
**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): September 5, 2018

DERMIRA, INC.

(Exact Name of the Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-36668

(Commission File Number)

27-3267680

(IRS Employer Identification No.)

**275 Middlefield Road, Suite 150
Menlo Park, California**

(Address of Principal Executive Offices)

94025

(Zip Code)

(650) 421-7200

(Registrant's Telephone Number, Including Area Code)

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 7.01 Regulation FD Disclosure.

On September 5, 2018, Dermira, Inc. issued a press release providing updates related to the upcoming launch and availability of its QBREXZA™ (glycopyrronium) cloth, an anticholinergic indicated for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly stated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
Exhibit 99.1	Press release dated September 5, 2018

SIGNATURES

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.

Dated: September 5, 2018

DERMIRA, INC.

By: /s/ Andrew L. Guggenime

Name: Andrew L. Guggenime

Title: Chief Financial Officer



Dermira Provides Launch Readiness Update for QBREXZA™ (glycopyrronium) Cloth for Primary Axillary Hyperhidrosis

- *Early commercial payer coverage for the therapy includes Express Scripts, Inc. and OptumRx*
- *Company announces DermiraConnect, a new patient access program that will provide patients broad access to QBREXZA*
- *Therapy is expected to be available in pharmacies nationwide beginning October 1, 2018*

MENLO PARK, Calif., Sept. 5, 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 people living with chronic skin conditions, today announced several updates related to the upcoming launch and availability of QBREXZA™ (glycopyrronium) cloth, an anticholinergic indicated for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older. QBREXZA was approved by the U.S. Food and Drug Administration (FDA) in June 2018.

Primary axillary hyperhidrosis, also known as excessive underarm sweating, is a chronic medical skin condition that results in sweating beyond what is needed for normal body temperature regulation. The exact cause is unknown, but it affects nearly 10 million people in the United States, with men and women having similar prevalence. QBREXZA (pronounced kew brex' zah) is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation.

"QBREXZA is the culmination of more than 10 years of clinical development work," said Tom Wiggans, chairman and chief executive officer of Dermira. "Based on discussions and interactions with dermatologists, we have long recognized that primary axillary hyperhidrosis patients have been underserved due to a lack of innovation and limited treatment options. We are pleased to offer a new therapy to the millions of patients living with this condition."

QBREXZA is expected to be available in pharmacies nationwide beginning on October 1, 2018.

QBREXZA will launch with a list price of \$550 per 30-day supply. To ensure that patients suffering from primary axillary hyperhidrosis have access to the therapy, Dermira has been working with leading national insurers to secure coverage for QBREXZA. Two of the largest pharmacy benefit managers in the United States, Express Scripts, Inc. and OptumRx, have agreed to provide immediate coverage of QBREXZA through their national formularies, effective October 1, 2018. To date, Dermira has secured contracted coverage for approximately 34% of the total U.S. commercial lives to date, with the goal of securing more than 50% coverage by January 1, 2019.*

“Our mission to provide a novel therapy to people living with excessive underarm sweating did not stop with the FDA approval of QBREXZA,” said Lori Lyons-Williams, chief commercial officer of Dermira. “We are committed to providing innovative solutions for patient access, which is an obligation we believe deserves our steadfast attention. The voice of the patient is at the center of all we do, and their insights helped us to design, refine and deliver a robust access program to meet their needs. We believe our approach will support broad and affordable access to QBREXZA for the patients who need it.”

Additional activities that will support the availability of QBREXZA for patients include:

- A commitment by Dermira to not increase the list price of QBREXZA in 2019 to ensure greater patient access.
 - The availability of QBREXZA by some commercial payers in a coverage category that makes the therapy affordable to patients with a monthly co-payment, lowering the overall out of pocket costs. Additionally, in most instances, patients will have access to QBREXZA without being required to try another treatment option first. Many insurers will also allow unrestricted access to QBREXZA or simply require documentation indicating that a patient has the medical condition.
 - DermiraConnect, a new patient support program that provides eligible patients with specialized services to assist with access to QBREXZA, will be available at launch. The program is designed to offer affordability and other support services to ensure a convenient access experience for patients and healthcare professionals. Key elements of the program include:
 - Access to an electronic benefit verification tool that assists healthcare professionals and patients to quickly understand insurance eligibility.
 - A patient savings card that allows commercially insured patients who enroll in the program to pay no more than \$35 for a 30-day supply of QBREXZA, the equivalent of \$1.17 per day. Patients who are underinsured or uninsured can expect to pay no more than \$70 for a 30-day supply of QBREXZA, or \$2.33 per day. Patients currently receiving coverage through government-sponsored insurance programs, such as Medicare and Medicaid, are not eligible to enroll in the savings card program.
 - Customized tools to assist patients with managing their condition and treatment, including adherence support and refill reminders. Patients will be able to opt in and receive information about managing their primary axillary hyperhidrosis while taking QBREXZA.
 - A dedicated team of treatment support professionals available by phone or online to assist patients and healthcare professionals with any questions related to QBREXZA access and other program offerings.
 - For more information about DermiraConnect, visit www.dermiraconnect.com or call 1-877-DERMIRA.
 - Hiring of an experienced Sales Team that will educate dermatologists and other healthcare professionals about the potential benefits of QBREXZA.
 - In June 2018, Ray Bassi joined the company as Vice President, Sales. Mr. Bassi brings more than 25 years of experience in sales and marketing to Dermira, with nearly 19 of those spent at Allergan plc in sales and marketing leadership roles.
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- Considering the needs of the dermatology and broader healthcare provider community, Dermira has also hired 112 therapeutic sales specialists, 14 division business managers and 2 regional business directors, most of whom have years of specialized sales experience in dermatology. These individuals will lead Dermira's efforts to provide important information about QBREXZA to healthcare professionals throughout the United States.

Added Wiggins, "We believe it is not enough to simply have a great philosophy regarding patient access and affordability, but a thoughtful, well-developed plan. Since the founding of the company eight years ago, our goal has been to ensure that the therapies we offer to patients are accessible, of the highest quality, provide meaningful clinical benefit and most importantly, are affordable for all patients who need them. We are confident that our efforts to date will ensure broad access to QBREXZA for those patients who are seeking an affordable way to more effectively manage the condition."

** As a percentage of an estimated 180 million commercial lives as reported by Managed Markets Insight & Technology, LLC.*

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.¹ 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.^{1,2}

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 and develop leading-edge medical dermatology programs. 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 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 anticipated commercial launch of QBREXZA and the expectation that QBREXZA will be commercially available in pharmacies nationwide on October 1, 2018; the anticipated level and quality of access to QBREXZA by patients suffering from primary axillary hyperhidrosis; Dermira's goal of securing contracted coverage for more than 50% of the total U.S. commercial lives by January 1, 2019; the expectation of future additional commercial insurance coverage and immediate patient access to QBREXZA once it becomes available; Dermira's goal of providing innovative solutions for patient access; the expectation that DermiraConnect will ensure a

convenient access experience for patients and healthcare professionals; the goals of ensuring that Dermira therapies will be accessible to patients, of the highest quality, provide meaningful clinical benefit and affordable for all patients who need them; and the belief that Dermira's efforts to date will ensure broad access to QBREXZA for patients who are seeking an affordable way to more effectively manage primary axillary hyperhidrosis. 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 manufacturers, suppliers and distributors; Dermira's ability to attract and retain key employees; Dermira's ability to obtain necessary additional capital; market acceptance of QBREXZA; 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 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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