash flows.***

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively called the ACA, became law. This law substantially changed the way health care is financed by both governmental and commercial payors, and continues to significantly impact our industry. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. Both the current Congress and President Trump have expressed their intention to repeal or repeal and replace the ACA, and as a result, certain sections of the ACA have not been fully implemented or were effectively repealed. In December 2019, the Fifth Circuit Court of Appeals upheld a district court's finding that the individual mandate in the Affordable Care Act is unconstitutional following removal of the penalty provision from the law. However, the Fifth Circuit reversed and remanded the case to the district court to determine if other reforms enacted as part of the Affordable Care Act but not specifically related to the individual mandate or health insurance could be severed from the rest of the Affordable Care Act so as not to have the law declared invalid in its entirety. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the Affordable Care Act will affect the implementation of that law and our business. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. Further, if reimbursement levels are inadequate, our business and results of operations could be adversely affected.

Further, the ACA established the Physician Payments Sunshine Act, or the Sunshine Act, which imposes reporting and disclosure requirements for applicable device manufacturers of covered products and those entities under common ownership that provide assistance and support to applicable manufacturers, with regard to payments or other transfers of value made to certain practitioners (including physicians and teaching hospitals) and certain investment ownership interests held by physicians in the reporting entity. We are not subject to the Physician Payments Sunshine Act provisions at this time. However, if the FDA later determines that the Adhesive Skin Sample Collection Kit or any of our current or future products are subject to premarket clearance or approval process and such products are considered to be reimbursable by Medicare or Medicaid, we would be subject to the Physician Payments Sunshine Act and thus its reporting requirements.

In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payors to reduce costs while expanding individual health care benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests or the amounts of reimbursement available for our tests from governmental or commercial payors. Any future changes to legal or regulatory requirements or new cost containment initiatives could have a materially adverse effect on our business, financial condition, results of operation, and cash flows.

### ***Our business could be adversely impacted by our failure or the failure of physicians to comply with the ICD-10-CM Code Set.***

Compliance with ICD-10-CM is required for all claims with dates of service on or after October 1, 2015. We believe we have fully implemented ICD-10-CM. However, our failure to effectively implement and apply the new code set could adversely impact our business. In addition, if physicians fail to provide appropriate codes for desired tests, we may not be reimbursed for tests we perform.

### ***Billing for our tests is complex and we must dedicate substantial time and resources to the billing process to be paid for our tests; long payment cycles of Medicare, Medicaid, and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.***

Billing for clinical laboratory testing services is complex, time-consuming, and expensive. Depending on the billing arrangement and applicable law, we will bill various payors, including Medicare, Medicaid, and commercial payors, all of which have different billing requirements. As required by law or contract, we routinely bill patients for co-payments, co-insurance, and deductible amounts owed. We may also face increased risks in our collection efforts, including potential write-offs of doubtful accounts, long collection cycles, and failure by third parties to properly process payment of claims in a timely manner that could adversely affect our business, results of operations, and financial condition. Several factors make the billing practice complex, including:

- compliance with complex federal and state regulations related to Medicare billing;
- disputes among payors as to which party is responsible for payment; resistance by patients to cover any substantial amount of the payment;
- differences in coverage among payors and effect of patient co-payments, co-insurance, or deductibles;
- differences in information and billing requirements among payors;

- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payors also conduct external audits to evaluate payments, which adds further complexity to the billing process.

Failure to comply with these billing requirements may result in non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. These billing complexities and the related uncertainties in obtaining reimbursement could negatively affect our cash flow and our ability to achieve profitability.

***Our business could be harmed by the loss, suspension, or other restriction on a license, certification, or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal, and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.***

The diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts. CLIA requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality, and proficiency testing requirements intended to ensure that testing services are accurate, reliable, and timely. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs. Further, many commercial payors 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.

We have a current certificate of accreditation from the Centers for Medicare and Medicaid Services, or CMS, to perform high-complexity testing, which is managed by California Laboratory Field Services, or CA LFS. To renew this certificate, we are subject to survey and inspection every two years. We hold a certificate of accreditation because we are accredited by the College of American Pathologists, or CAP, which sets standards that are higher than the CLIA regulations. CAP is an independent, non-governmental organization of board-certified pathologists that accredits laboratories nationwide on a voluntary basis. Because CAP has deemed status with CA LFS, our biennial inspections will be performed by teams formed by CAP. Sanctions for failure to comply with CAP or CLIA requirements, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as the imposition of significant fines or criminal penalties. In addition, we are subject to regulation under state laws and regulations governing laboratory licensure. Two states, one of which is New York, have enacted state licensure laws that are more stringent than CLIA.

Failure to maintain CLIA certification, CAP accreditation, or required state licenses could have a material adverse effect on the sales of our tests and the results of our operations. If we were to lose our CLIA certification, CAP accreditation or California laboratory license, whether as a result of a revocation, suspension, or limitation, we would no longer be able to offer our tests, which would limit our revenues and harm our business. If we were to lose our license in any other state where we are required to hold a license, we would not be able to test specimens from those states. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries. We have received samples from all 50 U.S. states and certain provinces in Canada. Each state maintains independent licensure, registration, or certification procedures with which we must maintain compliance in order to receive and test samples from that location. Maintaining compliance with the myriad of state and foreign requirements is time consuming and resource intensive and failure to maintain compliance could result in sanctions.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition, results of operation and cash flows. If the CLIA certificate of our laboratory is revoked, that could also impact our licensure or certification in the states or in foreign jurisdictions.

***If the FDA were to begin requiring approval or clearance of our current tests and our planned future tests, or our proprietary specimen collection kit, we could incur substantial costs and time delays associated with meeting requirements for premarket clearance or approval.***

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the federal Food, Drug, and Cosmetic Act, or FDCA, the FDA has jurisdiction over medical devices, including in vitro diagnostics and, therefore, potentially our clinical laboratory tests. 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. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as our and many other laboratories' tests, as medical devices, it has generally exercised enforcement discretion and is not otherwise regulating most tests developed and performed within a single high complexity CLIA-certified laboratory. The FDA could, at any time, change its policy with regard to this matter or Congress could take action to amend the law to change the current regulatory framework for in vitro diagnostics and LDTs. For example, the Verifying Accurate, Leading-edge IVCT Development, or VALID, Act recently introduced in Congress would codify into law the term "in vitro clinical test" in order to create a new medical product category separate from medical devices that would include products currently regulated as in vitro diagnostics as well as LDTs.

We believe that our tests, as utilized in our clinical laboratory, are and would be LDTs. As a result, we believe that pursuant to the FDA's current policies and guidance, the FDA does not require that we obtain regulatory clearances or approvals for our LDTs. In addition, we believe the Adhesive Skin Sample Collection Kit we provide for collection and transport of skin samples from a health care provider to our clinical laboratory is considered a Class I medical device subject to the FDA's general device controls but exempt from premarket review. However, the FDA could assert the specimen collection kit is non-exempt or is a Class II device, which would subject it to premarket clearance or approval processes, which could be time-consuming and expensive. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA, or other regulatory agencies, would agree with our determinations, and any determination by the government that we have violated the FDCA or any FDA regulations, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations, or financial condition.

Even though we commercialize our tests as LDTs, our tests may in the future become subject to more onerous regulation by the FDA. For example, the FDA may disagree with our assessment that our tests fall within the definition of an LDT and seek to regulate our tests as medical devices. The FDA has, for over the past decade, been introducing proposals to end enforcement discretion and to bring LDTs clearly under existing FDA regulatory frameworks and Congress has recently been working on legislation to create an LDT and in vitro diagnostic regulatory framework that would be separate and distinct from the existing medical device regulatory framework. On March 5, 2020, U.S. Representatives Diana DeGette (D-CO) and Dr. Larry Bucshon (R-IN) formally introduced the VALID Act in the House and an identical version of the bill was introduced in the U.S. Senate by Senators Michael Bennet (D-CO) and Richard Burr (R-NC). As anticipated from a discussion draft of the legislation released for or stakeholder comment in December 2018, the VALID Act would codify into law the term "in vitro clinical test," or IVCT, to create a new medical product category separate from medical devices, and bring all such products within the scope of FDA's oversight. It is unclear whether the VALID Act would be passed by Congress in its current form or signed into law by the President.

Absent any Congressional action, if the FDA begins to enforce its medical device requirements for LDTs, or if the FDA disagrees with our assessment that our tests are LDTs, our tests could for the first time be subject to a variety of regulatory requirements, including registration and listing, medical device reporting, and quality control, and we could be required to obtain premarket clearance or approval for our existing tests and any new tests we may develop, which may force us to cease marketing our tests until we obtain the required clearance or approval. The premarket review process for diagnostic products can be lengthy, expensive, time-consuming, and unpredictable. Further, obtaining premarket clearance or approval may involve, among other things, successfully completing clinical trials. Clinical trials require significant time and cash resources and are subject to a high degree of risk, including risks of experiencing delays, failing to complete the trial or obtaining unexpected or negative results. If we are required to obtain premarket clearance or approval and/or conduct premarket clinical trials, our development costs could significantly increase, our introduction of any new tests we may develop may be delayed, and sales of our existing tests could be interrupted or stopped. Any of these outcomes could reduce our revenue or increase our costs and materially adversely affect our business, prospects, results of operations, or financial condition. Moreover, any cleared or approved labeling claims may not be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. For instance, if we are required by the FDA to label our tests as investigational, or if labeling claims the FDA allows us to make are limited, order levels may decline and reimbursement may be adversely affected. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our existing tests or from tests we may develop. Until the FDA finalizes its regulatory position regarding LDTs, or federal legislation is passed concerning regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval as an medical device or an "in vitro clinical test" (as that category is being defined in the VALID Act, as introduced).

The requirement of premarket review could negatively affect our business until such review is completed and regulatory clearance or approval is obtained. The FDA could require that we stop selling our tests pending premarket clearance or approval. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a premarket submission, such as a 510(k) notification, a premarket approval, or PMA, application or a de novo device classification request to the FDA. If the FDA requires any form of premarket review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA premarket review and authorization of our tests if we determine that doing so would be appropriate.

Additionally, should future regulatory actions affect any of the reagents we obtain from suppliers and use in conducting our tests, our business could be adversely affected in the form of increased costs of testing or delays, limits, or prohibitions on the purchase of reagents necessary to perform our testing. While we qualify all materials used in our products in accordance with the regulations and guidelines of CLIA, the FDA could promulgate regulations or guidance documents impacting our ability to purchase materials necessary for the performance of our tests. If any of the reagents we obtain from suppliers and use in our tests are affected by future regulatory actions, our business could be adversely affected, including by increasing the cost of testing or delaying, limiting, or prohibiting the purchase of reagents necessary to perform testing with our products.

Failure to comply with any applicable FDA requirements could trigger a range of enforcement actions by the FDA, including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

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

If the FDA decides to require that we obtain 510(k) clearance, premarket approvals pursuant to a PMA, or any other type of premarket authorization in order for us to commercialize our current PLA, the Nevome test, or our planned future tests, we may be required to conduct additional clinical testing before submitting a regulatory submission for commercial marketing authorization. In addition, as part of our long-term strategy we may plan to seek FDA clearance or approval for certain gene expression tests in order to permit them to be offered by other clinical laboratories in addition to our own; however, we would need to conduct additional clinical validation activities on our tests before we could submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or the FDA may take certain enforcement actions or reject the data. We believe it would likely take two years or more to conduct the clinical studies and trials necessary to obtain approval from the FDA to commercially launch our current tests and our planned future tests outside of our clinical laboratory.

Even if clinical trials are completed as planned, we cannot be certain that their results would be able to support our test claims or that the FDA or foreign authorities will agree with our conclusions regarding the results of our clinical trials. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct clinical trials to support a premarket submission to the FDA, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that our current tests and our planned future tests are effective for the proposed indications for use, which could cause us to abandon a test candidate and may delay development of other tests.

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

***We are subject to numerous federal, local and foreign laws and regulations; complying with laws pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties and a material adverse effect to our business and operations.***

Our operations are subject to extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among other things:

- CLIA, which requires that laboratories obtain certification from the federal government, and state licensure laws;
- FDA laws and regulations;
- Health Insurance Portability and Accountability Act, or HIPAA, which imposes comprehensive federal standards with respect to the privacy and security of protected health information, or PHI, and requirements for the use of certain standardized electronic transactions; amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or HITECH, which strengthened and expanded HIPAA privacy and security compliance requirements, increased penalties for violators, extended enforcement authority to state attorneys general and imposed requirements for breach notification;
- state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program;
- the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- Section 216 of the PAMA, which requires applicable laboratories to report commercial payor data in a timely and accurate manner beginning in 2017 and every three years thereafter (and in some cases annually);
- state laws that impose reporting and other compliance-related requirements; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

In addition, in October 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was enacted as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or SUPPORT Act. EKRA is an all-payor anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. Further, certain of EKRA's exceptions, such as the exception applicable to relationships with employees that effectively prohibits incentive compensation, are inconsistent with the federal anti-kickback statute and regulations, which permit payment of employee incentive compensation, a practice that is common in the industry. Significantly, EKRA permits the U.S. Department of Justice to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but such regulations have not yet been issued. Laboratory industry stakeholders are reportedly seeking clarification regarding EKRA's scope and/or amendments to its language.

As a clinical laboratory, our business practices may face heightened scrutiny from government enforcement agencies such as the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS. The OIG has issued fraud alerts in recent years that identify certain arrangements between clinical laboratories and referring physicians as implicating the Anti-Kickback Statute. 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 the patient. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the federal self-referral prohibition, commonly known as the Stark Law or the Physician Self-Referral Law, unless the arrangement meets all criteria of an applicable exception. The government has actively enforced these laws against clinical laboratories in recent years.



These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to significant civil or criminal penalties, exclusion from participation in state and federal health care programs, individual imprisonment, disgorgement of profits, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, curtailment or restructuring of our operations, or prohibitions or restrictions on our laboratories' ability to provide or receive payment for our services, any of which could adversely affect our ability to operate our business and pursue our strategy. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payors.

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and other professions and from employing or engaging physicians and other professionals to practice medicine, generally referred to as the prohibition against the corporate practice of medicine and the professions, which could include physician laboratory directors. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed professional. For example, California's Medical Board has indicated that determining the appropriate diagnostic tests for a particular condition and taking responsibility for the ultimate overall care of a patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against the business corporation and/or the professional through licensure proceedings and criminal penalties.

The growth of our business and our expansion outside of the United States may increase the potential of violating similar foreign laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Any of the foregoing consequences could seriously harm our business and our financial results.

***We must comply with complex and overlapping laws protecting the privacy and security of health information and personal data.***

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. Under the administrative simplification provisions of HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of PHI used or disclosed by health care providers and other covered entities.

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

Moreover, HITECH, among other things, established certain health information security breach notification requirements. In the event of a breach of unsecured PHI, a covered entity must notify each individual whose PHI is breached, federal regulators and in some cases, must publicize the breach in local or national media. Breaches affecting 500 individuals or more are publicized by federal regulators who publicly identify the breaching entity, the circumstances of the breach and the number of individuals affected.

These laws contain significant fines and other penalties for wrongful use or disclosure of PHI. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. Adding to the complexity is that our operations are evolving and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services, or provide services involving the use or disclosure of PHI and incur compliance obligations as a business associate. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

We also are required to collect and maintain personal information about our employees, and we collect information about customers as part of some of our marketing programs, as well as receive and transfer certain payment information, to accept payments from our customers, including credit card information. Most states have adopted laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. The collection and use of such information may be subject to contractual obligations as well. If the security and information systems that we or our outsourced third-party providers use to store or process such information are compromised or if we, or such third parties, otherwise fail to comply with these laws, regulations, and contractual obligations, we could face litigation and the imposition of penalties that could adversely affect our financial performance.

We must comply with all applicable privacy and data security laws in order to operate our business and may be required to expend significant capital and other resources to ensure ongoing compliance, to protect against security breaches and hackers or to alleviate problems caused by such breaches. Breaches of health information and/or personal data may be extremely expensive to remediate, may prompt federal or state investigation, fines, civil and/or criminal sanctions and significant reputational damage.

***Our services present the potential for embezzlement, identity theft or other similar illegal behavior by our employees, consultants, service providers or commercial partners.***

Our operations involve the use and disclosure of personal and business information that could be used to impersonate third parties or otherwise gain access to their data or funds. If any of our employees, consultants, service providers or commercial partners takes, converts or misuses these funds or data, we could be liable for any resulting damages, which could harm our financial condition and damage our business reputation.

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

Clinical research is subject to federal, state, and, for studies conducted outside of the United States, international regulation. At the federal level, the Department of Health and Human Services imposes regulations for the protection of human subjects and requirements such as initial and ongoing institutional review board review, informed consent requirements, adverse event reporting and other protections to minimize the risk and maximize the benefit to research participants. Clinical studies done under an investigational device exemption for purposes of an anticipated FDA premarket submission are subject to an additional layer of human subject protection regulations. Many states also impose human subject protection laws that mirror or in some cases exceed federal requirements. HIPAA and other privacy laws also regulate the use and disclosure of PHI in connection with research activities. Research conducted overseas is subject to a variety of national protections such as mandatory ethics committee review, as well as laws regulating the use, disclosure and cross-border transfer of personal data. The costs of compliance with these laws may be significant and compliance with regulatory requirements may result in delay. Noncompliance may disrupt our research and result in data that is unacceptable to regulatory authorities, data lock, or other sanctions that may significantly disrupt our operations.

***Violation of a state's prohibition on the corporate practice of medicine could result in a material adverse effect on our business, financial condition, results of operation and cash flows.***

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

***We could be adversely affected by alleged violations of the Federal Trade Commission Act or other truth-in-advertising and consumer protection laws.***

Our advertising for laboratory services and tests is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission, or FTC, as well as comparable state consumer protection laws. Under the Federal Trade Commission Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution. Our direct-to-consumer advertising and social media presence, as well as our physician-directed advertising, are subject to these federal and state truth-in-advertising laws. Any actual or perceived non-compliance with those laws could lead to an investigation by the FTC or a comparable state agency, or could lead to allegations of misleading advertising by private plaintiffs. Any such action against us would disrupt our business operations, cause damage to our reputation, and result in a material adverse effects on our business, financial condition, results of operation, and cash flows.

***Medical product manufacturers' use of social media platforms presents new risks.***

We believe that our customer base and potential patient populations are active on social media and intend to engage through those platforms to elevate our national marketing presence. Social media practices in the pharmaceutical, biotechnology and medical device industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, one of our products, which could result in reporting obligations or the need for us to conduct an investigation. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our products on any social networking website. If any of these events were to occur or we otherwise fail to comply with any applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

**Intellectual Property Risks Related to Our Business**

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

We collaborate with several institutions, physicians, and researchers in scientific matters. Also, we rely on numerous third parties to provide us with adhesive patch samples and biological materials that we use to develop tests. If we cannot successfully negotiate sufficient ownership, licensing, and/or commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether.

***If we are unable to maintain intellectual property protection, our competitive position could be harmed.***

Our ability to protect our discoveries and technologies affects our ability to compete and to achieve profitability. Currently, we rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses, consulting agreements, work-for-hire agreements, and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know-how, trade secrets, and technological innovations designed to provide us with a competitive advantage in the marketplace as trade secrets. Currently, we own five issued U.S. patents, seven pending U.S. patent applications (two provisional and five non-provisional), several corresponding foreign counterpart patents and applications, and four PCT applications, relevant to our testing methodology and expression profiles. While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if patents are issued, third parties may independently develop similar or competing technology that avoids our patents. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information as well as the misuse of our patents and other intellectual property, particularly in foreign countries where we have not filed for patent protection.

From time-to-time the U.S. Supreme Court, other federal courts, the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. For instance, in 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court later reversed that decision in *Bilski v. Kappos*, finding that the “machine-or-transformation” test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. In 2012, in the case *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the U.S. Supreme Court reversed the Federal Circuit’s application of *Bilski* and invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature.

In 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court unanimously ruled that, “[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated,” thereby invalidating Myriad Genetics’ patents on the BRCA1 and BRCA2 breast cancer genes. However, the Supreme Court also held that manipulation of a gene to create something not found in nature, such as a strand of synthetically-produced complementary DNA, or cDNA, could still be eligible for patent protection. The Supreme Court noted that method patents, which concern technical procedures for carrying out a certain process, are not affected by the ruling.

More recently, the Federal Circuit has ruled on several patent cases—such as *Univ. of Utah Research Found. v. Ambray Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014), *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *Genetic Tech. Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016), and *Cleveland Clinic Found. v. True Health Diagnostics*, 859 F.3d 1352 (Fed. Cir. 2017)—that some diagnostic method claims are patent ineligible. These decisions have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving standards. In addition, this combination of decisions has created uncertainty as to the value of certain issued patents, in particular patents in the molecular biology analysis and diagnostic space. Moreover, there is additional uncertainty around the evolving standard in light of the USPTO Revised Patent Subject Matter Eligibility Guidance issued in Jan. 2019.

It should also be noted that in 2010, the Secretary’s Advisory Committee on Genetics, Health and Society voted to approve a report entitled “*Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests.*” That report defines “patent claims on genes” broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. The report also recommended that HHS should explore, identify, and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote nonexclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether HHS will act upon these recommendations, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future R&D. If acted upon, implementation of such provisions could have a material negative impact on our business.

***We may face intellectual property infringement claims that could be time-consuming and costly to defend, and could result in the loss of significant rights, the implementation of an injunction, and the assessment of treble damages.***

From time-to-time we may face intellectual property infringement or misappropriation claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third party to succeed on an infringement claim against us, we may be required to pay substantial damages, including treble damages if such infringement were found to be willful. In addition, we could face an injunction barring us from conducting the allegedly infringing activity, including an order preventing us from offering our current tests and future planned tests in the marketplace. The outcome of the litigation could require us to enter into a license agreement which may not be pursuant to acceptable or commercially reasonable or practical terms or which may not be available at all.

It is also possible that an adverse finding of infringement against us may require us to dedicate substantial resources and time in developing non-infringing alternatives, which may or may not be possible. In the case of diagnostic tests, we would also need to include non-infringing technologies, which would require us to re-validate the test. Any such re-validation, in addition to being costly and time-consuming, may be unsuccessful. Finally, we may initiate claims to assert or defend our own intellectual property against third parties. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time-consuming, and could divert and distract our management’s attention from our business and negatively affect our operating results or financial condition.

## **Tax Risks Related to Our Business**

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

Our net operating loss, or NOL, carryforwards, may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law, and therefore could expire unused. Under tax legislation commonly referred to as the Tax Cuts and Jobs Act, or TCJA, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely and NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, under the TCJA, as modified by the CARES Act, for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in taxable years beginning after December 31, 2017 is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to the TCJA, as modified by the CARES Act.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its carryforwards to offset future taxable income. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we underwent an ownership change in connection with or after the Business Combination, our ability to utilize NOLs could be further limited by Section 382 of the IRC. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the IRC. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing and any future NOLs could expire or otherwise be unavailable to offset future income tax liabilities. We have not conducted a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since inception due to the significant complexity and cost associated with such a study.

### ***U.S. federal income tax reform could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law the TCJA that significantly reforms the IRC. 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 on the deductibility of interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs generated in taxable years beginning after December 31, 2017 to 80% of current year taxable income, elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, reduction or 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. The CARES Act modifies certain provisions of the TCJA. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increases the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA, as modified by the CARES Act, is uncertain and our business and our financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the TCJA, as modified by the CARES Act. The impact of the TCJA, as modified by the CARES Act, on holders of our common stock is also uncertain and could be adverse. You are urged to consult with your legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

## **Risks Related to Our Securities**

### ***There is no assurance that we will continue satisfying the listing requirements of the Nasdaq Capital Market.***

Our common stock is listed on the Nasdaq Capital Market. To maintain our listing we are required to satisfy continued listing requirements. There can be no assurance we will continue satisfying such continued listing requirements, which include that the closing bid price of our common stock be at least \$1 per share, that we have at least 300 round lot holders and at least 500,000 publicly held shares, that the market value of our publicly held securities be at least \$1 million, and that we meet one of these standards: stockholders' equity of at least \$2.5 million; market value of listed securities of at least \$35 million; or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the three most recently completed fiscal years. The delisting of our common stock for whatever reason could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, the loss of confidence in our company by investors and employees, and in fewer financing, strategic and business development opportunities; and result in potential breaches of agreements under which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations. In addition, the delisting of our common stock for whatever reason may materially impair our stockholders' ability to buy and sell shares of our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock.

***We are an emerging growth company, and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our securities less attractive to investors.***

We are an emerging growth company, under the Jumpstart Our Business Startups Act and a smaller reporting company under SEC regulations. For so long as we remain an emerging growth company or smaller reporting company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements applicable to other public companies that are not emerging growth companies or smaller reporting companies. These exemptions include:

- for so long as we are an emerging growth company, 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 consolidated financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved for so long as we are an emerging growth company.

We may choose to take advantage of some, but not all, of the available exemptions. Emerging growth companies may take advantage of an extended transition period for complying with new or revised accounting standards, allowing emerging growth companies to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We will continue to be an emerging growth company until the earliest to occur of (i) the last day of the fiscal year during which we had total annual gross revenues of at least \$1.07 billion, (ii) the day 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, measured as of our most recently completed second fiscal quarter, (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period, and (iv) December 31, 2022. In addition, we are eligible to remain a smaller reporting company for so long as we have a public float (based on our common equity) of less than \$250 million measured as of the last business day of our most recently completed second fiscal quarter or, a public float (based on our common equity) of less than \$700 million as of this date and annual revenues of less than \$100 million during the most recently completed fiscal year.

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

***Future issuances of equity securities may dilute the interests of our security holders and reduce the price of our securities.***

Any future issuance of our equity securities could dilute the interests of our then existing security holders and could substantially decrease the trading price of our securities. We may issue equity or equity-linked securities for a number of reasons, including to finance our operations and business strategy, to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of then-outstanding options or other equity-linked securities, if any, or for other reasons.

***We may amend the terms of our publicly traded warrants currently trading on the Pink Market under the ticker symbol "DMTKW," or the publicly traded warrants, in a manner that may be adverse to holders with the approval by the holders of a majority of the then outstanding publicly traded warrants. As a result, the exercise price of the publicly traded warrants could be increased, the exercise period could be shortened and the number of shares purchasable upon exercise of a publicly traded warrant could be decreased, all without your approval.***

Our publicly traded warrants are subject to the Warrant Agreement. The Warrant Agreement provides that the terms of the publicly traded warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of a majority of the then outstanding publicly traded warrants to make any change that adversely affects the interests of the registered holders. Accordingly, we may amend the terms of the publicly traded warrants in a manner adverse to a holder if holders of a majority of the then outstanding publicly traded warrants approve of such amendment. Although our ability to amend the terms of the publicly traded warrants with the consent of a majority of the then outstanding publicly traded warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the publicly traded warrants, shorten the exercise period or decrease the number of shares of common stock purchasable upon exercise of the publicly traded warrants.

***We may redeem your unexpired publicly traded warrants prior to their exercise at a time that is disadvantageous to you, thereby making your publicly traded warrants worthless.***

We will have the ability to redeem our outstanding publicly traded warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the last reported sales price of our common stock equals or exceeds \$36.00 per share for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date we give notice of redemption. If and when the publicly traded warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding publicly traded warrants could force you (i) to exercise your publicly traded warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your publicly traded warrants at the then-current market price when you might otherwise wish to hold your publicly traded warrants or (iii) to accept the nominal redemption price which, at the time the outstanding publicly traded warrants are called for redemption, is likely to be substantially less than the market value of your publicly traded warrants.

***Because we have no current plans to pay cash dividends on our shares for the foreseeable future, you may not receive any return on investment unless you sell your shares for a price greater than that which you paid for it.***

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our shares unless you sell your shares of the Company for a price greater than that which you paid for them.

***If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.***

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, market or competitors. If no securities or industry analysts publish reports about us, our share price and trading volume would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our shares of common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our shares of common stock would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline.

***Provisions of our charter documents or Delaware law could delay or prevent an acquisition of us, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change our management.***

Provisions in our Amended and Restated Certificate of Incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy however created, whether by the expansion of our board of directors, the resignation, death or removal of a director, or otherwise;
- a requirement that special meetings of our stockholders be called only by our board of directors, the chairman of our board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of at least 75% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with his, her or its affiliates, owns or within the last three years has owned 15% or more of the company's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage delay or prevent a change in control of the Company.

In addition, our Amended and Restated Certificate of Incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum, or the Delaware Chancery forum provision, for: any derivative action or proceeding brought on our behalf; any action or proceeding asserting a breach of fiduciary duty owed to us, our stockholders, or any of our current or former directors, officers or other employees; 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 the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation, or our bylaws; any action or proceeding to interpret apply, enforce or determine the validity of our Amended and Restated Certificate of Incorporation or our Bylaws; any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Act, the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction.

The Delaware Chancery forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the exclusive 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, which could harm our business, results of operations and financial condition.

Further, on March 18, 2020, the Delaware Supreme Court ruled that provisions of a Delaware corporation's certificate of incorporation that designate a federal forum for securities claims brought pursuant to the Securities Act, or federal forum provisions, are valid and enforceable under Delaware law, or the March 2020 Ruling. Consistent with the March 2020 Ruling, on April 12, 2020, our board of directors approved a Certificate of Amendment to the Amended and Restated Certificate of Incorporation, or the 2020 Certificate of Amendment, which was submitted to our stockholders for their approval at our upcoming 2020 annual meeting of stockholders. If the 2020 Certificate of Amendment is approved by our stockholders, we will file the 2020 Certificate of Amendment with the Delaware Secretary of State to add a federal forum provision to our Amended and Restated Certificate of Incorporation which provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Various U.S. Supreme Court cases offer support for the argument that federal forum provisions do not violate federal policy. However, the March 2020 Ruling applies only to claims brought in Delaware state courts, and it is not binding on any other state court or the federal courts. Therefore, we are unable to predict whether a state court in any other state or a federal court would enforce a federal forum provision such as the one set forth in the 2020 Certificate of Amendment.

We proposed adoption of the 2020 Certificate of Amendment to reduce the costs and inefficiencies to the Company that would result from a Securities Act claim being litigated in both state and federal courts, which is permissible under our Amended and Restated Certificate of Incorporation. Such simultaneous state and federal litigation could also result in inconsistent judgments and rulings, and adopting the 2020 Certificate of Amendment could reduce this risk. However, the federal forum provision set forth in the 2020 Certificate of Amendment may discourage Securities Act claims or limit a stockholder's ability to submit claims in a judicial forum that the stockholder finds favorable, and may result in additional costs for a stockholder seeking to bring such a claim.

Provisions in our charter and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

***We expect the price of our common stock may be volatile and may fluctuate substantially.***

The stock market in general and the market for life sciences companies in particular, have experienced extreme volatility that has often been unrelated to companies' operating performance. In addition, the stock market in general has recently experienced relatively large price and volume fluctuations in response to the COVID-19 pandemic. The market price for our common stock may be influenced by many factors, including:

- the results of our efforts to develop and commercialize our tests;
- actual or anticipated results from, and any delays in, any future clinical trials, as well as results of regulatory reviews relating to the approval of any test candidates we may choose to develop that require such approval;
- commencement or termination of any collaboration or licensing arrangement;



- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technology;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the life sciences industry;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and
- other factors described in this “Risk Factors” section.

In the past, following periods of volatility in companies’ stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business and financial condition.

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

On February 4, 2020, we issued to a registered placement agent, or the Placement Agent, and its designees, warrants, or the 2020 Placement Agent Warrants, exercisable for an aggregate of 15,724 shares of our common stock at an exercise price of \$9.54 per share, in connection with the Placement Agent’s assistance in marketing and selling preferred units of DermTech Operations in offerings conducted between 2016 and 2018. The 2020 Placement Agent Warrants may be exercised on or prior to February 4, 2027 by delivery of a notice of exercise and the exercise price to the Company. The 2020 Placement Agent Warrants expire at 5:00 p.m. Pacific time on February 4, 2027.

The exercise price under the 2020 Placement Agent Warrants is payable by wire transfer or certified, cashier’s or other check acceptable to the Company, or, if applicable, upon surrender and cancellation of indebtedness. Additionally, the 2020 Placement Agent Warrants may be exercised on a cashless basis. If a holder of the 2020 Placement Agent Warrants elects to exercise such warrants on a cashless basis, the electing holder would pay the exercise price by surrendering the applicable 2020 Placement Agent Warrants for that number of shares equal to the quotient obtained by dividing (x) the product of the number of shares underlying the 2020 Placement Agent Warrants, multiplied by the difference between the exercise price of the 2020 Placement Agent Warrants and the “fair market value” (defined below) by (y) the fair market value. The “fair market value” for purposes of the 2020 Placement Agent Warrants is the closing bid price of our common stock or the closing price quoted on the national securities exchange on which our common stock is listed, as applicable, on the first trading day preceding the date of determination of the fair market value.

The exercise price and number of shares issuable on exercise of the 2020 Placement Agent Warrants may be adjusted in certain circumstances, including in the event of a reorganization, recapitalization, merger or consolidation of the Company, a reclassification of our shares, or a subdivision or consolidation of the shares of our common stock. No fractional shares will be issued upon the exercise of the 2020 Placement Agent Warrants.

The issuances of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder as transactions by an issuer not involving any public offering. The recipients of the securities represented their intentions to acquire the securities for investment only and not with a view to, or for sale in connection with, any distribution thereof, and appropriate legends were affixed to the securities.

**Item 6. Exhibits.**

The following documents are filed as part of this Form 10-Q.

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed Herewith</b>	<b>Form</b>	<b>Incorporated by Reference File No.</b>	<b>Date Filed</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Company, as amended</a>		10-K	001-38118	3/11/2020
4.1	<a href="#">2020 Form of Placement Agent Warrant</a>		S-1/A	333-235780	2/6/2020
4.2	<a href="#">Form of Omnibus Warrant Amendment for 2015 and July 2016 Placement Agent Warrants</a>		S-1	333-237991	5/4/2020
4.3	<a href="#">Omnibus Warrant Amendment for December 2016, 2017 and 2018 Placement Agent Warrants, dated as of March 30, 2020 by and between the Company and Paulson Investment Company, LLC</a>		S-1	333-237991	5/4/2020
10.1	<a href="#">Fifth Amendment to Lease and Signage Lease, dated February 5, 2020, by and between the Company and HCP Torrey Pines, LLC</a>		S-1/A	333-235780	2/6/2020
10.2*	<a href="#">2020 Form of Stock Option Agreement and Forms of Stock Option Grant Notice under the Amended and Restated 2010 Stock Plan of the Company</a>		8-K	001-38118	1/21/2020
10.3*	<a href="#">2020 Form of Restricted Stock Unit Agreement and Forms of Restricted Stock Unit Award Grant Notice under the Amended and Restated 2010 Stock Plan of the Company</a>		8-K	001-38118	1/21/2020
10.4*	<a href="#">Non-Employee Director Compensation Policy, dated January 30, 2020</a>		10-K	001-38118	3/11/2020
10.5	<a href="#">Securities Purchase Agreement, dated February 28, 2020, by and among the Company and the Purchasers identified on the signature pages thereto</a>		8-K	001-38118	3/2/2020
10.6	<a href="#">Form of Registration Rights Agreement by and among the Company and the Purchasers</a>		8-K	001-38118	3/2/2020
10.7*	<a href="#">2020 Corporate Bonus Plan of the Company</a>		8-K	001-38118	3/24/2020
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X			
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X			
32.1	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema Document	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X			
*	Management contract or compensatory plan or arrangement.				

**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.

DermTech, Inc.

Date: May 13, 2020

By: \_\_\_\_\_  
/s/ John Dobak  
**John Dobak, M.D.**  
**Chief Executive Officer**  
*(Principal Executive Officer)*

Date: May 13, 2020

By: \_\_\_\_\_  
/s/ Kevin Sun  
**Kevin Sun**  
**Chief Financial Officer**  
*(Principal Financial and Accounting Officer)*





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

In connection with the Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020 of DermTech, Inc. (the “Company”), as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 13, 2020

By: \_\_\_\_\_  
/s/ John Dobak  
John Dobak  
**Chief Executive Officer**  
(principal executive officer)

Date: May 13, 2020

By: \_\_\_\_\_  
/s/ Kevin Sun  
Kevin Sun  
**Chief Financial Officer**  
(principal financial and accounting officer)

This certification accompanies the Quarterly Report on Form 10-Q to which it relates and shall not be deemed filed with the Securities and Exchange Commission or incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.