
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 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): August 7, 2019

DERMIRA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36668
(Commission
File Number)

27-3267680
(I.R.S. Employer
Identification Number)

275 Middlefield Road, Suite 150
Menlo Park, California
(Address of Principal Executive Offices)

94025
(Zip Code)

Registrant's telephone number, including area code: (650) 421-7200

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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, \$0.001 par value	DERM	The Nasdaq Global Select 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 August 7, 2019, Dermira, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2019. The press release is being furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
99.1	Press release dated August 7, 2019.

The information furnished in this Current Report under Item 2.02 and the exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DERMIRA, INC.

Date: August 7, 2019

By: /s/ Andrew L. Guggenheimer
Andrew L. Guggenheimer
Chief Financial Officer

Dermira Reports Second Quarter 2019 Financial Results and Provides Corporate Update

- *QBREXZA™ (glycopyrronium) cloth net product sales of \$8.1M, more than triple first quarter 2019 sales*
- *End-of-Phase 2 FDA meeting for lebrikizumab completed, Phase 3 initiation on schedule for later this year*
- *Company provides revenue guidance for the second half of 2019*

MENLO PARK, Calif., Aug. 7, 2019 – Dermira, Inc. (NASDAQ: DERM), a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions, today reported financial results for the quarter ended June 30, 2019 and provided a corporate update.

“We’ve set ambitious goals for ourselves and continue to successfully deliver on them. For QBREXZA, our broad payer coverage, the positive product experience and an improved gross-to-net discount have established a strong foundation that we are leveraging to drive patient activation and substantial revenue growth,” said Tom Wiggans, chairman and chief executive officer of Dermira. “For lebrikizumab, we completed a very productive end-of-phase 2 meeting with the FDA and announced plans to move forward with our partner Almirall to develop lebrikizumab in Europe. As we look to the second half of the year, we are focused on continuing to generate demand for QBREXZA and rapidly initiating the lebrikizumab Phase 3 clinical development program by the end of the year.”

Second Quarter 2019 Financial Results

- Revenue for the second quarter totaled \$66.6 million, comprised of \$8.1 million in QBREXZA product sales and \$58.6 million in collaboration and license revenue associated with the Almirall S.A. agreement, compared with \$39.1 million in collaboration and license revenue related to a prior collaboration for the comparable quarter in 2018.
- Total costs and operating expenses for the quarter ended June 30, 2019 were \$82.9 million compared to \$60.3 million for the second quarter of 2018.
 - Cost of sales for the second quarter of 2019 was \$1.3 million related to QBREXZA.
 - Research and development (R&D) expenses for the second quarter of 2019 were \$18.3 million compared to \$19.5 million for the comparable prior-year period. This decrease was primarily due to reductions in clinical trial activities associated with the company’s prior acne program and in personnel-related costs, which were partially offset by increases in activities related to QBREXZA and other R&D costs.
 - Selling, general and administrative (SG&A) expenses for the second quarter of 2019 were \$63.3 million compared to \$40.8 million for the comparable prior-year period. This increase was primarily driven by costs associated with the QBREXZA commercial launch, particularly advertising and promotional expenses associated with patient activation activities as well as higher personnel-related costs. The second quarter 2019 results were consistent with the company’s expectations and guidance that the period would represent the peak SG&A expense quarter for the year.

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- For the quarter ended June 30, 2019, Dermira reported a net loss of \$18.0 million compared with a net loss of \$23.9 million for the same period in 2018.
 - As of June 30, 2019, Dermira had cash and investments of \$327.2 million and 54.4 million common shares outstanding.

Key Operational Highlights

- Generated 28,609 prescriptions for QBREXZA as reported by Symphony PHAST monthly data for the second quarter of 2019, an increase of over 20 percent compared to the first quarter of 2019 despite a decrease in April prescriptions related to changes to the co-pay savings card program.
- Drove a significant improvement in the QBREXZA gross-to-net discount to 39 percent in the second quarter of 2019 from 76 percent in the first quarter.
- Secured QBREXZA coverage for approximately 85 percent of the total U.S. commercial lives (calculated based on Dermira data on file) as of August 1, 2019.
- Completed a successful end-of-Phase 2 meeting for lebrikizumab with the U.S. Food and Drug Administration (FDA) in June 2019. Management continues to expect to initiate the lebrikizumab Phase 3 clinical development program by the end of 2019.
- Announced in June 2019 that Almirall exercised its option to license rights to develop lebrikizumab for the treatment or prevention of dermatology indications, including but not limited to atopic dermatitis, and commercialize lebrikizumab for the treatment or prevention of all indications in Europe, pursuant to the option and license agreement entered into in February 2019. As a result of this option exercise, Dermira received \$50 million in July and will be eligible to receive additional payments upon the achievement of certain milestones, including an aggregate of \$30 million in connection with the initiation of clinical studies related to the lebrikizumab Phase 3 program.

Operational and Financial Expectations

- For QBREXZA, management expects net product sales for the full year 2019 in the low-\$30 million range, and the gross-to-net discount for the second half of the year to remain at approximately 40 percent.
- Management expects collaboration and license revenue related to the Almirall agreement of approximately \$2 million for each of the third and fourth quarters of 2019.
- Management maintains its previously issued guidance for cost of sales and operating expenses. The company previously guided for 2019 R&D and SG&A expenses to be between \$295 and \$315 million, including estimated stock-based compensation expense of approximately \$35 million, plus an additional \$20 million acquired in-process research and development expense related to the anticipated milestone payment due to Roche upon the initiation of the lebrikizumab Phase 3 trials.

Conference Call Details

Dermira will host a conference call to discuss the second quarter financial results today, August 7, 2019, beginning at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. The live call can be accessed by phone by dialing 1-866-211-3117 from the U.S. and Canada or +1-647-689-6606 internationally and using the passcode 3394726. The webcast can be accessed live on the Investor Relations section of the Company's website at <http://investors.dermira.com>. It will be archived for 30 days following the call.

About Hyperhidrosis

Hyperhidrosis is a condition of sweating beyond what is physiologically required for normal thermal regulation and affects an estimated 4.8 percent of the U.S. population, or approximately 15 million people. Of these, 65 percent, or nearly 10 million people, suffer from sweating localized to the underarms (axillary disease). Studies have demonstrated that excessive sweating often impedes normal daily activities and can also result in occupational, emotional, psychological, social and physical impairment.

About QBREXZA™ (glycopyrronium) cloth

QBREXZA (pronounced kew brex' zah) is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older. QBREXZA is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation. For more information visit www.QBREXZA.com.

Important Safety Information

CONTRAINDICATIONS

QBREXZA is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of QBREXZA.

WARNINGS AND PRECAUTIONS

Worsening of Urinary Retention: Use with caution in patients with a history or presence of documented urinary retention.

Control of Body Temperature: In the presence of high ambient temperature, heat illness (hyperpyrexia and heat stroke due to decreased sweating) can occur with the use of anticholinergic drugs such as QBREXZA.

Operating Machinery or an Automobile: Transient blurred vision may occur with use of QBREXZA. If blurred vision occurs, the patient should discontinue use until symptoms resolve. Patients should be warned not to engage in activities that require clear vision such as operating a motor vehicle or other machinery, or performing hazardous work until the symptoms have resolved.

ADVERSE REACTIONS

The most common adverse reactions seen in ≥2% of subjects treated with QBREXZA were dry mouth (24.2%), mydriasis (6.8%), oropharyngeal pain (5.7%), headache (5.0%), urinary hesitation (3.5%), vision blurred (3.5%), nasal dryness (2.6%), dry throat (2.6%), dry eye (2.4%), dry skin (2.2%) and constipation (2.0%). Local skin reactions of erythema (17.0%), burning/stinging (14.1%) and pruritus (8.1%) were also common.

It is important for patients to understand how to correctly apply QBREXZA (see Patient Product Information). Instruct patients to wash their hands with soap and water immediately after discarding the used cloth.

Please see [Full Prescribing Information](#)

About Atopic Dermatitis

Atopic dermatitis is the most common and severe form of eczema, a chronic inflammatory condition that can present as early as childhood and continue into adulthood. A moderate-to-severe form of the disease is characterized by rashes on the skin that often cover much of the body and also includes redness, cracking, dryness and intense, persistent itching. The skin condition can have a negative impact on patients' mental and physical functioning, limiting their daily activities and health-related quality of life. Patients with moderate-to-severe atopic dermatitis have reported a larger impact on quality of life than patients with psoriasis.

About Lebrikizumab

Lebrikizumab is a novel, injectable, humanized monoclonal antibody designed to bind IL-13 with very high affinity, specifically preventing the formation of the IL-13R α 1/IL-4R α heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13 in a targeted and efficient fashion. IL-13 is believed to be a central pathogenic mediator that drives multiple aspects of the pathophysiology of atopic dermatitis by promoting type 2 inflammation and mediating its effects on tissue, resulting in skin barrier dysfunction, itch, skin thickening and infection.

About Dermira

Dermira is a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions. Dermira is committed to understanding the needs of both patients and physicians and using its insight to identify, develop and commercialize leading-edge medical dermatology products. The company's approved treatment, QBREXZA™ (glycopyrronium) cloth, is indicated for pediatric and adult patients (ages 9 and older) with primary axillary hyperhidrosis (excessive underarm sweating). Please see the QBREXZA prescribing information. Dermira is evaluating lebrikizumab for the treatment of moderate-to-severe atopic dermatitis (a severe form of eczema) and plans to initiate a Phase 3 clinical development program by the end of 2019. Dermira also has early-stage research and development programs in other areas of dermatology. Dermira is headquartered in Menlo Park, Calif. For more information, please visit <http://www.dermira.com>. Follow Dermira on LinkedIn, Instagram and Twitter.

In addition to filings with the Securities and Exchange Commission (SEC), press releases, public conference calls and webcasts, Dermira uses its website (www.dermira.com), LinkedIn page (<https://www.linkedin.com/company/dermira-inc/>), corporate Instagram account (https://www.instagram.com/dermira_inc/) and corporate Twitter account (@DermiraInc) as channels of distribution of information about its company, product candidates, planned financial and other announcements, attendance at upcoming investor and industry conferences and other matters. Such information may be deemed material information and Dermira may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Dermira's website, LinkedIn page, Instagram and Twitter accounts in addition to following its SEC filings, news releases, public conference calls and webcasts.

Forward-Looking Statements

The information in this news release contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the “safe harbor” created by those sections. This news release contains forward-looking statements that involve substantial risks and uncertainties, including statements with respect to Dermira’s goal of bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions; Dermira’s plans to generate demand for QBREXZA and to drive patient activation and substantial revenue growth; Dermira’s plans to move forward with its partner Almirall to develop lebrikizumab in Europe; the anticipated timing of initiation of the Phase 3 clinical development program for lebrikizumab by the end of the year; guidance that the second quarter of 2019 represents the peak SG&A expense quarter for the year; the anticipated receipt and timing of payments from Almirall upon the achievement of certain future milestones; expectations regarding net product sales for the full year 2019 and the gross-to-net discount and collaboration and license revenue for the second half of 2019; and estimated R&D, SG&A, stock-based compensation expense and acquired in-process research and development expense for 2019. These statements deal with future events and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to Dermira’s dependence on third-party clinical research organizations, manufacturers, suppliers and distributors; the design and implementation of Dermira’s clinical trials; the outcomes of future meetings with regulatory agencies; Dermira’s ability to attract and retain key employees; Dermira’s ability to manage the growth and complexity of its organization; Dermira’s ability to maintain, protect and enhance its intellectual property; and Dermira’s ability to continue to stay in compliance with its material contractual obligations, applicable laws and regulations. You should refer to the section entitled “Risk Factors” set forth in Dermira’s Annual Report on Form 10-K, Dermira’s Quarterly Reports on Form 10-Q and other filings Dermira makes with the SEC from time to time for a discussion of important factors that may cause actual results to differ materially from those expressed or implied by Dermira’s forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this news release. Dermira undertakes no obligation to publicly update any forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

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Dermira, Inc.
Selected Consolidated Statement of Operations Data
(in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Product sales	\$ 8,060	\$ —	\$ 10,512	\$ —
Collaboration and license revenue	58,585	39,080	58,585	39,379
Total revenue	66,645	39,080	69,097	39,379
Costs and operating expenses:				
Cost of sales (1)	1,335	—	2,261	—
Research and development (1)	18,285	19,545	33,854	45,136
Selling, general and administrative (1)	63,327	40,770	112,006	71,280
Impairment of intangible assets	—	—	—	1,126
Total costs and operating expenses	82,947	60,315	148,121	117,542
Loss from operations	(16,302)	(21,235)	(79,024)	(78,163)
Interest and other income, net	1,970	2,037	3,521	3,771
Interest expense	(3,630)	(4,734)	(7,291)	(8,988)
Loss before taxes	(17,962)	(23,932)	(82,794)	(83,380)
Benefit for income taxes	—	—	—	194
Net loss	<u>\$ (17,962)</u>	<u>\$ (23,932)</u>	<u>\$ (82,794)</u>	<u>\$ (83,186)</u>
Net loss per share, basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.57)</u>	<u>\$ (1.70)</u>	<u>\$ (1.99)</u>
Weighted-average common shares used to compute net loss per share, basic and diluted	<u>54,033</u>	<u>41,922</u>	<u>48,838</u>	<u>41,875</u>

(1) Amounts include stock-based compensation expense as follows:

Cost of sales	\$ 16	\$ —	\$ 31	\$ —
Research and development	2,371	2,408	4,831	5,261
Selling, general and administrative	5,123	4,898	10,629	9,559
Total stock-based compensation expense	<u>\$7,510</u>	<u>\$7,306</u>	<u>\$15,491</u>	<u>\$14,820</u>

Dermira, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)

	June 30, 2019	December 31, 2018
Cash and investments	\$ 327,166	\$ 316,002
Working capital	377,597	296,853
Total assets	447,266	344,321
Term loan	32,731	32,566
Convertible notes, net	282,145	281,223
Accumulated deficit	(827,832)	(745,038)
Total stockholders' equity (deficit)	65,556	(9,039)