
**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): November 7, 2018

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))

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, 2018, Dermira, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. The press release is being furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Dermira Inc. Press Release dated November 7, 2018

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.

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.

DERMIRA, INC.

Date: November 7, 2018

By: /s/ Andrew L. Guggenheimer

Name: Andrew L. Guggenheimer

Title: Chief Financial Officer



Dermira Reports Third Quarter 2018 Financial Results

- Conference call today at 1:30 p.m. PT / 4:30 p.m. ET

MENLO PARK, Calif., November 7, 2018 – 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 September 30, 2018 and provided an update on the launch of QBREXZA™ (glycopyrronium) cloth and the lebrikizumab clinical development program.

Corporate Highlights

- Launched QBREXZA in the United States on October 1, 2018 for the treatment of adult and pediatric patients (9 years of age and older) living with primary axillary hyperhidrosis, also commonly known as excessive underarm sweating.
- Secured QBREXZA coverage for approximately 53% of the total U.S. commercially-insured lives as of October 1, 2018, including coverage from Express Scripts, Inc. and OptumRx, two of the largest pharmacy benefit managers in the U.S.
- In October 2018, partnered with Christian Siriano, a Council of Fashion Designers of America, Inc. fashion designer, to launch a new initiative to raise awareness of hyperhidrosis as a medical condition and inspire people to share stories about the physical and emotional impact the condition has on their lives.
- Presented results from a new post-hoc analysis from the ARIDO long-term safety study data during the European Academy of Dermatology and Venereology Congress in September 2018 showing that pediatric patients treated with glycopyrronium tosylate for primary axillary hyperhidrosis experienced similar rates of reduced sweat production, improvements in disease severity and favorable quality of life measures compared to adult patients.
- Completed patient enrollment in the Phase 2b dose-ranging study evaluating lebrikizumab, an anti-IL13 monoclonal antibody, in patients with moderate-to-severe atopic dermatitis in October 2018, with topline efficacy and safety results from the study expected by early April 2019.
- Ended the quarter with cash and investments of \$389.7 million.

“The launch of QBREXZA, the first FDA-approved medicated cloth designed to treat people living with primary axillary hyperhidrosis, represented an important inflection point for Dermira. As a commercial-stage company, we are now delivering on our commitment to provide new therapies to people living with chronic, underserved skin conditions,” said Tom Wiggans, chairman and chief executive officer of Dermira. “We are very encouraged by the response from dermatologists and the promising start to the launch, with over 2,800 patient starts through only four weeks on the market. We continue to generate

interest in QBREXZA utilization by educating physicians, obtaining broad, quality payer coverage and activating patients. Going forward, we intend to maintain the launch momentum and communicate topline results from our lebrikizumab Phase 2b data study by early April of next year.”

Third Quarter 2018 Financial Results

- Total revenue for the quarter ended September 30, 2018 was \$0.7 million, comprised exclusively of QBREXZA product sales, compared with \$1.1 million of collaboration and license revenue for the comparable quarter in 2017. QBREXZA revenue is recognized upon delivery of product to wholesalers or a preferred dispensing partner, net of estimated rebates and other reserves. The company commenced QBREXZA shipments in late September to make QBREXZA available to patients starting on October 1st.
- Total costs and operating expenses for the quarter ended September 30, 2018 were \$66.0 million, compared to \$179.1 million for the third quarter of 2017. Operating expenses for the quarter ended September 30, 2017 included \$128.6 million in acquired in-process research and development expenses related to the licensing agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc.
 - Cost of sales for the third quarter of 2018 was \$0.2 million related to QBREXZA sales.
 - Research and development expenses for the third quarter of 2018 were \$16.3 million, compared to \$30.8 million for the comparable prior-year period. This decrease was primarily due to a reduction in clinical trial activities associated with the company’s acne, psoriasis and hyperhidrosis programs, which were partially offset by an increase in activities related to the atopic dermatitis clinical program.
 - Selling, general and administrative expenses for the third quarter of 2018 were \$49.5 million, compared to \$19.8 million for the comparable prior-year period. This increase was primarily driven by the preparation for and execution of the QBREXZA commercial launch, including sales force hiring and readiness, physician education and patient awareness marketing activities.
- For the quarter ended September 30, 2018, Dermira reported a net loss of \$66.5 million, or \$1.58 per share, compared with a net loss of \$179.2 million, or \$4.30 per share, for the same period in 2017.
- As of September 30, 2018, Dermira had cash and investments of \$389.7 million and 42.1 million common shares outstanding.

2018 Financial Guidance

Management reiterates its previously issued financial guidance for full year 2018, consisting of operating expenses of \$250.0 to \$270.0 million, including estimated stock-based compensation expense of approximately \$35.0 million. Management is not providing 2018 QBREXZA product sales guidance.

Conference Call Details

Dermira will host a conference call to discuss third quarter financial results today, November 7, 2018, beginning at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. The live call can be accessed by phone by dialing 1-877-359-9508 from the U.S. and Canada or +1-224-357-2393 internationally and using the passcode 1453469. 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 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 $\geq 2\%$ 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 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 programs. 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). Dermira is also evaluating lebrikizumab in a Phase 2b clinical trial for the treatment of moderate-to-severe atopic dermatitis (a severe form of eczema) and has early-stage research 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 [Twitter](#), [LinkedIn](#) and [Instagram](#).

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; the successful completion of, and timing expectations for the receipt and announcement of topline data from, the Phase 2b dose-ranging study of lebrikizumab for moderate-to-severe atopic dermatitis; Dermira's ability to continue to generate interest in QBREXZA utilization by educating physicians, obtaining broad, quality coverage and activating patients; Dermira's ability to maintain momentum in connection with its commercial launch of QBREXZA; and financial guidance for full year 2018, including estimated operating expenses and stock-based compensation expense. 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; market acceptance of Dermira's current and potential products; the impact of competitive products and therapies; Dermira's ability to obtain necessary additional capital; Dermira's ability to manage the complexity of its organization; Dermira's ability to attract and retain key employees; the design, implementation and outcomes of Dermira's clinical trials; the outcomes of Dermira's future meetings with regulatory agencies; Dermira's ability to maintain, protect and enhance its intellectual property; and Dermira's ability to continue to stay in compliance with 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 undertake 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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Product sales	\$ 717	\$ —	\$ 717	\$ —
Collaboration and license revenue	—	1,066	39,379	3,198
Total revenue	717	1,066	40,096	3,198
Costs and operating expenses:				
Cost of sales	237	—	237	—
Research and development (1)	16,292	30,788	61,428	76,626
Acquired in-process research and development	—	128,555	—	128,555
Selling, general and administrative (1)	49,510	19,754	120,790	44,667
Impairment of intangible assets	—	—	1,126	—
Total costs and operating expenses	66,039	179,097	183,581	249,848
Loss from operations	(65,322)	(178,031)	(143,485)	(246,650)
Interest and other income, net	2,198	1,721	5,969	3,585
Interest expense	(3,420)	(2,864)	(12,408)	(4,184)
Loss before taxes	(66,544)	(179,174)	(149,924)	(247,249)
Benefit for income taxes	—	—	194	—
Net loss	\$(66,544)	\$(179,174)	\$(149,730)	\$(247,249)
Net loss per share, basic and diluted	\$ (1.58)	\$ (4.30)	\$ (3.57)	\$ (6.15)
Weighted-average common shares used to compute net loss per share, basic and diluted	42,066	41,625	41,939	40,172

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

Research and development	\$2,511	\$2,104	\$ 7,772	\$ 5,918
Selling, general and administrative	5,371	3,397	14,930	9,302
Total stock-based compensation expense	\$7,882	\$5,501	\$22,702	\$15,220

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

	September 30,	December 31,
	2018	2017
Cash and investments	\$ 389,728	\$ 550,993
Working capital	318,908	451,256
Total assets	409,922	560,794
Accrued payments related to acquired in-process research and development	29,727	50,161
Convertible notes, net	280,764	279,389
Accumulated deficit	(673,228)	(553,393)
Total stockholders' equity	53,847	149,649