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 September 30, 2019

OR

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

For the transition period from to

Commission File Number: 001-38118

DERMTECH, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**84-2870849**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11099 N. Torrey Pines Road, Suite 100 La Jolla, CA	**92037**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 7, 2019, the registrant had 11,964,329 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 21,437	$ 4,753
Accounts receivable, net	814	580
Inventory	44	40
Prepaid expenses and other current assets	1,399	26
Total current assets	23,694	5,399
Property and equipment, net	210	215
Other assets	84	50
Total assets	$ 23,988	$ 5,664
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,004	$ 286
Accrued compensation	1,099	480
Accrued liabilities	171	286
Deferred revenue	1,457	1,552
Deferred underwriting fees	1,363	—
Convertible notes payable, net	—	5,019
Derivative liability	—	2,880
Total current liabilities	5,094	10,503
Notes payable, noncurrent	—	516
Total liabilities	5,094	11,019
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value per share; 5,000,000 and zero Series A shares authorized as of September 30, 2019 and December 31, 2018; 1,231 and zero shares issued and outstanding at September 30, 2019 and December 31, 2018; $6.9 million and zero liquidation preference at September 30, 2019 and December 31, 2018	—	—
Series C convertible preferred stock, $0.0001 par value per share; zero and 1,626,106 Series C shares authorized as of September 30, 2019 and December 31, 2018; zero and 1,524,122 shares issued and outstanding at September 30, 2019 and December 31, 2018; zero and $14.5 million liquidation preference at September 30, 2019 and December 31, 2018	—	—
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share; 50,000,000 and 15,099,554 shares authorized as of September 30, 2019 and December 31, 2018; 11,964,329 and 4,411,567 shares issued and outstanding at September 30, 2019 and December 31, 2018	1	1
Additional paid-in capital	104,889	66,021
Accumulated deficit	(85,996)	(71,377)
Total stockholders' equity (deficit)	18,894	(5,355)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 23,988	$ 5,664

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Assay revenue	$ 385	$ 321	$ 905	$ 853
Contract revenue	180	320	870	960
Total revenues	565	641	1,775	1,813
Cost of revenues	779	687	2,100	2,038
Gross loss	(214)	(46)	(325)	(225)
Operating expenses:				
Sales and marketing	1,976	675	3,872	2,173
Research and development	757	549	1,847	1,616
General and administrative	3,212	840	6,446	2,622
Total operating expenses	5,945	2,064	12,165	6,411
Loss from operations	(6,159)	(2,110)	(12,490)	(6,636)
Other income (expense):				
Gain on debt extinguishment	928	—	928	—
Interest expense, net	(364)	(100)	(2,657)	(108)
Other expense	(131)	—	(355)	—
Total other income (expense)	433	(100)	(2,084)	(108)
Net loss and comprehensive loss	$ (5,726)	$ (2,210)	$ (14,574)	$ (6,744)
Weighted average shares outstanding used in computing net loss per share, basic and diluted	7,134,642	4,411,255	5,331,876	4,410,789
Net loss per common share outstanding, basic and diluted	$ (0.80)	$ (0.50)	$ (2.73)	$ (1.53)

See accompanying notes to condensed consolidated financial statements.

DERMTECH, INC.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
Periods Ended September 30, 2019 & September 30, 2018
(in thousands, except share data)

	Series C convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount			
Balance, December 31, 2017	1,017,583	$ —	4,410,841	$ 1	$ 60,567	$ (61,373)	$ (805)
Issuance of Series C preferred stock and common stock warrants at $9.54. net of $0.2 million issuance costs	473,216	—	—	—	4,319	—	4,319
Stock-based compensation	—	—	—	—	226	—	226
Net loss	—	—	—	—	—	(2,281)	(2,281)
Balance, March 31, 2018	1,490,799	—	4,410,841	1	65,112	(63,654)	1,459
Issuance of Series C preferred stock and common stock warrants at $9.54. net of $0.1 million issuance costs	33,323	—	—	—	218	—	218
Stock-based compensation	—	—	—	—	250	—	250
Net loss	—	—	—	—	-	(2,253)	(2,253)
Balance, June 30, 2018	1,524,122	—	4,410,841	1	65,580	(65,907)	(326)
Issuance of common stock	—	—	726	—	5	—	5
Stock-based compensation	—	—	—	—	246	—	246
Net loss	—	—	—	—	—	(2,210)	(2,210)
Balance, September 30, 2018	1,524,122	$ —	4,411,567	$ 1	$ 65,831	$ (68,117)	$ (2,285)

	Series A convertible preferred stock		Series C convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	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	—	—	1,524,122	—	4,411,567	1	66,279	(76,578)	(10,298)
Issuance of common stock	—	—	—	—	37,264	—	41	—	41
Stock-based compensation	—	—	—	—	—	—	258	—	258
Net loss	—	—	—	—	—	—	—	(3,692)	(3,692)
Balance, June 30, 2019	—	—	1,524,122	—	4,448,831	1	66,578	(80,270)	(13,691)
Issuance of common stock	—	—	—	—	647,411	—	718	—	718
Conversion of Series C preferred stock to common stock	—	—	(1,524,122)	—	1,524,122	—	—	—	—
Conversion of convertible notes to common stock	—	—	—	—	2,267,042	—	12,687	—	12,687
Additional paid in capital assumed in Business Combination	—	—	—	—	—	—	420	—	420
Issuance of Series A preferred stock at $3,250 per share	1,231	—	—	—	—	—	4,000	—	4,000
Issuance of common stock at $6.50 per share, net of $0.2 million issuance costs	—	—	—	—	3,076,923	—	19,802	—	19,802
Stock-based compensation	—	—	—	—	—	—	684	—	684
Net loss	—	—	—	—	—	—	—	(5,726)	(5,726)
Balance, September 30, 2019	1,231	$ —	—	$ —	11,964,329	$ 1	$ 104,889	$ (85,996)	$ 18,894

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (14,574)	$ (6,744)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	58	57
Stock-based compensation	1,200	722
Amortization of debt discount and issuance costs	1,983	81
Change in fair value of derivative liability	355	—
Gain on extinguishment of convertible notes	(928)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(235)	(81)
Inventory	(4)	4
Prepaid expenses and other current assets	(1,407)	(13)
Accounts payable and accrued compensation	1,330	(58)
Accrued liabilities and deferred revenue	511	(128)
Net cash used in operating activities	(11,711)	(6,160)
Cash flows from investing activities:		
Purchases of property and equipment	(53)	(12)
Net cash used in investing activities	(53)	(12)
Cash flows from financing activities:		
Proceeds from convertible notes payable	2,600	1,500
Payments of debt issuance costs	—	(110)
Payments of notes payable	(516)	—
Proceeds from issuance of Series A Convertible Preferred Stock	4,000	—
Proceeds received from close of Business Combination	1,802	—
Proceeds from issuance of common stock	19,803	—
Proceeds from sale of convertible preferred stock and common stock warrants, net of issuance costs	—	4,538
Proceeds from exercise of stock options	759	5
Net cash provided by financing activities	28,448	5,933
Net increase/(decrease) in cash and cash equivalents	16,684	(239)
Cash and cash equivalents, beginning of period	4,753	1,242
Cash and cash equivalents, end of period	$ 21,437	$ 1,003
Supplemental cash flow information:		
Debt discount and derivative liability at issuance of convertible notes payable	$ 270	$ 364
Purchases of property and equipment recorded in accounts payable	$ 10	—

See accompanying notes to condensed consolidated financial statements.

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. 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. 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.

(b) Basis of Presentation, Reverse Stock Split and Going Concern

These condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, ("U.S. GAAP"), which contemplate continuation of the Company as a going concern, for interim financial information and with the instructions to Form 10-Q and Article 10 of Securities and Exchange Commission, ("SEC"), Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included.

The Company has incurred net losses since the Company's formation and has an accumulated deficit of $86.0 million and a negative operating cash flow of $11.7 million as of September 30, 2019 and does not have adequate cash on hand to fund operations for the next year. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed consolidated financial statements and notes to the condensed consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

The Company has evaluated the expected cash requirements for a 12-month period from the issuance date of the condensed consolidated financial statements through November 2020 and do not believe they will have sufficient cash on hand to fund operations. Management intends to pursue additional equity and debt financings and believes this will be sufficient to provide the Company with the ability to continue, to support its planned operations and to continue developing and commercializing gene expression tests. There can be no assurances as to the availability of additional financing or the terms upon which additional financing may be available to the Company. If the Company is unable to obtain sufficient funding at acceptable terms, it may be forced to significantly curtail its operations, and the lack of sufficient funding may have a material adverse impact on the Company's ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

(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, derivative liability, the realization of deferred tax assets, and common and preferred stock valuations. 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 $20,000 and $19,000 for the three months ended September 30, 2019 and 2018, respectively, and $0.1 million and $0.1 million for the nine months ended September 30, 2019 and 2018, respectively. No property or equipment was disposed of during the three and nine months ended September 30, 2019 and 2018. 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 and nine months ended September 30, 2019 and 2018.

(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) 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. The Company maintains $21.2 million in a bank deposit account that 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 September 30, 2019 and December 31, 2018.

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.

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 Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("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 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. Application of the modified retrospective method for the Company's contract revenue did require a cumulative effect adjustment upon adoption, which resulted in an adjustment of $45,000 to increase accumulated deficit and deferred revenue. Application of the modified retrospective method for the Company's assay revenue does not materially impact amounts previously reported by the Company, nor does it require a cumulative effect adjustment upon adoption, as the Company's method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for the Company to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

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 in detail 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. Laboratory revenues result 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.

Contracts

As part of the Company's contract revenue, the Company has established agreements and work orders with the Company's pharmaceutical partners that fall under the scope of ASC 606.

Performance Obligations

ASC 606 requires an entity to assess the goods or services promised in a contract and identify as a performance obligation each promise to transfer to the customer either a good or service (or a bundle of goods or services) that is distinct, or a series of distinct goods or services that are substantially the same and that have the same pattern of transfer to the customer. Based upon review of existing contracts, a majority of the Company's contract revenue agreements contain three performance obligations:

(1) Adhesive patch kits

(2) RNA extractions and analysis

(3) Certain project management fees

Many of the Company's contract revenue agreements contain promises such as start-up activities and quality system setup fees, which are activities that the Company performs to fulfill the agreement and they do not transfer any good or service to the customer. These promises encompass the administrative tasks associated with beginning and initiating a new project or study with a pharmaceutical company. In accordance with ASC 606, an entity does not account for these activities as a promised good or service within the agreement nor evaluate whether they are a performance obligation.

Transaction Price

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in an agreement with a customer may include fixed amounts, variable amounts, or both.

The transaction prices of the Company's performance obligations are listed in its agreements on a per unit basis and are fixed for adhesive patch kits and RNA extractions and analysis. The project management fees are assessed based on a monthly service fee which range within the agreements depending on certain factors which include length of the project and the amount of kits or RNA extractions and analysis promised within the agreement. The fixed and variable rates are materially consistent within the Company's agreements. Therefore, the Company utilizes the prices listed in our agreements as the transaction price for each performance obligation.

In determining the transaction price, ASC 606 requires an entity to adjust the promised amount of consideration for the effects of the time value of money if the agreement contains a significant financing component. The Company's agreements state fixed transaction prices for each deliverable associated with the agreement and do not qualify for the significant financing component of ASC 606.

Allocate the Transaction Price

The Company's contracts have a directly observable transaction price pertaining to each promised good or service. Those prices are consistent across agreements for adhesive patch kits and RNA extractions and analysis, with the exception of the Company's project management fees, which the Company's believes encompass a sufficiently narrow range of prices that are dictated upon factors of each agreement previously discussed above. Therefore, the Company's relies on those transaction prices as the basis to allocate the stand-alone selling prices to the performance obligations of the agreement.

Most of the Company's agreements contain a discount that is allocated to items within the agreement, whether they are performance obligations or not. Those items that are not performance obligations (e.g. quality system setup and start up fees) have the associated discount allocated to the transaction prices of the performance obligations evenly.

Recognize Revenue

An entity should recognize revenue when (or as) it satisfies a performance obligation by transferring a promised good or service to a customer. A good or service is transferred when (or as) the customer obtains control of that good or service. The adhesive patch kits are recognized at a point in time when shipped to the customer. The RNA extraction and analysis are recognized at a point in time when the extraction and analysis process is complete and the results are sent to the customer. The Company provides its project management service over the life of the agreement, providing equal benefit to the customer throughout the life of the project or study. Therefore, the revenue related to the Company's project management fees is recognized straight-line over the life agreement.

Deferred Revenue and Remaining Performance Obligations

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 goods/services are completed or delivered. Deferred revenue at September 30, 2019 and December 31, 2018 was $1.5 million and $1.6 million, respectively.

Remaining performance obligations include deferred revenue and amounts the Company expects to receive for goods and services that have not yet been delivered or provided under existing agreements. For agreements that have an original duration of one year or less, the Company has elected the practical expedient applicable to such agreements and does not disclose the remaining performance obligations at the end of each reporting period and when the Company expects to recognize this revenue. As of September 30, 2019, the estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed agreements with an original duration of one year or more was approximately $1.7 million. The Company expects to recognize revenue on the majority of these remaining performance obligations over the next two to three years.

Assay Revenue

The Company generates revenues from its Pigmented Lesion Assay ("PLA") and Nevome services it provides to dermatologists in various states throughout the United States to assist in a clinician's diagnosis of melanoma. The Company provides prescribing dermatologists 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.

Contracts

The Company's customer is the patient. However, the Company does not enter into a formal reimbursement agreement with a patient, as formal reimbursement agreements are more commonly established with insurance payers. Accordingly, the Company establishes an agreement with a patient in accordance with other customary business practices.

- Approval of an agreement is established by the use of the Company's adhesive patch kit on a patient by an ordering physician, which is then sent to the Company's central lab for testing.
- The Company is obligated to perform the Company's laboratory services upon receipt of a sample from a physician, and the patient and/or applicable payer are obligated to reimburse us for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits.
- Once the Company delivers a patient's test result to the ordering physician, the Company is legally able to collect payment and bill an insurer and/or patient, depending on payer agreement status or patient insurance benefit status.
- The Company's consideration is deemed to be variable, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

Performance Obligations

A performance obligation is a promise in an agreement to transfer a distinct good or service (or a bundle of goods or services) to the customer. The customer is able to order a PLA test. However, a Nevome test cannot be ordered separately from the PLA test and it is contingent on being run only when a PLA test comes back positive on a sample. The Nevome test would not qualify as a distinct service. Therefore, the PLA test is recognized as a single performance obligation and the Nevome test, if rendered, is bundled with the single PLA performance obligation.

Transaction Price

The transaction price is the amount of consideration that the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected from an agreement with a customer may include fixed amounts, variable amounts, or both.

The consideration derived from the Company's agreements is deemed to be variable, though the variability is not explicitly stated in any agreement. Rather, the implied variability is due to several factors, such as the amount of contractual adjustments, any patient co-payments, deductibles or patient compliance incentives, the existence of secondary payers and claim denials.

The Company estimates the amount of variable consideration using the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, the Company considers several factors, such as historical collections experience, patient insurance eligibility and payer reimbursement agreements.

The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, the Company recognizes revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made. Revenue recognized from changes in transaction prices was not material for the three and nine months ended September 30, 2019 and 2018, respectively.

The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more consideration than it originally estimated for an agreement with a patient, it will account for the change as an increase in the estimate of the transaction price (i.e., an upward revenue adjustment) in the period identified. Similarly, if the Company subsequently determines that the amount it expects to collect from a patient is less than it originally estimated, it will generally account for the change as a decrease in the estimate of the transaction price (i.e., a downward revenue adjustment), provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

When the Company does not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon delivery of a patient's test result to the ordering physician, with recognition, generally occurring at the date of cash receipt.

Allocate the Transaction Price

The entire transaction price is allocated entirely to the single performance obligation contained within the agreement with a patient.

Recognize Revenue

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

If a Nevome test service is ordered and completed in conjunction with the Company's PLA service, then the Company will recognize revenue upon the delivery of both final reports to the physician. The delivery of the Company's Nevome test results is typically after the Company's PLA results are delivered due to the circumstances of how the Company processes the Nevome test. However, this length in time is determined to not materially impact the final overall revenue recognition timing.

(c) Disaggregation of Revenue

The following tables present the Company's revenues disaggregated by revenue source during the three months ended September 30, 2019 and 2018, respectively, and during the nine months ended September 30, 2019 and 2018, respectively (in thousands):

	Three Months Ended September 30,	
	2019	2018
Assay Revenue		
PLA Test	$ 385	$ 321
Contract Revenue		
Adhesive Patch kits	101	103
RNA Extractions	—	144
Project Management Fees	79	55
Other	—	18
Total Revenue	$ 565	$ 641

	Nine Months Ended September 30,	
	2019	2018
Assay Revenue		
PLA Test	$ 905	$ 853
Contract Revenue		
Adhesive Patch kits	436	323
RNA Extractions	200	396
Project Management Fees	232	154
Other	2	87
Total Revenue	$ 1,775	$ 1,813

(d) Contract Balances

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.

Deferred revenue balances are presented on the Company's condensed consolidated balance sheets and were $1.5 million and $1.6 million as of September 30, 2019 and December 31, 2018, 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 September 30, 2019, 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 $0.5 million and $0.3 million of contract accounts receivable as of September 30, 2019 and December 31, 2018, 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 accrues an allowance for doubtful accounts against its accounts receivable when it is probable that an account is not collectible, based on write off history, credit risk of specific accounts, aging analysis and other information available on specific accounts. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral. Accounts receivable are written off when all efforts to collect the balance have been exhausted. Historically, the Company's bad debt expense has not been significant. Adjustments for implicit price concessions attributable to variable consideration are incorporated into the measurement of the accounts receivable balances and are not part of the allowance for doubtful accounts. The Company recorded $0.4 million and $0.3 million of gross assay accounts receivable as of September 30, 2019 and December 31, 2018, respectively. In addition, the Company established an allowance for doubtful accounts of $0.1 million and $0.1 million as of September 30, 2019 and December 31, 2018, 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 and nine months ended September 30, 2019 and 2018, 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 and nine months ended September 30, 2019 excludes the effect of anti-dilutive equity instruments including 615,385 shares of common stock issuable upon conversion of the Company's preferred stock, 4,226,785 shares of common stock issuable upon the exercise of outstanding common stock warrants and 964,995 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 September 30, 2018 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, 1,435,315 shares of common stock issuable upon the exercise of outstanding warrants and 982,760 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 earnings (loss) per share given that the Company's convertible participating securities do not participate in losses.

(o) Stock-Based Compensation

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 straight-line 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 determine 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, net of estimated forfeitures, using the straight-line 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. 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 have a requisite service period of 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 straight-line basis over the requisite service periods of the awards, taking into consideration estimated forfeitures. RSUs that are granted to employees have a requisite service period between two and four years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Assumed risk-free interest rate	1.68%	2.77%	1.68% - 2.50%	2.46% - 2.94%
Assumed volatility	73.50%	77.27%	73.20% - 73.50%	77.27% - 78.25%
Expected option term	6.02 years	6.02 years	6.02 - 6.08 years	5.76 - 6.04 years
Expected dividend yield	—	—	—	—

The Company recorded stock-based compensation expense for employee options, RSUs, common stock warrants, and consultant options of $0.7 million and $0.2 million for the three months ended September 30, 2019 and 2018, respectively and $1.2 million and $0.7 million for the nine months ended September 30, 2019 and 2018, respectively. The total compensation cost related to non-vested awards not yet recognized at September 30, 2019 was $0.5 million, which is expected to be recognized on a straight-line basis over a weighted average term of 2.47 years.

(p) Derivative Liability

From time-to-time, the Company may issue convertible notes that contain embedded features that require derivative accounting including the determination of the fair value of the financial instruments at the execution of the contract and the change in such fair values through each reporting period until such time the liability is extinguished. The Company's convertible notes, as further discussed in Note 3, have embedded derivatives that required bifurcation from the host instrument.

(q) 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 September 30, 2019. The following table provides a summary of the assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2018 (in thousands):

Fair Value Measurements at Reporting Date Using

	December 31, 2018			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Liabilities:				
Derivative liability	$ —	$ —	$ 2,880	$ 2,880
Total liabilities	$ —	$ —	$ 2,880	$ 2,880

The fair value of the derivative liability was determined based on a probability weighted valuation model of the various embedded features of the Company's outstanding convertible debt. The fair value is subjective and is affected by changes in inputs to the valuation model including management's assumptions regarding estimates of timing and the probability of each embedded conversion feature occurring. An initial fair value valuation was performed at each date of issuance of the outstanding convertible debt and subsequently remeasured as of August 29, 2019, which was the date the convertible debt converted to common stock. The accumulated change in fair value between measurement dates was determined to be a $0.1 million and $0.4 million loss for the three and nine months ended September 30, 2019, respectively, which was recognized as Other expense within the condensed consolidated Statement of Operations and Comprehensive Loss. As the convertible debt converted to common stock, this conversion eliminated the derivative liability on August 29, 2019. Changes in these assumptions can materially affect the fair value.

There were no other assets or liabilities that were measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018. 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.

(r) Accounting Pronouncement Recently Adopted

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)," which will supersede virtually all existing revenue guidance. Under this standard, an entity is required to recognize revenue upon transfer of promised goods or services to customers in an amount that reflects the expected consideration received in exchange for those goods or services. As such, an entity will need to use more judgment and make more estimates than under the current guidance. This standard should be applied retrospectively either to each prior reporting period presented in the condensed consolidated financial statements, or only to the most current reporting period presented in the condensed consolidated financial statements with a cumulative effect adjustment recorded in retained earnings. In March 2016, the FASB issued ASU 2016-08, "Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," which clarifies the principal versus agent guidance in the new revenue recognition standard. In April 2016, the FASB issued

ASU 2016-10, “Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,” which clarifies the guidance on accounting for licenses of intellectual property and identifying performance obligations in the new revenue recognition standard. In May 2016, the FASB issued ASU 2016-12, “Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients,” which does not change the core principles of the guidance in Topic 606, but further clarifies and improves various narrow aspects of Topic 606. In December 2017, the FASB issued ASU 2016-20, “Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers,” which clarifies the codification and corrects unintended application of Topic 606. These new standards are effective for interim and annual periods beginning after December 15, 2018 and early adoption is permitted.

The Company adopted the standard as of January 1, 2019 utilizing the modified retrospective approach. Further information regarding the standard is discussed in Note 1(i) Revenue Recognition. As a result of adoption, the Company made a $45,000 adjustment to accumulated deficit to account for prior year contract revenue amounts being lower under ASC 606. The Company noted no material impact associated with the adoption of ASC 606 on assay revenue.

(s) 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. This new standard is effective for interim and annual periods beginning January 1, 2020 and early adoption is permitted. The Company is currently evaluating the impact of this standard on its condensed consolidated financial statements.

In June 2019, the 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 resulting from expanding the scope of Topic 718, Compensation—Stock Compensation, to 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 is currently evaluating the impact of this standard on its 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 is currently evaluating the impact of this standard on its condensed consolidated financial statements.

2. Balance Sheet Details

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

	September 30, 2019	December 31, 2018
Prepaid expenses and other current assets:		
Prepaid insurance	$ 1,281	$ 2
Prepaid trade shows	94	19
Other current assets	24	5
Total prepaid expenses and other current assets	$ 1,399	$ 26
Property and equipment, gross:		
Laboratory equipment	$ 343	$ 314
Computer equipment	9	3
Furniture and fixtures	34	34
Leasehold improvements	32	14
Total property and equipment, gross	418	365
Less accumulated depreciation	(208)	(150)
Total property and equipment, net	$ 210	$ 215

	September 30, 2019	December 31, 2018
Accrued liabilities:		
Accrued consulting services	$ 40	$ 23
Accrued interest	—	164
Deferred rent	85	85
Other accrued expenses	46	14
Total accrued liabilities	$ 171	$ 286
Accrued compensation:		
Accrued paid time off	$ 350	$ 234
Accrued bonus and deferred compensation	471	246
Accrued severance	278	—
Total accrued compensation	$ 1,099	$ 480

3. Debt

Wilson, Sonsini, Goodrich & Rosati Note

On January 7, 2016, DermTech Operations converted $0.6 million of its accounts payable due to Wilson, Sonsini, Goodrich & Rosati (DermTech Operations' general legal counsel) into a three-year promissory note bearing 3% interest and maturing on January 7, 2019, or earlier under certain circumstances. There were no principal payments due until the note reached maturity. On October 25, 2017, DermTech Operations amended and restated its promissory note with Wilson, Sonsini, Goodrich & Rosati by paying down $0.1 million on the principal balance of the note while extending its maturity date to January 7, 2020, or earlier under certain circumstances, at a continued interest rate of 3%. The Company recorded $3,000 and $4,000 of interest expense relating to this note payable during the three months ended September 30, 2019 and 2018, respectively, and $11,000 and $12,000 for the nine months ended September 30, 2019 and 2018, respectively. On September 16, 2019, the Company paid all outstanding principal and accrued interest in the amount of $0.6 million on this note payable.

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.

In the event DermTech Operations consummated, on or before the maturity date, an equity financing pursuant to which it sold shares of equity in a transaction that did not constitute a Qualified Financing, then the note holders had the option, but not the obligation, to elect to treat such equity financing as a Qualified Financing on the same terms set forth in these 2018 Bridge Notes.

In addition, the note holders could have elected to convert at any time all of the outstanding principal balance under these 2018 Bridge Notes, together with any accrued but unpaid interest, into shares of the DermTech Operations' Series C Preferred Stock ("Optional Conversion"). Upon Optional Conversion of these notes, the note holders were entitled to receive a number of shares of DermTech Operations' Series C Preferred Stock equal to the quotient obtained by dividing the unpaid principal amount of these notes plus interest accrued but unpaid by $9.54, subject to adjustment upon certain events. The note holders would have also received common stock warrants, in substantially the same form as the common stock warrants issued to any purchasers of DermTech Operations' Convertible Series C Preferred Stock.

In the event of a Change of Control (as defined in the 2018 Bridge Note agreements) transaction prior to the payment in full or conversion of these 2018 Bridge Notes, then the note holders could have elected to either:

1) effect the Optional Conversion feature, as discussed above, or

2) demand payment of the outstanding principal amount and the current accrued but unpaid interest of these 2018 Bridge Notes ("Base Amount") plus an amount equal to the Base Amount multiplied by a specified percentage.

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 $0.1 million and $0 for the three months ended September 30, 2019 and 2018, respectively, and were $0.4 million and $0 for the nine months ended September 30, 2019 and 2018, 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 (a "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 5th and June 10th, 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; (iii) the consummation of a liquidation or dissolution of DermTech Operations; (iv) a Liquidation Transaction; or (v) the consummation of a merger of DermTech Operations with Merger Sub, a 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.

In addition to the Qualifying Merger feature, the 2019 Bridge Notes were issued with the same embedded features as the 2018 Bridge Notes, as discussed above, prior to the May 23, 2019 amendment. 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 and nine months ended September 30, 2019 and 2018, the Company recognized losses of $11,000 and $0, respectively, and $14,000 and $0, respectively, on the change in fair value of the derivative liability recognized as other expense on the condensed consolidated Statement of Operations and Comprehensive Loss.

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.

The following table summarizes information about the liability components the Company's 2018 Bridge Notes (in thousands):

2018 Bridge Notes	September 30, 2019	December 31, 2018
Principal amount outstanding	$ —	$ 6,800
Unamortized discount and issuance costs	—	(1,781)
Total current convertible notes payable, net	$ —	$ 5,019

There was no liability balance for the Company's 2019 Bridge Notes as of September 30, 2019 and December 31, 2018.

4. 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

In an effort to raise additional capital, 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 with this offering, exclusive of compensatory warrants issued to the placement agent. During 2018, 506,538 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 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. The following were the features of the Series C Convertible Preferred Stock of DermTech Operations immediately prior to the close of the Business Combination:

Preferred Dividends

Holders of Series C Convertible Preferred Stock were entitled to non-cumulative dividends at a rate of 6% per share of the initial purchase price when and if declared by the board of directors. Any additional dividends shall be distributed to the common shareholders.

Preferred Liquidation Preference

Series C Convertible Preferred Stock was entitled to a per share liquidation preference equal to the initial purchase price plus declared but unpaid dividends. In the event of a liquidation transaction, holders of Series C Convertible Preferred Stock were entitled to receive prior and in preference to any distribution to common stock shareholders.

Redemption

Series C Convertible Preferred Stock did not contain any mandatory redemption features. The Company's convertible preferred stock had 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 control events outside of the Company's control, including liquidation, sale or transfer of control of the Company. The Company had determined not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because of the uncertainty, at the time such convertible preferred stock was outstanding, as to whether or when such events would occur.

Conversion

Series C Convertible Preferred Stock was convertible into common stock at a rate calculated by dividing the initial purchase price by the conversion price. The initial conversion price was equal to the initial purchase price. Under this conversion feature, each share of Series C Convertible Preferred Stock was convertible at the option of the holder or automatically into fully paid, non-assessable shares of common stock at the then effective conversion price for such share immediately upon the earlier of (i) the closing of a public offering of the Company's common stock involving aggregate proceeds of at least $15 million prior to underwriting discounts, commissions and other expense, and a per share price of at least $19.08 (as adjusted for stock splits, stock dividends, reclassifications and the like); or (ii) the date specified by vote or written consent of the holders of a majority of the then outstanding shares of Series C Convertible Preferred Stock voting together as a single class.

Voting Rights

Each holder of common stock is entitled to one vote per share held. Each holder of Series C Convertible Preferred Stock was entitled to the number of votes equal to the number of common shares into which their holdings could be converted. Pursuant to the terms of a voting agreement, preferred and common stockholders voted together as a single class on an as-if-converted basis on all matters including the election of all members of the board of directors.

(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. An aggregate of 1,231 shares of Series A Convertible Preferred Stock for an aggregate purchase price of $4.0 million was issued to certain accredited investors.

Preferred Dividends

Holders of 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 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

Series A Convertible Preferred Stock does not contain any mandatory redemption features. The Company's 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 shares of the Company's common stock at a conversion price per share equal to $3.25, provided that in no event may any shares of the Company's 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 Company's 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) 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.

(e) 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 both September 30, 2019 and December 31, 2018.

Series C Warrants

In connection with DermTech Operations' Series C Preferred Stock financing, 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 229,222 and 292,119 at September 30, 2019 and December 31, 2018, 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. Outstanding placement agent warrants totaled 241,180 at both September 30, 2019 and December 31, 2018.

(f) 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 reserved shares for issuance increased by 203,263 and 255,415 shares for the years ended December 31, 2018 and 2017, respectively. 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. 18,197 and 0.7 million options remain available for future grant under the Plan as of September 30, 2019 and December 31, 2018, 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 vest monthly over a four-year period. Outstanding Management Warrants totaled 22,320 at September 30, 2019 and December 31, 2018.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at September 30, 2019 and December 31, 2018 (in thousands):

	September 30, 2019	December 31, 2018
Warrants to purchase common stock	493	1,177
Public Warrants to purchase common stock*	3,734	3,734
Stock options issued and outstanding	499	535
Restricted stock units issued and outstanding	465	466
Authorized for future option grants	18	689
Total common stock reserved for future issuance	5,209	6,601

* 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 September 30, 2019 and December 31, 2018, respectively, and the effective income tax rate for the Company's provision for income taxes was 0% at September 30, 2019, and December 31, 2018, 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.

During 2018 and 2019, DermTech Operations issued convertible bridge notes that required bifurcation of embedded derivatives for financial statement purposes. As such deferred taxes were established for both the host instrument and the bifurcated embedded derivatives. Although the deferred tax balances offset at issuance, they will differ as the bifurcated embedded derivatives will be marked to fair value on an ongoing basis while the debt discount will be accounted for under the effective interest method.

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 are all parties to the reorganization under IRC Section 368(b). As the transaction qualifies as reorganization under IRC Section 368(a), there are no tax consequences to either DermTech Operations or the Company and all tax attributes retain 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 connection with the Business Combination, the Company assumed all obligations under the lease, as amended, from DermTech Operations. 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 $0.2 million and $0.2 million for the three months ended September 30, 2019 and 2018, respectively, and $0.5 million and $0.5 million for the nine months ended September 30, 2019 and 2018, respectively.

Future minimum operating lease payments for the operating facilities as of September 30, 2019 were (in thousands):

Remainder of 2019	$	142
2020		582
2021		599
2022		153
Total future minimum lease payments	$	1,476

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. If the Company fails to raise such funds by the one-year anniversary of the Business Combination, then then Company will pay to the Underwriters $0.7 million within one week of the one-year anniversary of the Business Combination, and Cowen will have the option to extend the Company's payment deadline for the remaining balance of $0.7 million or receive $0.7 million in value of the Company's common stock (the "Equity Payment") based on the then fair market value of the Company's common stock. The Company's payment to the Underwriters of $1.4 million, or its payment of $0.7 million plus the Equity Payment, in either case, shall satisfy the Company's obligation to pay Cowen the deferred underwriting fees in full, and no further payment of any kind shall 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 $0.2 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, the Company engaged EVERSANA Life Science Services, LLC, or EVERSANA, to provide certain marketing services to the Company. Leana Wood, the spouse of Todd Wood, the Company's Chief Commercial Offer, is an employee of EVERSANA. The Company incurred $0.2 million in costs for both the three and nine months ended September 30, 2019.

There were no other related party transactions identified in 2019 or 2018.

10. Subsequent Events

The Company considered subsequent events through November 7, 2019, 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, 2018 included in our Registration Statement on Form S-4 filed with the Securities and Exchange Commission, or the SEC, on August 7, 2019, as amended.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document, 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. These forward-looking statements are not purely historical regarding DermTech's or its management's intentions, beliefs, expectations and strategies for the future. 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 diagnostics company developing and marketing novel non-invasive gene expression tests to aid in the earliest diagnosis of various skin conditions, including skin cancer, inflammatory diseases, and aging-related conditions. Our technology provides a highly accurate alternative to surgical biopsy, eliminating patient pain, scarring, and risk of infection, while maximizing convenience. Our scalable gene expression assays have been designed to work with a proprietary "adhesive patch biopsy" that provides a tissue sample for analysis non-invasively.

We are initially commercializing tests that will address unmet needs in the diagnostic pathway of pigmented skin lesions, such as moles or dark colored skin spots. Our current products facilitate the clinical assessment of pigmented skin lesions for melanoma. We have initially marketed this test directly to a concentrated group of dermatologists and plan to eventually market the test to primary care physicians and through telemedicine channels. We process our tests in a high complexity molecular laboratory that is Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified and have applicable laboratory licenses in all 50 states in the United States and is certified by the College of American Pathologists. We also provide laboratory services to large pharmaceutical companies on a contract basis for their use in their clinical trials for new drugs. We have a history of net losses since our inception.

Financial Overview

Revenue

We generate revenue through laboratory services that are billed to 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 providers 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, or ASC, 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 increased costs from being a public company.

Recent Developments

Convertible Bridge Notes

On May 23, 2019, DermTech Operations, Inc. (formerly known as DermTech, Inc., or DermTech Operations), a wholly-owned subsidiary of the Company, and various holders of our 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; (iii) the consummation of a liquidation or dissolution of the Company (iv) a Liquidation Transaction; or (v) the consummation of a merger with or into the Company or any of its subsidiaries.

Between June 5th and June 10th, 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; (iii) the consummation of a liquidation or dissolution of DermTech Operations; (iv) a Liquidation Transaction: or (v) the consummation of a merger of DermTech Operations with DT Merger Sub, Inc., a 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 the 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.

Shortly 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. 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 (on a split-adjusted basis) under the ticker symbol "DMTK."

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 PIPE Financing, an aggregate of 3,076,925 shares of common stock and 1,231 shares of Series A Convertible Preferred Stock, 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.

Results of Operations

Three and Nine Months Ended September 30, 2019 and September 30, 2018

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. Billable samples increased to 3,596 for the three months ended September 30, 2019 compared to 3,043 for the three months ended September 30, 2018. As a result of the increase in billable samples, assay revenues increased $0.1 million or 20% to $0.4 million for the three months ended September 30, 2019 compared to $0.3 million for the three months ended September 30, 2018. Billable samples increased to 8,809 for the nine months ended September 30, 2019 compared to 8,449 for the nine months ended September 30, 2018. As a result of the increase in billable samples, assay revenues increased $0.1 million or 6% to $0.9 million for the nine months ended September 30, 2019 compared to $0.9 million for the nine months ended September 30, 2018. 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 decreased $0.1 million or 44% to $0.2 million for the three months ended September 30, 2019, compared to $0.3 million for the three months ended September 30, 2018. Contract revenues with major pharmaceutical companies decreased $0.1 million or 9% to $0.9 million for the nine months ended September 30, 2019, compared to $1.0 million for the nine months ended September 30, 2018. 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 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 September 30, 2019, the deferred revenue amount for these contracts, which is the advanced payments minus the value of work performed, was $1.5 million. These advanced payments will remain in deferred revenue until we process the laboratory portion of the contracts allowing it to recognize the revenue.

Cost of Revenue

Cost of revenues increased $0.1 million or 13% to $0.8 million for the three months ended September 30, 2019 compared to $0.7 million for the three months ended September 30, 2018. Cost of revenues increased $0.1 million or 3% to $2.1 million for the nine months ended September 30, 2019 compared to $2.0 million for the nine months ended September 30, 2018. The increase was largely attributable to a higher billable sample volume in 2019 and to the integration of a new laboratory information system, which was implemented in March of 2019. 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 costs 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 $1.3 million or 193% to $2.0 million for the three months ended September 30, 2019 compared to $0.7 million for the three months ended September 30, 2018. Sales and marketing expenses increased $1.7 million or 78% to $3.8 million for the nine months ended September 30, 2019 compared to $2.2 million for the nine months ended September 30, 2018. The increase was primarily attributable to higher compensation related costs from the hiring of a new Chief Commercial Officer and expansion of the existing sales force as well as increased spending on advertising activities to increase market exposure. As additional funding becomes available and approval by Medicare nears, we expect to significantly add to our specialty sales force and payer access teams throughout 2020 and 2021, which would significantly increase our sales and marketing expenses.

Research and Development

R&D expenses increased $0.2 million or 38% to $0.8 million for the three months ended September 30, 2019 compared to $0.5 million for the three months ended September 30, 2018. R&D expenses increased $0.2 million or 14% to $1.8 million for the nine months ended September 30, 2019 compared to $1.6 million for the nine months ended September 30, 2018. 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 $2.4 million, or 282%, to $3.2 million for the three months ended September 30, 2019 compared to $0.8 million for the three months ended September 30, 2018. General and administrative expenses increased $3.8 million, or 146%, to $6.4 million for the nine months ended September 30, 2019 compared to $2.6 million for the nine months ended September 30, 2018. The increase was largely due to higher audit and legal costs surrounding the filing of the Registration Statement and other SEC statements in connection with the Business Combination and preparing quarterly condensed consolidated financial statements. As a result of the completion of the Business Combination, we expect to have increased public company expenses including much higher legal, accounting, stock exchange and insurance costs. Also, as we grow our sales force, additional infrastructure such as human resources, information technology and legal resources will be necessary.

Interest Expense

Interest expense increased $0.3 million or 263% to $0.4 million for the three months ended September 30, 2019 compared to interest expense of $0.1 million for the three months ended September 30, 2018. Interest expense increased $2.5 million or 2,687% to $2.7 million for the nine months ended September 30, 2019 compared to interest expense of $0.1 million for the nine months ended September 30, 2018. The significant increase was primarily due to the interest and amortization of debt discount related to our previously outstanding convertible bridge notes. As these convertible bridge notes were extinguished in connection with the Business Combination, we do not expect any additional significant interest expense for future reporting periods.

Other Expense

Other expense increased $0.1 million or 100% to $0.1 million for the three months ended September 30, 2019 compared to other expense of zero for the three months ended September 30, 2018. Other expense increased $0.4 million or 100% to $0.4 million for the nine months ended September 30, 2019 compared to other expense of zero for the nine months ended September 30, 2018. This increase is related to change in fair value of derivative liability of the previously outstanding convertible bridge notes from financial reporting periods. As these convertible bridge notes were extinguished in connection with the Business Combination, we do not expect to incur other expense in future reporting periods.

Liquidity and Capital Resources

We have never been profitable and have historically incurred substantial net losses, including net losses of $8.4 million in 2017, $10.0 million in 2018 and $14.6 million for the nine months ended September 30, 2019. As of September 30, 2019, our accumulated deficit was $86.0 million, and we had negative operating cash flow of $11.7 million. In connection with the Business Combination, we completed a 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. 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 operations and cash flows.

As of September 30, 2019, our cash and cash equivalents totaled approximately $21.4 million. Based on our current business operations, we believe our current cash and cash equivalents will not be sufficient to meet our anticipated cash requirements for at least the next twelve months. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements including due to changes in our business operations, a lengthier sales cycle, lower demand for our products or other risks, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. 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;
- 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
- costs related to international expansion.

Cash Flow Analysis

Nine Months Ended September 30, 2019

Net cash used in operating activities for the nine months ended September 30, 2019 totaled $11.7 million, primarily driven by the $14.6 million net loss offset by non-cash related items, including $2.0 million in amortization of the convertible bridge notes debt discount, $1.2 million in stock-based compensation and $0.4 million in the change in the convertible bridge notes derivative liability, offset by the gain on extinguishment of convertible notes of $0.9 million. In addition, we amassed $1.3 million of cash inflow through the buildup of accounts payables and accrued compensation offset by the cash outflow of $1.4 million related to payments for prepaid insurance payments for increased insurance coverage.

Net cash used in investing activities totaled $0.1 million, which relates predominantly to the purchase of laboratory equipment. As we scale our sales force and the resulting assay volume, additional laboratory equipment investment will be needed to install complex automation systems and other genomic testing equipment.

Net cash provided by financing activities was $28.4 million for the nine months ended September 30, 2019, which was driven by the $25.6 million in net proceeds raised from the Business Combination and related PIPE financing. In order to continue to fund future operations, we expect to complete a private or public offering during 2020.

Off-Balance Sheet Arrangements

As of September 30, 2019 and December 31, 2018, 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

The preparation of condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles 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 but not limited to those related to test revenue, warrants, stock-based compensation, accounts receivable, expense accruals, convertible debt, the realization of deferred tax assets, and common and preferred stock valuations. Actual results may differ from those estimates.

While our significant accounting policies are more fully described in Note 1 of our condensed consolidated financial statements included in this quarterly report, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition

Our revenue is generated from two revenue streams, contract revenue and assay revenue. We account for revenue in accordance with ASC 606.The core principle of ASC 606 is that we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect 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 recognize revenue from our contract and assay goods and service in accordance with that core principle and key aspects considered by us include the following:

(a) 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. laboratory revenues result 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 our patented adhesive patch biopsy devices, assay development for research partners, ribonucleic acid, or RNA isolation, expression, amplification and detection, including data analysis and reporting.

Contracts

As part of our contract revenue, we have established contracts and work orders with pharmaceutical partners that all fall under the scope of ASC 606.

Performance obligations

ASC 606 requires an entity to assess the goods or services promised in a contract and identify as a performance obligation each promise to transfer to the customer either a good or service (or a bundle of goods or services) that is distinct, or a series of distinct goods or services that are substantially the same and that have the same pattern of transfer to the customer. Based upon review of existing contracts, a majority of our contract revenue contracts contain three performance obligations:

(1) Adhesive patch kits

(2) RNA extractions and analysis

(3) Certain project management fees

Many of the contract revenue contracts contain promises such as start-up activities and quality system setup fees, which are activities that are performed to fulfill the contract and they do not transfer any good or service to the customer. These promises encompass the administrative tasks associated with beginning and initiating a new project or study with a pharmaceutical company. In accordance with ASC 606, an entity does not account for these activities as a promised good or service within the contract nor evaluate whether they are a performance obligation.

Transaction price

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

The transaction prices of all the performance obligations are listed in each contract on a per unit basis and are fixed based for the adhesive patch kits and RNA extractions and analysis. The project management fees are assessed based on a monthly service fee which range within the contracts depending on certain factors which include length of project and amount of kits or RNA extractions and analysis promised within the contract. The fixed and variable rates are materially consistent within all contracts. Therefore, we utilize the prices listed in each of our contracts as the transaction price for each performance obligation.

In determining the transaction price, ASC 606 requires an entity to adjust the promised amount of consideration for the effects of the time value of money if the contract contains a significant financing component. All contracts state fixed transaction prices for each deliverable associated with the contract and does not qualify for the significant financing component of ASC 606.

Allocate the transaction price

All contracts have a directly observable transaction price pertaining to each promised good or service. Those prices are consistent across all contracts for adhesive patch kits and RNA extractions and analysis, with the exception of project management fees, which encompass a sufficiently narrow range of prices that are dictated upon factors of each contract previously discussed above. Therefore, we rely on those transaction prices as the basis to allocate the stand-alone selling prices to the performance obligations of the contract.

Most contracts contain a discount that is allocated to all items within the contract, whether they are performance obligations or not. Those items that are not performance obligations (e.g. quality system setup and start up fees) have the associated discount allocated to the transaction prices of the performance obligations evenly.

Recognize Revenue

An entity should recognize revenue when (or as) it satisfies a performance obligation by transferring a promised good or service to a customer. A good or service is transferred when (or as) the customer obtains control of that good or service. The adhesive patch kits are recognized as point in time when shipped to the customer. The RNA extraction and analysis are recognized at a point in time when the extraction process is complete, and the results are sent to the customer. We provide project management service over the life of the contract, providing equal benefit to the customer throughout the life of the project or study. Therefore, the revenue related to project management fees is recognized straight-line over the life contract.

(b) Assay Revenue

We generate revenues from our Pigmented Lesion Assay, or PLA, and Nevome services we provide to dermatologists in various states throughout the United States to assist in a clinician's diagnosis of melanoma. We provide prescribing dermatologists with our 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 our CLIA laboratory for analysis. The patient RNA and deoxyribonucleic acid, or 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 results of the pigmented skin lesion indicating whether the sample collected is indicative of melanoma or not. A detailed analysis of payments made to us by private health insurance companies for the assays over several quarters is used to estimate the ultimate receipt of funds for payment of billed amounts. These payments can vary widely from insurer to insurer and can be halted for routine audits or other reasons.

Contracts

Our customer is the patient. However, we do not enter into a formal reimbursement contract with a patient, as formal reimbursement contracts are more commonly established with insurance payers. Accordingly, we establish a contract with a patient in accordance with other customary business practices.

- Approval of a contract is established by the use of the adhesive patch kit on a patient by an ordering physician, which is then sent to our central lab for testing.
- We are obligated to perform our laboratory services upon receipt of a sample from a physician, and the patient and/or applicable payer are obligated to reimburse us for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits.
- Once the patient's test results are delivered to the ordering physician, we are legally able to collect payment and bill an insurer and/or patient, depending on payer contract status or patient insurance benefit status.
- Consideration is deemed to be variable, and we consider collection of such consideration to be probable to the extent that it is unconstrained.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. The customer is able to order a PLA test. However, a Nevome test cannot be ordered separately from the PLA test and it is contingent on being run only when a PLA test comes back positive on a sample. The Nevome test would not qualify as a distinct service. Therefore, the PLA test is recognized as a single performance obligation and the Nevome test, if rendered, is bundled with the single PLA performance obligation.

Transaction price

The transaction price is the amount of consideration that we expect to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected from a contract with a customer may include fixed amounts, variable amounts, or both.

The consideration derived from our contracts is deemed to be variable, though the variability is not explicitly stated in any contract. Rather, the implied variability is due to several factors, such as the amount of contractual adjustments, any patient co-payments, deductibles or patient compliance incentives, the existence of secondary payers and claim denials.

We estimate the amount of variable consideration using the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, we consider several factors, such as historical collections experience, patient insurance eligibility and payer reimbursement contracts.

We limit the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, We recognize revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made.

We monitor our estimates of transaction price to depict conditions that exist at each reporting date. If we subsequently determine that we will collect more consideration than we originally estimated for a contract with a patient, we will account for the change as an increase in the estimate of the transaction price (i.e., an upward revenue adjustment) in the period identified. Similarly, if we subsequently determine that the amount we expect to collect from a patient is less than it originally estimated, we will generally account for the change as a decrease in the estimate of the transaction price (i.e., a downward revenue adjustment), provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

When we do not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon delivery of a patient’s test result to the ordering physician, with recognition, generally occurring at the date of cash receipt.

Allocate the transaction price

The entire transaction price is allocated entirely to the single performance obligation contained within the contract with a patient.

Recognize revenue

Our single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient’s successful test result is delivered to the patient’s ordering physician. We consider this date to be the time at which the patient obtains control of the final results of the promised test service.

If a Nevome test service is ordered and completed in conjunction with our PLA service, then we will recognize revenue point in time upon the delivery of the both final reports to the physician. The delivery of our Nevome test results is commonly after our PLA results are delivered due to the circumstances of how we process the Nevome test. However, this length in time is determined to not materially impact the final overall revenue recognition timing.

Stock-Based Compensation

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 straight-line basis.

We grant 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, outside valuation experts and quoted prices of our stock in active markets. The board of directors and outside valuation experts determine the fair value of the underlying stock by considering a number of factors, including historical and projected financial results, the risks we faced at the time, the preferences of our debt holders and preferred stockholders, and the lack of liquidity of our common stock that occurred prior to the Business Combination.

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, net of estimated forfeitures, using the straight-line 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. 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 our expectation of not paying dividends in the foreseeable future.

We account 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 have a requisite service period of 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, or RSU, 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, input from outside valuation experts and subsequent to the close of the Business Combination, the closing stock price on the date of grant. We recognize stock-based compensation expense based on the fair value on a straight-line basis over the requisite service periods of the awards, taking into consideration estimated forfeitures. RSUs that are granted to employees have a requisite service period between two and four years.

Recent accounting pronouncements

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. This new standard is effective for interim and annual periods beginning January 1, 2020 and early adoption is permitted. We are currently evaluating the impact of this standard on our condensed consolidated financial statements.

In June 2019, the 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 resulting from expanding the scope of Topic 718, Compensation—Stock Compensation, to 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. We are currently evaluating the impact of this standard 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. We are currently evaluating the impact of this standard on our condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Our exposure to market risk is principally confined to our cash and cash equivalents. The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds, U.S. Treasury debt and corporate debt securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

Our assets and liabilities are denominated in U.S. dollars. Consequently, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

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 September 30, 2019, 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.

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.

PART II—OTHER INFORMATION

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.

Risks Related to DermTech's Business

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 sustained profitability.

We have historically incurred substantial net losses in each year since our inception, including net losses of $14.6 million for the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $86.0 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.

Our independent registered public accounting firm's report for the years ended December 31, 2018 and 2017 includes an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

Due to the deficit that we have accumulated since our inception, in their report on our audited annual condensed consolidated financial statements as of and for the years ended December 31, 2018 and 2017, our auditors, which we inherited from DermTech Operations at the time of the Business Combination, included an explanatory paragraph regarding concerns about our ability to continue as a going concern. Recurring losses from operations raise substantial doubt about our ability to continue as a going concern. 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. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our condensed consolidated financial statements. In addition, the inclusion of an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern and our lack of cash resources may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

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 for any of our tests as we operate under the CLIA guidelines. 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 test;
- the reimbursement of our tests by Medicare and private payers;
- our ability to obtain and maintain any necessary regulatory approval for any of our tests in the United States and foreign jurisdictions;
- potential side effects of our tests that could delay or prevent commercialization, limit the indications for any of our tests, require the establishment of risk evaluation and mitigation strategies, 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 products;
- our ability to establish or maintain collaborations, 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 products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary technology platform to discover and develop additional product 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.

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 condensed consolidated financial statements.

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

Physicians, including dermatologists, may not order our current Pigmented Lesion Assay, or PLA, our Nevome test, or our planned tests unless third-party payers, such as managed care organizations and government payers (e.g., Medicare and Medicaid), pay a substantial portion of the test price. Coverage and reimbursement by a third-party payer may depend on a number of factors, including a payer'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 payer reimbursement of any test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payers and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation. We filed an application for a technology assessment in April of 2018, and the comment period for the accompanying Medicare Draft Local Coverage Decision, or Draft LCD, closed in August of 2018. In March 2019, a Draft LCD proposed coverage for the PLA. In late October 2019, the AMA provided DermTech with a Proprietary Laboratory Assay code ("PLA Code") of 0089U. Pricing for the PLA Code is expected to be published as part of the CMS Laboratory Fee Schedule for 2020 in late December 2019. A Medicare Final Coverage Decision, or Final LCD, could be available in the fourth quarter of 2019. If the Final LCD maintains the coverage proposal in the Draft LCD, the PLA will be eligible for Medicare reimbursement. If the Final LCD reverses the coverage proposal in the Draft LCD, our business will be significantly impacted due to lack of Medicare coverage. In addition, after submission of the technology assessment in April of 2018, we are prohibited from submitting claims to Medicare. Therefore, although we previously submitted claims to Medicare which were reviewed on a case-by-case basis, we no longer have any Medicare revenue stream pending the outcome of the technology assessment and the finalization of a Local Coverage Decision. Currently the Nevome test does not have Medicare reimbursement.

Because each payer generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our tests, seeking payer 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 payers 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 payers 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 and adequate reimbursement rates for our tests. If we cannot obtain coverage and reimbursement from private and governmental payers 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 Medicare Clinical Laboratory Fee Schedule. These reductions may also impact our PLA and Nevome tests and may also impact tests we develop in the future. Because of the cost-trimming trends, third-party payers 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 payers 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 payers 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 payers 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 payers 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 payers 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 typically are unable to collect substantial payments from patients beyond that which is paid by their insurance and therefore experiences 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 payers;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid;
- disputes among payers as to which party is responsible for payment;
- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- 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 payers 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 September 30, 2019, our cash and cash equivalents totaled approximately $21.4 million. Based on our current business operations, we believe our current cash and cash equivalents, will not be sufficient to meet our anticipated cash requirements for at least the following twelve months. If our available cash balances are insufficient to satisfy our liquidity requirements including due to changes in our business operations, a lengthier sales cycle, lower demand for our products, or other risks described in this report, we may seek to raise additional capital through equity offerings, debt financings, collaborations, or licensing arrangements. 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 development activities and efforts of any 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
- costs related to 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 DermTech, or a combination of both. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled "*DermTech Management's Discussion and Analysis of Financial Condition and Results of Operations – Nine Months Ended September 30, 2019 and 2018 – 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 payers 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 sustained 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 nine months ended September 30, 2019, DermTech's R&D expenses were $1.8 million, our sales and marketing expenses were $3.9 million and our general and administrative expenses were $6.4 million. For the year ended December 31, 2018, our R&D expenses were $2.1 million, our sales and marketing expenses were $2.8 million and our general and administrative expenses were $3.5 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 develops new tests. As a result, we need to generate significant revenues in order to achieve sustained profitability.

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

We launched 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 that 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 or 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 or meet our anticipated revenue projections.

If we are unable to execute our marketing strategy for PLA or the Nevome test 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 healthcare 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 programs, and other third-party payers 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.

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, and results of operations.

Our future success will depend in part upon our ability to enhance our PLA, the Nevome test, 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, the Nevome test, 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.

As we develop 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 Fischer 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 and Nevome tests, 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 manufacturing 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 and results of operation.

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 the scope of 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.

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 Food and Drug Administration, or 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 payers 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 and the Nevome test changes the decision-making of the dermatologist toward making a surgical biopsy decision, particularly to avoid making 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 Carcinome 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 plan to introduce, 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., DermTech’s Chief Executive Officer and President. 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 and President, 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 executive officers have 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 currently rely on third-party suppliers for critical materials needed to perform our current tests and our planned future tests and any problems experienced by them could result in a delay or interruption of their supply to us.

We currently purchase raw materials for our tests and products under purchase orders and does not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our materials or reagents, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in manufacturing or performing our tests while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier’s operations could have a significant negative impact on our ability to perform tests in a timely manner.

Some of the components used in our current or planned products are currently sole source, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our single source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities. In addition, one or more components used in our current, or future planned, products may be patented by a third party and may not have any substantial non-infringing uses, in which case, any inability to secure a license to such components on terms that are commercially reasonable to us may have a material impact on our business and render it difficult or impracticable for us to continue to offer our current and future planned tests and products.

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, 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 bring new equipment on line, implement new 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 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 us 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, the Nevome test, 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;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes, or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our current 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 disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

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

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

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit, and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve, or it deteriorates, our business, including our access to patient samples and the addressable market for diagnostic tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payers, could be adversely affected, resulting in a negative impact on our business, financial condition, and results of operations.

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

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

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. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended and strengthened the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also created notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have 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. 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.

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 payers, 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 an adverse effect on our business.

We rely on Federal Express Corporation, or FedEx, and United Parcel Service of America, Inc., or UPS, for the distribution of our products and, if FedEx or UPS incurs any damage to the facilities where our products are processed or is unable to distribute 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 products. The FedEx or UPS facilities where our products are processed may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, power outages, communications failure, or terrorism. Any material destruction to the facilities where our products are processed 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 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 products to be returned, or receipt of products 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.

Regulatory Risks Relating to Our Business

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

In the United States, the current trend is toward legislative and regulatory changes at the federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, became law. The ACA substantially changed the way healthcare is financed by both commercial payers and government payers and thus significantly impacted our industry. The ACA contained a number of provisions expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in state and federal health care programs, reimbursement changes and fraud and abuse, which will impact existing state and federal health care programs and will result in the development of new programs. For instance, the ACA required each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, and began to apply to sales of taxable medical devices after December 31, 2012. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. It is unclear at this time when, or if, sales of our laboratory developed tests, or LDTs, will trigger the medical device tax, and it is possible that this tax will apply to some or all of our existing tests or tests we may develop in the future. If so, the taxes imposed by the ACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us and lower reimbursement by payers for our tests, any of which may have a material adverse impact on our business, financial condition, results of operations or cash flows. The ACA also contains a number of other provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse, which we expect will impact our industry and our operations in ways that we still cannot predict.

Further, the ACA established the Physician Payments Sunshine Act, or the Sunshine Act, which imposes new 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 Sunshine Act provisions of the ACA at this time. However, if the FDA later determines that

the Adhesive Skin 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 would be subject to its reporting requirements. In addition, certain of our subsidiaries may be found to be subject to the reporting requirements to the extent they provide assistance and support to us with respect to the manufacturing, marketing promotion, sale or distribution of our covered products. It is difficult to predict how the requirements would impact existing relationships among manufacturers, distributors, physicians, and teaching hospitals. The Sunshine Act preempts similar state reporting laws, but we or our subsidiaries could be required to report under certain provisions of such state laws. Failure to comply with the Sunshine Act could subject us to civil monetary penalties.

Additionally, the ACA introduced mechanisms to reduce the per capita rate of growth in Medicare spending if expenditures exceed certain targets. Any such reductions could affect reimbursement payments for our tests. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from payers, including commercial payers and government payers. We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or how any such legislation or regulation may affect us. For instance, the payment reductions imposed by the ACA and the changes to reimbursement amounts paid by Medicare for tests such as ours based on the procedure set forth in PAMA, could limit the prices we will be able to charge or the amount of available reimbursement for our tests, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future. For instance, there is uncertainty regarding the continued effect of the ACA in its current form following the results of the 2016 U.S. presidential election and in light of the policies of the current administration. Since 2016 there have been efforts to repeal all or part of the ACA, and the current Presidential Administration and the U.S. Congress have taken action to roll back certain provisions of the ACA. For example, the Tax Cuts and Jobs Act, or the TCJA, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. The current Presidential Administration and the U.S. Congress may take further action regarding the ACA, including, but not limited to, repeal or replacement. Additionally, all or a portion of the ACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business. Further, the impact on our business of the expansion of the federal and state governments' role in the U.S. healthcare industry generally, including the social, governmental, and other pressures to reduce healthcare costs while expanding individual benefits, is uncertain. Any future changes or initiatives could have a materially adverse effect on our business, financial condition, results of operations, and cash flows.

Similarly, commercial payers may seek to reduce costs by reducing coverage or reimbursement for our tests. Any government-adopted reform measures or changes to commercial third-party payer coverage and reimbursement policies could cause significant pressure on the pricing of, and reimbursement for, health care products and services, including our tests, which could decrease demand for our tests, and adversely affect our sales and revenue.

In addition, some payers have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as us, of active laboratory benefit management by third parties is unclear, and we expect that it would have a negative impact on our revenue in the short term. It is possible that payers will resist reimbursement for tests that we offer, in favor of less expensive tests, may require pre-approval for our tests or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our tests. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current tests and any future tests we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of payers for our tests. However, we cannot predict whether, under what circumstances, or at what payment levels payers will cover and reimburse our tests. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

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

CMS adopted a new coding set for diagnoses, commonly known as ICD-10-CM, which significantly expanded the previous coding 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 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 payers, 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 payers, including Medicare, Medicaid, private insurance companies, and patients, all of which have different billing requirements. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased 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 which 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 payers as to which party is responsible for payment; resistance by patients to cover any substantial amount of the payment;
- differences in coverage among payers and effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- 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. Payers also conduct external audits to evaluate payments, which add 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. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many private third-party payers, for laboratory testing services. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance, and inspections. We have a current certificate of registration from 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. Moreover, CA LFS and/or CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The biennial survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization. Sanctions for failure to comply with 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. Some states have enacted state licensure laws that are more stringent than CLIA.

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. Currently we are receiving samples from all 50 U.S. states and certain provinces in Canada. Each state maintains independent licensure, registration, or certification procedures that it must maintain compliance with 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. If the CLIA certificate of our laboratory is revoked, that could also impact our licensure or certification in the states or in foreign jurisdictions.

We are also accredited from the College of American Pathologists, or CAP, which is a higher standard than that of the CLIA regulations. CAP is an independent, non-governmental organization of board-certified pathologists that accredits laboratories nationwide on a voluntary basis and that has been recognized by CMS as an accreditation organization to inspect laboratories to determine adherence to the CLIA standards. Since CAP has deemed status with CA LFS, our post-CAP re-accreditation inspections will be performed by teams formed by CAP. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. Failure to maintain CAP accreditation 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.

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

Although the FDA maintains that it has authority to regulate the development and use of LDTs, such as our and many other laboratories' test as medical devices, it has not exercised its authority with respect to most LDTs as a matter of enforcement discretion. The FDA could, at any time, change its policy with regard to this matter.

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. 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 regulation, but is currently exempt from premarket review by the FDA. However, the FDA could assert this device is Class II, which would subject it and our assay 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 determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations, or financial condition.

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. Moreover, the FDA has issued draft guidance and a 2017 Discussion Paper to allow for further public discussion about an appropriate LDT oversight approach and to give congressional committees the opportunity to develop a legislative solution. The FDA has also solicited public input and published two draft guidance documents relating to FDA oversight of NGS-based tests. These two draft guidance documents describe the FDA's thinking and proposed approach regarding the possible use of FDA-recognized standards to support analytical validity, and public human genetic variant databases to support clinical validity, of these tests. Additionally, two different bi-partisan bills have been circulated as discussion drafts in Congress, both of which reflect FDA policy positions and seek to establish new regulatory frameworks for laboratory testing, including the type of testing we provide.

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, we could for the first time be subject to enforcement of 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 can be lengthy, expensive, time-consuming, and unpredictable. Further, obtaining premarket clearance 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.

The requirement of premarket review could negatively affect our business until such review is completed and clearance to market or approval is obtained. The FDA could require that we stop selling our tests pending premarket clearance or approval. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are limited, orders from dermatologists or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) or other premarket submission, or filing a premarket approval application, or PMAA, with the FDA. If the FDA requires 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 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 uses 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 the 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.

If we were required 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 approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.

If the FDA decides to require that we obtain 510(k) clearance, premarket approvals pursuant to a PMAA, or any other type of premarket submission in order to commercialize our current PLA, the Nevome test, or our planned future tests, we may be required to conduct additional premarket clinical testing before submitting a regulatory notification or application for commercial sales. In addition, as part of our long-term strategy we may plan to seek FDA clearance or approval; however, we would need to conduct additional clinical validation activities on our tests before we can submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or the FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our tests. We believe we 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 our clinical trials are completed as planned, we cannot be certain that their results will 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 premarket clinical trials, 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 indicated uses, 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. 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 or to achieve sustained profitability.

If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition.

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;
- 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 strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general and impose 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 law, or the 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 payer, including private insurers;
- the Sunshine Act, which requires medical device manufactures to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members;
- Section 216 of the PAMA, which requires applicable laboratories to report private payer 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 (EKRA) was enacted as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). EKRA is an all-payer 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.

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 civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratories' ability to provide or receive payment for our services. 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 payers.

We are subject to numerous federal and state healthcare statutes 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.

Federal and state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, unlawful trade practices, kickbacks, patient inducement and statutory or common law fraud restrict the provision of items or services for free or at reduced charge to government health care program beneficiaries. Such state laws may also restrict the provision of items or services for free or at a reduced charge to non-government health care program beneficiaries. These laws and regulations relating to the provision of items or services for free are complex and are subject to interpretation by the courts and by government agencies. We do not currently charge Medicare or Medicaid beneficiaries for our tests nor do we submit claims to any federal healthcare program.

To the extent our business operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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 and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including current or future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the 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 patients. 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 prohibitions, commonly known as the Stark Law, unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories.

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 may be required to comply with laws and contractual obligations governing the transmission, security, and privacy of health information, or other information, including personally identifiable information and payment information, including credit card information, that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of HIPAA, HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of 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. The collection and use of such information is regulated at the federal and state levels, and may be subject to contractual obligations as well. The regulatory environment related to information security and privacy is increasingly demanding. 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. Our reputation as a brand or as an employer could also be adversely affected from these types of security breaches or regulatory violations, which could impair our sales or ability to attract and keep qualified employees.

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

In the United States, the current trend is toward legislative and regulatory changes at the federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA, became law. This law substantially changed the way health care is financed by both commercial payers and government payers, and significantly impacted our industry. Since 2016 there have been efforts to repeal all or part of the ACA, and the current Presidential Administration and the U.S. Congress have taken action to roll back certain provisions of the ACA. For example, the Tax Cuts and Jobs Act, or the TCJA, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. The current Presidential Administration and the U.S. Congress may take further action regarding the ACA, including, but not limited to, repeal or replacement. Additionally, all or a portion of the ACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

The ACA contained a number of provisions expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in state and federal health care programs, reimbursement changes and fraud and abuse, which will impact existing state and federal health care programs and will result in the development of new programs. For instance, the ACA required each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, and began to apply to sales of taxable medical devices after December 31, 2012. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The taxes imposed by the ACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us and lower reimbursement by payers for our tests, any of which may have a material adverse impact on our business, financial condition, results of operations or cash flows.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from payers, including commercial payers and government payers.

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

Clinical research is subject to federal, state, and, for studies conducted outside of the United States, international regulation. At the federal level, the FDA imposes regulations for the protection of human subjects and requirements such as initial and ongoing institutional review board review; informed consent requirements, adverse event reporting and other protections to minimize the risk and maximize the benefit to research participants. Many states impose human subject protection laws that mirror or in some cases exceed federal requirements. HIPAA also regulates the use and disclosure of 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.

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

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our PLA could lead to product liability claims if someone were to allege that it failed to perform as it was designed. We may also be subject to liability for errors in results we provide to physicians or for misunderstanding of, or inappropriate reliance upon, the information we provide. We may also be subject to similar types of claims related to products we may develop in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims, or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions 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 cause injury to our reputation or cause us to suspend sales of our product. The occurrence of any of these events could have an adverse effect on our business results of operations.

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 sustained 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, four pending U.S. patent applications, and their corresponding foreign counterpart patents and patent 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. Ambry 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.

In general, 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 net operating loss carryforwards, or NOLs, may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after a merger transaction, 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.

The recently passed comprehensive tax reform bill 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 net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, 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 overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of the combined company's 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 condensed 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 securityholders and reduce the price of our securities.

Any future issuance of our equity securities could dilute the interests of our then existing securityholders 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, dated June 19, 2017, between us and Continental Stock Transfer & Trust Company, as warrant agent. 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 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 created by the expansion of our board of directors or the resignation, death or removal of a director;
- 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 not less than 66 2/3% 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 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 for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; 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 Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

This choice of 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 choice of forum provisions contained in our 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.

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. 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 product 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.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference File No.	Date Filed
2.1	Agreement and Plan of Merger, dated as of May 29, 2019, by and among the Company, DermTech Operations, Inc. and DT Merger Sub, Inc., as amended, included as Annex A to the proxy statement/prospectus/information statement forming a part of the referenced filing.		S-4/A	333-232181	8/7/2019
2.2	First Amendment to Agreement and Plan of Merger, dated as of August 1, 2019, by and among the Company, DermTech Operations, Inc. and DT Merger Sub, Inc.		S-4/A	333-232181	8/2/2019
3.1	Amended and Restated Certificate of Incorporation of the Company, included as Annex D to the proxy statement/prospectus/information statement forming a part of the referenced filing.		S-4/A	333-232181	8/7/2019
3.2	Form of Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, included as Annex F to the proxy statement/prospectus/information statement forming a part of the referenced filing.		S-4/A	333-232181	8/7/2019
3.3	Form of Certificate of Designation of Preferences Rights and Limitations of Series A Convertible Preferred Stock of the Company		S-4/A	333-232181	8/2/2019
3.4	Bylaws of the Company, included as Annex C to the proxy statement/prospectus/information statement forming a part of the referenced filing.		S-4/A	333-232181	8/7/2019
4.1	Specimen Warrant Certificate of the Company		S-1/A	333-218093	6/9/2017
4.2	Warrant Agreement, dated June 19, 2017, between the Company and Continental Stock Transfer & Trust Company		8-K	001-38118	6/23/2017
4.3	Form of Management Warrant		8-K	001-38118	9/5/2019
4.4	Form of Series C Warrant		8-K	001-38118	9/5/2019
4.5	Form of Placement Agent Warrant		8-K	001-38118	9/5/2019
10.1	Form of Indemnification Agreement of the Registrant		8-K	001-38118	9/5/2019
10.2	Registration Rights Agreement, dated August 29, 2019, by and among the Company, certain stockholders of the Company and certain stockholders of DermTech Operations, Inc.		8-K	001-38118	9/5/2019
10.3	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital (AM) Investors, L.P.		S-4/A	333-232181	8/7/2019
10.4	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital F5 Master I, L.P.		S-4/A	333-232181	8/7/2019
10.5	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital Institutional Partners, L.P.		S-4/A	333-232181	8/7/2019

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference File No.	Date Filed
10.6	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital Institutional Partners II, L.P.		S-4/A	333-232181	8/7/2019
10.7	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital Institutional Partners III, L.P.		S-4/A	333-232181	8/7/2019
10.8	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital Offshore Investors II, L.P.		S-4/A	333-232181	8/7/2019
10.9	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Farallon Capital Partners, L.P.		S-4/A	333-232181	8/7/2019
10.10	Amended and Restated Subscription Agreement, dated August 1, 2019, between the Company and Four Crossings Institutional Partners V, L.P.		S-4/A	333-232181	8/7/2019
10.11	Subscription Agreement, dated May 22, 2019, between the Company and Victory RS Science and Technology Fund		S-4/A	333-232181	8/7/2019
10.12	Subscription Agreement, dated May 22, 2019, between the Company and The Irwin Mark and Joan Klein Jacobs Family Trust UA DTD 6/20/80		S-4/A	333-232181	8/7/2019
10.13	Subscription Agreement, dated May 23, 2019, between the Company and Jacobs Investment Company LLC		S-4/A	333-232181	8/7/2019
10.14	Subscription Agreement, dated May 23, 2019, between the Company and RTW Master Fund, Ltd. and RTW Innovation Master Fund, Ltd.		S-4/A	333-232181	8/7/2019
10.15	Omnibus Common Share Subscription Agreement Amendment, dated as of August 1, 2019, by and among the Company and the Common Share Purchasers		S-4/A	333-232181	8/7/2019
10.16	Subscription Agreement, dated August 1, 2019, between the Company and HLM Venture Partners IV, L.P.		S-4/A	333-232181	8/7/2019
10.17	Amendment No. 1 to Letter Agreement, dated August 28, 2019 by and among the Company and each of its previous sponsor, directors and officers.	X			
10.18	Employment Agreement, dated June 26, 2012, between DermTech Operations and John Dobak		S-4/A	333-232181	8/7/2019
10.19	Amendment to Employment Agreement, dated February 28, 2014, between DermTech Operations and John Dobak		S-4/A	333-232181	8/7/2019
10.20	Offer of Employment Letter, dated March 5, 2015, from DermTech, Inc. to Zuxu Yao		S-4/A	333-232181	8/7/2019
10.21	Offer of Employment Letter, dated October 1, 2015, from DermTech Operations to Burkhard Jansen		S-4/A	333-232181	8/7/2019
10.22	Offer of Employment Letter, dated December 7, 2018, from DermTech Operations to Todd Wood		S-4/A	333-232181	8/7/2019
10.23	Offer of Employment Letter, dated August 14, 2019, from the Company to Kevin Sun		8-K	001-38118	9/17/2019

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference File No.	Date Filed
10.24	Amendment Number 1 to Deferred Underwriting Fee Assignment Agreement, dated September 4, 2019, by and among the Company, DermTech Operations and Cowen and Company, LLC		8-K	001-38118	9/5/2019
10.25	Standard Multi-Tenant Officer Lease–Net and Addendum to Lease, dated January 25, 2013, by and between DermTech Operations and AG/Touchstone TP, LLC		8-K	001-38118	9/5/2019
10.26	First Amendment to Standard Rental Lease, Storage Lease and Signage to Expand and Extend Term, dated January 30, 2014, by and between DermTech Operations and AG/Touchstone TP, LLC		8-K	001-38118	9/5/2019
10.27	Assignment, Consent to Assignment, and Second Amendment to Standard Multi-Lease–Net, dated November 21, 2016, by and between DermTech Operations and AG/Touchstone TP, LLC		8-K	001-38118	9/5/2019
10.28	Third Amendment to Lease, dated August 6, 2019, by and between DermTech Operations and HCP Torrey Pines, LLC		8-K	001-38118	9/5/2019
10.29	Fourth Amendment to Lease, dated as of September 10, 2019, by and between the Company and HCP Torrey Pines, LLC.		8-K	001-38118	9/23/2019
10.30	Amended and Restated 2010 Stock Plan of the Company, included as Annex E to the proxy statement/prospectus/information statement forming a part of the referenced filing		S-4/A	333-232181	8/7/2019
31.1*	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.	X			
31.2*	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.	X			
32.1*	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.	X			
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

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: November 7, 2019 By: /s/ John Dobak, M.D.

John Dobak, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2019 By: /s/ Kevin Sun

Kevin Sun
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.17

AMENDMENT NO. 1
TO
LETTER AGREEMENT

This Amendment No. 1 (this "***Amendment***"), dated as of August 28, 2019, to the Letter Agreement (as defined below) is made by and among Constellation Alpha Capital Corp., a British Virgin Islands company (the "***Company***") and Centripetal, LLC, a Delaware limited liability company, Rajiv Shukla, Craig Pollak, Alan Rosling, Kewal Handa and John Alexander (collectively, the "***Insiders***"). All terms used but not defined herein shall have the meanings assigned to them in the Letter Agreement.

WHEREAS, the Company and the Insiders entered into an Letter Agreement dated as of June 19, 2017 (the "***Letter Agreement***"); and

WHEREAS, Section 3(a) of the Letter Agreement sets forth the terms that govern restrictions on the transfer of the Insider Shares by the Insiders; and

WHEREAS, in connection with the Business Combination contemplated by that certain Agreement and Plan of Merger, dated as of May 29, 2019, as amended, by and among the Company, DermTech, Inc., a Delaware corporation, and DT Merger Sub, Inc., a wholly owned subsidiary company of the Company incorporated in Delaware, the Company will issue to certain investors, shares of the Company's common stock, par value $0.0001 per share (the "***Common Stock***"), at a price of $3.25 per share (the "***PIPE***"); and

WHEREAS, as a result of the PIPE, the Company and the Insiders have agreed to adjust the closing price of the Ordinary Shares, which will be exchanged for shares of Common Stock in connection with the Business Combination, at which the Insider Shares will be released from the lock-up provided in the Letter Agreement from $12.50 to $4.00.

NOW THEREFORE, IT IS AGREED:

1. Section 3(a) of the Letter Agreement is hereby amended to delete the term "$12.50" and replace it with the term "$4.00" in the only place it appears.

2. Section 3(a) of the Letter Agreement is hereby amended further to add the following language to the end of the section: "Notwithstanding the provisions set forth herein, Transfers of the securities that are held by the Sponsor, any Insider or any of their permitted transferees (that have complied with this paragraph), are permitted (i) to affiliates of the Sponsor, to any of the Company's officers or directors, to officers, directors, members or beneficial owners of the Sponsor, to any affiliates or family members of any of the foregoing or to any trust where any of the foregoing is the primary beneficiary; (ii) in the case of any beneficial owner of the Sponsor or an individual, by gift to a member of one of the members of the beneficial owners of the Sponsor or individual's immediate family, to a trust, the beneficiary of which is a member of one of the beneficial owners of the Sponsor or individual's immediate family, an affiliate of any such person or beneficial owner, or to a charitable organization; (iii) in the case of an individual, by virtue of laws of descent and distribution upon death of the individual; (iv) in the case of an individual, pursuant to a qualified domestic relations order; (v) in connection with the consummation of the Company's initial Business Combination at prices no greater than the price at which the applicable securities were originally purchased; (vi) in the case of an entity, as a distribution to its partners, stockholders or members upon liquidation; (vii) by virtue of the laws of Delaware or the Sponsor's amended and restated limited liability company agreement upon dissolution of the Sponsor; or (viii) in the event of the Company's completion of a liquidation, merger, stock exchange or other similar transaction which results in all of the Company's stockholders having the right to exchange their ordinary shares for cash, securities or other property subsequent to the Company's completion of its initial Business Combination; provided, however, that in the case of clauses (i) through (vi), these permitted transferees must agree to be bound by the restrictions herein."

3. All other provisions of the Letter Agreement shall remain unaffected by the terms hereof.

4. This Amendment may be signed in any number of counterparts, each of which shall be an original and all of which shall be deemed to be one and the same instrument, with the same effect as if the signatures thereto and hereto were upon the same instrument. A facsimile signature shall be deemed to be an original signature for purposes of this Amendment.

5. This Amendment is intended to be in full compliance with the requirements for an amendment to the Letter Agreement as required by Section 21 of the Letter Agreement, and every defect in fulfilling such requirements for an effective amendment to the Letter Agreement is hereby ratified, intentionally waived and relinquished by all parties hereto.

6. This Amendment shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflicts of law principles that would result in the application of the substantive laws of another jurisdiction.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have duly executed this Amendment No. 1 to the Letter Agreement as of the date first written above.

CONSTELLATION ALPHA CAPITAL CORP.

By: /s/ Rajiv Shukla
Name: Rajiv Shukla
Title: Chief Executive Officer and Chairman

CENTRIPETAL, LLC

By: /s/ Rajiv Shukla
Name: Rajiv Shukla
Title: Managing Member

/s/ Rajiv Shukla
Rajiv Shukla

/s/ Craig Pollak
Craig Pollak

/s/ Alan Rosling
Alan Rosling

/s/ Kewal Handa
Kewal Handa

/s/ John Alexander
John Alexander

Exhibit 31.1

CERTIFICATION 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

I, John Dobak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019 of DermTech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2019

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

Exhibit 31.2

CERTIFICATION 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

I, Kevin Sun, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019 of DermTech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2019

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

Exhibit 32.1

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 September 30, 2019 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: November 7, 2019 By: /s/ John Dobak
John Dobak
Chief Executive Officer
(principal executive officer)

Date: November 7, 2019 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.