
**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): February 26, 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))

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 February 26, 2019, Dermira, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2018. 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 February 26, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DERMIRA, INC.

Date: February 26, 2019

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



Dermira Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

- *QBREXZA™ (glycopyrronium) cloth 2018 net product sales of \$3.0 million*
- *Over 14,500 prescriptions for QBREXZA written in first three months of launch*
- *Secured QBREXZA coverage for approximately 76% of total U.S. commercial lives*
- *Entered into option and license agreement with Almirall for rights to lebrikizumab in Europe*
- *Lebrikizumab topline Phase 2b data expected in second half of March*

MENLO PARK, Calif., Feb. 26, 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 and year ended December 31, 2018.

“We’re very pleased by the progress of the QBREXZA launch and will continue our efforts to raise awareness of primary axillary hyperhidrosis as a medical condition and ensure seamless access to the therapy for patients,” said Tom Wiggans, chairman and chief executive officer of Dermira. “As we look ahead to 2019, in addition to generating growth in QBREXZA awareness and use, a key focus will be on our lebrikizumab clinical development program. We believe that lebrikizumab may offer a compelling combination of safety, efficacy and convenience for people living with moderate-to-severe atopic dermatitis. We look forward to reporting topline results from our ongoing Phase 2b study in the second half of March. If the data support a differentiated product profile and significant commercial opportunity, we plan to initiate a Phase 3 program by the end of this year.”

Financial Highlights

Fourth Quarter 2018 Financial Results

- Total revenue for the fourth quarter was \$2.2 million, comprised exclusively of QBREXZA product sales, compared with \$1.3 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.
- Total costs and operating expenses for the quarter ended December 31, 2018 were \$72.7 million compared to \$55.0 million for the fourth quarter of 2017.
 - Cost of sales for the fourth quarter of 2018 was \$0.9 million related to QBREXZA sales.
 - Research and development expenses for the fourth quarter of 2018 were \$19.1 million compared to \$27.8 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.

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- Selling, general and administrative expenses for the fourth quarter of 2018 were \$51.8 million compared to \$27.2 million for the comparable prior-year period. This increase was primarily driven by the execution of the QBREXZA commercial launch, including higher personnel-related costs associated with the addition of a sales force and other positions within the commercial organization, and patient awareness and physician education marketing activities.
 - For the quarter ended December 31, 2018, Dermira reported a net loss of \$71.8 million compared with a net loss of \$56.0 million for the same period in 2017.

Full Year 2018 Financial Results

- Total revenue for the year ended December 31, 2018 was \$42.3, compared with \$4.5 million in 2017. Revenue for 2018 was comprised of \$3.0 million in QBREXZA product sales and \$39.4 million in collaboration and license revenue, which was primarily driven by a \$39.0 million milestone payment from UCB Pharma S.A.
- Total costs and operating expenses for 2018 were \$256.3 million compared to \$304.9 million for 2017.
 - Cost of sales for 2018 was \$1.2 million related to QBREXZA sales.
 - Research and development expenses for 2018 were \$80.5 million compared to \$104.4 million for the prior year. Dermira also recognized acquired in-process research and development expenses of \$128.6 million in 2017 related to its licensing agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (together Roche), pursuant to which Dermira obtained exclusive, worldwide rights to develop and commercialize lebrikizumab for atopic dermatitis and all other indications.
 - Selling, general and administrative expenses for 2018 were \$172.6 million, compared to \$71.9 million for the prior year.
- For the year ended December 31, 2018, Dermira reported a net loss of \$221.5 million compared with a net loss of \$303.3 million for the same period in 2017.

Cash, Cash Equivalents and Investments

- As of December 31, 2018, Dermira had cash and investments of \$316.0 million and 42.3 million common shares outstanding. In the fourth quarter of 2018, Dermira received net proceeds of approximately \$33.2 million in connection with a credit facility it entered into with funds managed by Athyrium Capital Management (Athyrium), and made a \$30.0 million milestone payment for completion of enrollment of the lebrikizumab Phase 2b clinical study in connection with the license agreement with Roche.

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- Dermira anticipates that its cash and investments on hand are sufficient to meet the company's anticipated cash requirements, excluding costs to conduct a potential Phase 3 program for lebrikizumab, to at least mid-2020.

Recent Operational Highlights and Clinical Pipeline Update

- 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.
- Generated 14,786 prescriptions for QBREXZA as reported by Symphony PHAST monthly data for the fourth quarter of 2018, which represents the first three months of the QBREXZA launch.
- Secured QBREXZA coverage for approximately 76% of the total U.S. commercial lives (calculated based on Dermira data on file).
- 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. The study enrolled 280 patients ages 18 years and older in the United States. The study is evaluating three different lebrikizumab treatment dosing arms compared to a placebo arm.
- Bolstered the balance sheet by entering into a credit facility with Athyrium. The financing agreement provides up to \$125 million of borrowing capacity available in three tranches. An initial tranche of \$35 million was funded at the December 2018 closing and an additional \$90 million is available at Dermira's option, subject to certain conditions.
- Entered into an option and license agreement with Almirall in February 2019, under which Almirall acquired an option to exclusively 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. In exchange, Dermira will receive an upfront option fee of \$30 million. If Almirall exercises its option to obtain the license following the results of the ongoing Phase 2b study, Dermira will receive a \$50 million option exercise fee and will be eligible to receive additional development, regulatory and sales milestone payments, including \$30 million in connection with the initiation of certain Phase 3 clinical studies, as well as double-digit royalties.
- Initiated a proof-of-concept study to evaluate the efficacy and safety of QBREXZA in people living with primary palmar hyperhidrosis, or excessive sweating of the hands. The study is expected to enroll approximately 60 patients ages 9 years and older at eight sites in the United States. Findings from the study are expected in the second half of 2019 and will inform next steps for a potential primary palmar hyperhidrosis development program.

Key Milestones and Expectations

- Announce topline results from the Phase 2b study evaluating the safety and efficacy of lebrikizumab in patients with moderate-to-severe atopic dermatitis in the second half of March 2019.

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- If the data from the lebrikizumab Phase 2b study support a differentiated product profile and significant commercial opportunity, initiate a Phase 3 program by the end of 2019.
 - Issue 2019 financial guidance after the disclosure of the lebrikizumab Phase 2b trial topline results.
 - Launch a branded direct-to-consumer QBREXZA advertising campaign by the end of March.

Conference Call Details

Demira will host a conference call to discuss the fourth quarter financial results today, February 26, 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 1-877-359-9508 from the U.S. and Canada or +1-224-357-2393 internationally and using the passcode 2269419. The webcast can be accessed live on the Investor Relations section of the Company's website at <http://investors.demira.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% 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, humanized monoclonal antibody designed to bind IL-13 with very high affinity, specifically preventing the formation of the IL-13 α R1/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 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 nine 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 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 [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; Dermira's plans to generate growth in QBREXZA awareness and use and ensure seamless access to QBREXZA for patients; the belief that lebrikizumab may offer a compelling combination of safety, efficacy and convenience for people living with moderate-to-severe atopic dermatitis; the successful completion of, and timing expectations for the receipt and announcement of topline data from, the Phase 2b study of lebrikizumab for the treatment of moderate-to-severe atopic dermatitis; plans to initiate a Phase 3 program of lebrikizumab for the treatment of moderate-to-severe atopic dermatitis by the end of this year if data from the Phase 2b study support a differentiated product profile and significant commercial opportunity; the anticipation that Dermira's cash and investments on hand are sufficient to meet the company's anticipated cash requirements, excluding costs to conduct a potential Phase 3 program for lebrikizumab, to at least mid-2020; the future availability of an additional \$90 million to Dermira under the credit facility; the potential exercise of the option by Almirall and the anticipated fees, payments and royalties associated therewith; the design of, the successful completion of, and timing expectations for the receipt and announcement of topline data from, the proof-of-concept study to evaluate the efficacy and safety of QBREXZA™ (glycopyrronium) cloth in people living with primary palmar hyperhidrosis; potential development plans for QBREXZA in primary palmar hyperhidrosis; Dermira's plan to issue 2019 financial guidance after the disclosure of the lebrikizumab Phase 2b trial topline results; and the timing and successful launch of a branded direct-to-consumer QBREXZA advertising campaign. 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, implementation and outcomes of Dermira's clinical trials; the outcomes of future meetings with regulatory agencies; Dermira's ability to develop and maintain collaborations and license products and intellectual property; Dermira's ability to attract and retain key employees; Dermira's ability to obtain necessary additional capital; market acceptance of Dermira's current and future products; the impact of competitive products and therapies; 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		Year Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Product sales	\$ 2,243	\$ —	\$ 2,960	\$ —
Collaboration and license revenue	—	1,343	39,379	4,541
Total revenue	2,243	1,343	42,339	4,541
Costs and operating expenses:				
Cost of sales (1)	939	—	1,176	—
Research and development (1)	19,119	27,783	80,547	104,409
Acquired in-process research and development	891	—	891	128,555
Selling, general and administrative (1)	51,791	27,236	172,581	71,903
Impairment of intangible assets	—	—	1,126	—
Total costs and operating expenses	72,740	55,019	256,321	304,867
Loss from operations	(70,497)	(53,676)	(213,982)	(300,326)
Interest and other income, net	1,918	1,620	7,887	5,205
Interest expense	(3,231)	(3,956)	(15,639)	(8,140)
Loss before taxes	(71,810)	(56,012)	(221,734)	(303,261)
Benefit for income taxes	—	—	194	—
Net loss	<u>\$(71,810)</u>	<u>\$(56,012)</u>	<u>\$(221,540)</u>	<u>\$(303,261)</u>
Net loss per share, basic and diluted	<u>\$ (1.70)</u>	<u>\$ (1.34)</u>	<u>\$ (5.27)</u>	<u>\$ (7.48)</u>
Weighted-average common shares used to compute net loss per share, basic and diluted	<u>42,194</u>	<u>41,720</u>	<u>42,003</u>	<u>40,562</u>

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

Cost of sales	\$ —	\$ —	\$ 7	\$ —
Research and development	2,173	2,088	9,945	8,006
Selling, general and administrative	4,766	3,395	19,696	12,697
Total stock-based compensation expense	<u>\$ 6,939</u>	<u>\$ 5,483</u>	<u>\$ 29,648</u>	<u>\$ 20,703</u>

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

	December 31,	December 31,
	2018	2017
Cash and investments	\$ 316,002	\$ 550,993
Working capital	296,853	451,256
Total assets	344,321	560,794
Accrued payments related to acquired in-process research and development	—	50,161
Term Loan	32,566	—
Convertible notes, net	281,223	279,389
Accumulated deficit	(745,038)	(553,393)
Total stockholders' equity (deficit)	(9,039)	149,649