

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 7, 2019

DERMTECH, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38118
(Commission
File Number)

84-2870849
(IRS Employer
Identification No.)

11099 N. Torrey Pines Road, Suite 100
La Jolla, CA 92037
(Address of Principal Executive Offices and Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02. **Results of Operations and Financial Condition.**

On November 7, 2019, DermTech, Inc., or the Company, issued a press release announcing its financial results for the quarter ended September 30, 2019 and certain other information. This press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this Item 2.02 and in Exhibit 99.1 is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibit is not to be incorporated by reference in any filing of the Company under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 7, 2019

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 hereunto duly authorized.

DERMTECH, INC.

Date: November 7, 2019

By: /s/ Kevin Sun

Name: Kevin Sun
Title: Chief Financial Officer

DermTech, Inc. Reports Third Quarter 2019 Financial Results and Provides Corporate Update

LA JOLLA, Calif.--(BUSINESS WIRE)-- November 7, 2019 - DermTech, Inc. (NASDAQ: DMTK) ("DermTech" or the "Company"), a leader in precision dermatology enabled by a non-invasive skin genomics platform, today reported business and financial results as of and for the quarter ended September 30, 2019 and provided a corporate update.

Third Quarter 2019 Business Highlights:

- Received Proprietary Laboratory Analyses ("PLA") code (0089U) and favorable crosswalk recommendation to code 0005U by Clinical Diagnostic Laboratory Test Committee ("CDLT")
- Signed new agreements for \$1.4 million of contract revenue with pharmaceutical partners with the majority of these amounts expected to be recognized as revenue in the fourth quarter
- Strengthened the senior leadership team with the hiring of CFO and COO
- Continued to expand the commercial team with the hiring of Sr. VP of Payer Access, Director of Managed Care and Payor Contracts and built out the direct sales force
- Initiated the TRUST clinical study to further confirm the Pigmented Lesion Assay's high negative predictive value, through repeat clinical assessment and genomic testing of suspicious lesions after up to two years follow-up
- Announced the publication of consensus expert panel recommendations for use for the Pigmented Lesion Assay
- Expanded patent portfolio to include PRAME, a key gene in the non-invasive assessment of melanoma using genomics
- Presented 1-year Pigmented Lesion Assay real-world registry study data

Third Quarter 2019 Financial Highlights:

- Closed Business Combination and PIPE financing to list on The Nasdaq Capital Market, and generated gross cash proceeds of approximately \$29 million
- Reported assay revenue of \$0.4 million, a 20% increase compared to the third quarter of 2018
- Reported billable sample volume increase of 18% to 3,596 for the third quarter of 2019 compared to 3,043 for the same period in 2018
- Ended the quarter with \$21.4 million in cash and cash equivalents

"We spent much of the last quarter building the foundation to scale our commercial operations around our breakthrough Pigmented Lesion Assay for enhanced early melanoma detection. Key areas of success included: completing the business combination and financing, strengthening our senior management team with seasoned executives from the life sciences industry, expanding our payor access team and direct sales force, and establishing our reimbursement code and anticipated price with Medicare. We are off to a strong start as a newly public company and I look forward to a successful year," said John Dobak, M.D., Chief Executive Officer of DermTech.

Third Quarter 2019 Financial Results

Assay revenue increased 20% to \$0.4 million for the three months ended September 30, 2019, compared to \$0.3 million for the same period of 2018. Total revenues were \$0.6 million for each of the three months ended September 30, 2019 and 2018. Contract revenue decreased to \$0.2 million for the three months ended September 30, 2019, compared to \$0.3 million for the same period of 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.

Gross margin for the three months ended September 30, 2019 was (38)% compared to (7)% in the same period of 2018. The decrease in gross margin is due to the decrease in contract revenue which produces higher positive gross margins than assay revenue.

Sales and marketing expense increased \$1.3 million to \$2.0 million for the three months ended September 30, 2019, compared to \$0.7 million for the same period of 2018. The increase was primarily attributable to sales force expansion and increased marketing investment.

Research and development expense increased \$0.2 million to \$0.8 million for the three months ended September 30, 2019, compared to \$0.5 million for the same period of 2018. The increase was primarily attributable to higher compensation and recruiting costs related to expanding the research and development team as well as increased laboratory supplies.

General and administrative expense increased \$2.4 million to \$3.2 million for the three months ended September 30, 2019, compared to \$0.8 million for the same period of 2018. The increase was primarily due to additional public company costs, including higher audit and legal costs related to SEC filings in connection with the Business Combination and preparing quarterly financial statements.

Loss from operations was \$6.2 million for the three months ended September 30, 2019, which included \$0.7 million of non-cash stock-based compensation. We incurred approximately \$1.8 million in non-recurring operating costs for the three months ended September 30, 2019, predominantly related to legal fees, Registration Statement filing fees, audit fees and an acceleration of stock-based compensation expense associated with the close of the Business Combination.

Net loss for the three months ended September 30, 2019 was \$5.7 million, compared to a net loss of \$2.2 million for the same period of 2018.

Cash and cash equivalents totaled \$21.4 million as of September 30, 2019.

Closed Business Combination

On August 29, 2019, DermTech completed its business combination with Constellation Alpha Capital Corp. ("Constellation") (the "Business Combination"), a publicly traded special purpose acquisition company prior to the Business Combination. As a result of the Business Combination, the previous DermTech stockholders own a controlling interest in the combined company (the "Company"). Shortly following the completion of the Business Combination, the Company effected a one-for-two reverse stock split of its common stock. DermTech's Business Combination with Constellation was funded through proceeds received from a private sale of Constellation stock at a split-adjusted price of \$6.50 per common share, and cash remaining in Constellation's trust account after giving effect to stockholder

redemptions. As a result of the Business Combination, the Company generated gross proceeds of approximately \$29 million, which exceeded the \$15 million closing cash requirement previously announced. Participating investors included experienced life sciences investors such as RTW Investments, HLM Venture Partners, Irwin and Gary Jacobs, the founding family of Qualcomm, Inc., and two institutional investors each with over \$10 billion in assets under management.

PLA Code Issued

The American Medical Association (“AMA”) has issued a PLA Common Procedural Terminology (CPT®) code for the DermTech Pigmented Lesion Assay. This PLA code (0089U) was published online with an effective date of July 1, 2019 and is included in the CPT 2020 publication. The CDLT voted nearly unanimously to crosswalk the reimbursement of our code to a currently priced CPT code, 0005U. Final Medicare rate setting for this PLA code is currently in process, with the final fee schedule expected to be published in December 2019. We currently have a draft Local Coverage Determination (“LCD”) from MolDX and anticipate that we will have the final LCD policy by year-end. These activities will enable us to establish our coding, coverage, and reimbursement for the Pigmented Lesion Assay with Medicare for dates of service in early 2020 following the receipt of the final LCD.

New Contract Revenue Agreements

During the three months ended September 30, 2019, DermTech entered into \$1.4 million of new agreements with two large pharmaceutical companies to support their clinical trials. We expect the majority of these amounts will be recognized as revenue prior to year-end.

New Leadership Hires

In September, the Company announced that Kevin Sun was appointed Chief Financial Officer, Treasurer and Secretary. Mr. Sun brings nearly two decades of corporate finance experience, including debt and equity financings, acquisitions, commercial product launches and infrastructure scaling and expansion projects mostly in the medical device and diagnostic industries. From 2008 to 2018, Mr. Sun served in various executive and management roles for DexCom, Inc., a NASDAQ-listed medical device company, including most recently as Vice President, Corporate Controller and Treasury, Interim Chief Financial Officer, and Vice President, Finance. Prior to DexCom, Mr. Sun held various roles of increasing responsibility at Biosite Incorporated, a NASDAQ-listed leader in rapid point of care diagnostics. Mr. Sun holds a B.S. in Business with a dual major in Accounting and Finance, a minor in Psychology, a Masters in Strategic Management and an MBA from the Kelley School of Business at Indiana University.

In November, Claudia Ibarra started employment as the Company’s Chief Operating Officer. Ms. Ibarra has over 25 years of experience in clinical laboratory operations, in the areas of oncology, immunology and molecular biology. In her leadership roles, she grew and developed the laboratory operations of renowned diagnostic companies to a highly efficient and successful state, with high quality, service level and inspection track records. Before joining DermTech, Ms. Ibarra served as Senior Vice President, Laboratory Operations at Exagen, Director of the molecular oncology laboratory at Genoptix, Inc., where she was also the Molecular Genetic Training Program Coordinator, and other reference clinical laboratories focused on immunology and solid tumors. Ms. Ibarra holds a degree in Biochemistry with specialization in clinical laboratory science from the University of Buenos Aires, Argentina and a California License as Clinical Laboratory Scientist.

Commercial Team Expansion

In November, Dan Visage started employment as the Company's Senior Vice President of Payor Access. Mr. Visage has over 20 years of health care leadership experience, principally in developing high-performing teams to contract and manage health plan relationships. These include, large national payors, Blues plans, and other large local payors. He has held many diverse leadership roles that give him a unique understanding of the Sales, Marketing, Sales Management, Operations, and Finance functions of a healthcare organization. He most recently was the Vice-President of Managed Care at Progenity and prior to that has held leadership positions at Bio Reference Laboratories / OPKO Health and LabCorp. In each role he has expanded covered lives and obtained coverage for several diagnostic technologies. These include, whole exome sequencing, non-invasive prenatal testing, targeted oncology genomic sequencing, expanded carrier screening genetic testing and a prostate cancer algorithmic test. He also has extensive experience working at various health plans and has held management roles at Florida Blue, Kaiser Permanente and CareCentrix. He has an Accounting degree from Cal State Sacramento, an MBA from the University of Tampa, and is a CPA (inactive).

In September, Chris Murphy started employment as the Company's Director of Managed Care and Payor Contracting. Mr. Murphy has over 15 years of leadership experience across the legal, consulting, and healthcare industries. Within healthcare, Mr. Murphy has worked with niche-product/service providers in the areas of durable medical equipment, cardiac diagnostics, post-acute care, and home dialysis. In these roles, he has deployed effective contracting and business strategies and collaborated with large national payors, Blues plans, and other large local payors, in which he expanded market access and established mutually beneficial processes with the payor partner. Mr. Murphy also has extensive operational experience in the areas of reimbursement, compliance and sales management. Before joining DermTech, Mr. Murphy served as the Director of Revenue Cycle at Fresenius Medical Care, Director of Revenue Management at NxStage Kidney Care, and Manager, Contracts at ZOLL Services. Mr. Murphy holds a B.A. in History from the University of Wisconsin, and a J.D. from the UIC John Marshall Law School in Chicago, Illinois.

During the third quarter we continued to increase our direct sales force from 7 sales reps at the beginning of the year to 23 sales reps as of the beginning of the fourth quarter. All sales reps have significant experience direct selling and launching new products in dermatology. In preparation for our anticipated LCD from Medicare, territory locations for hiring were determined by assessing Medicare procedure volumes for melanoma surgical biopsies.

Initiated TRUST Clinical Study

The TRUST study is the first of its kind for the Company to provide repeat clinical assessments and genomic testing on pigmented lesions suspicious for melanoma that were initially tested negative with the Pigmented Lesion Assay. This study will further confirm the high negative predictive value of the Pigmented Lesion Assay (>99%), by examining the long-term clinical behavior of pigmented lesions initially determined to be negative for melanoma after testing with the Pigmented Lesion Assay. The study will perform the repeat assessment and testing 1 to 2 years following the initial test. We expect the results to be available in 2020.

Inclusion in Clinical Management Recommendations

In October, the Company announced its inclusion in Clinical Management Recommendations, “Appropriate Use Criteria for the Integration of Diagnostic and Prognostic Gene Expression Profile Assays into the Management of Cutaneous Malignant Melanoma: An Expert Panel Consensus-Based Modified Process Assessment” published in the September issue of SKIN. A panel of dermatologists and dermatopathologists with expertise in pigmented lesions, melanoma, and gene expression technology evaluated commercially available gene expression tests and recommended use of DermTech’s non-invasive Pigmented Lesion Assay, or 2-Gene Expression Profile test, in cases in which patients present with atypical lesions requiring additional assessment beyond visual inspection in order to inform the decision to surgically biopsy. This recommendation closely aligns with the previously published utility data on the Pigmented Lesion Assay (Ferris et al., Melanoma Research, 2018), which found that clinicians appropriately biopsied all Pigmented Lesion Assay positive lesions while managing 99% of Pigmented Lesion Assay negative lesions with surveillance and without surgical biopsies.

Expanded Patent Portfolio

In October, the Company announced the issuance of a patent, US 10,407,729, to further expand the Company’s intellectual property and leadership position. This patent is entitled “Diagnosis of melanoma by nucleic acid analysis” and includes claims in connection with DermTech’s technology to non-invasively obtain genomic information for characterizing skin lesions. The patent includes claims related to using expression levels of PRAME (also known as preferentially expressed antigen in melanoma, which is overexpressed in this type of cancer) to differentiate melanoma from non-melanoma skin samples obtained via the company’s adhesive patch-based sample collection platform. DermTech has discovered that PRAME is a key gene in the non-invasive assessment of melanoma using genomics.

Presentation of 1-Year Pigmented Lesion Assay Registry Study Data

In August, the Company presented 1-year Pigmented Lesion Assay registry data on 3,418 real-world cases from 53 US-based sites at the ‘Practical Symposium,’ an annual well recognized dermatology conference held in Beaver Creek, CO. The Pigmented Lesion Assay reduced avoidable biopsies by over 90%. Pigmented Lesion Assay positive cases were surgically biopsied 98% of the time and Pigmented Lesion Assay negative cases were clinically monitored and not surgically biopsied in over 99%. Clinicians follow the guidance of the Pigmented Lesion Assay.

About DermTech:

DermTech is a leader in the new category of medicine, precision dermatology. DermTech’s mission is to transform the practice of dermatology through more accurate diagnosis and treatment, and the elimination of unnecessary surgery, leading to improved patient care and lower costs. DermTech provides genomic analysis of skin samples collected non-invasively using an adhesive patch rather than a scalpel. DermTech markets and develops products that facilitate the early detection of skin cancers, assess inflammatory diseases, and customize drug treatments. For additional information on DermTech, please visit DermTech’s investor relations site at: www.DermTech.com.

Forward-looking Statement

This press release includes “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. The expectations, estimates, and projections of DermTech may differ from their actual results and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “continue,” and similar expressions are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, expectations with respect to the Company’s ability to recognize contract revenue and its ability to establish coding, coverage and reimbursement for the Pigmented Lesion Assay with Medicare following the receipt of the final LCD. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the control of DermTech and are difficult to predict. Factors that may cause such differences include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against the company; (2) the inability to maintain the listing of the company’s securities on Nasdaq; (3) the ability to recognize the anticipated benefits of the recently completed business combination, which may be affected by, among other things, competition, the ability of the company to grow and manage growth profitably and retain its key employees; (4) costs related to or resulting from the business combination; (5) changes in applicable laws or regulations; (6) the demand for the company’s services together with the possibility that the company may be adversely affected by other economic, business, and/or competitive factors; and (7) other risks and uncertainties included in (x) the “Risk Factors” sections of the Registration Statement on Form S-4 filed with the SEC by the company, and (y) other documents filed or to be filed with the SEC by the company. DermTech cautions that the foregoing list of factors is not exclusive. You should not place undue reliance upon any forward-looking statements, which speak only as of the date made. DermTech does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in their expectations or any change in events, conditions, or circumstances on which any such statement is based.

Contact information

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

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
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	<u>\$ 23,988</u>	<u>\$ 5,664</u>
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)	<u>\$ 23,988</u>	<u>\$ 5,664</u>

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	<u>\$ (5,726)</u>	<u>\$ (2,210)</u>	<u>\$ (14,574)</u>	<u>\$ (6,744)</u>
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)