Dermira, Inc.
Form 8-K
February 12, 2019

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 11, 2019

DERMIRA, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36668	27-3267680
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

275 Middlefield Road, Suite 150	
Menlo Park, California	94025
(Address of Principal Executive Offices)	(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 1.01 Entry into a Material Definitive Agreement.

On February 11, 2019 (the "Effective Date"), Dermira, Inc. ("Dermira") entered into an option and license agreement (the "Agreement") with Almirall S.A. ("Almirall") pursuant to 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. Pursuant to the Agreement, following the availability of topline data from Dermira's ongoing Phase 2b clinical study of lebrikizumab in moderate-to-severe atopic dermatitis ("Phase 2b Trial"), Dermira will provide to Almirall a data package consisting of topline and additional data, along with a development plan ("Data Package and Development Plan"), after which Almirall will have forty-five (45) days to exercise its option.

The Agreement includes the following terms, among others:

- Almirall will have the following payment obligations to Dermira under the Agreement:
  - an option fee of $30 million, payable within ten (10) business days after delivery by Dermira of an invoice for such amount following the Effective Date;
  - an option exercise fee of $50 million if Almirall exercises its option within the 45-day period to obtain the license following receipt of the Data Package and Development Plan, payable within ten (10) business days after delivery by Dermira of an invoice for such amount following the option exercise;
  - up to an additional $30 million in connection with the initiation by Dermira of certain Phase 3 clinical studies (each, a "Phase 3 Trial"), each payable within twenty-five (25) days after achievement of such milestone;
  - up to an additional $40 million in connection with the achievement by Almirall of certain regulatory milestones, each payable within twenty-five (25) days after delivery by Dermira of an invoice for such amount following achievement of such milestone;
    - $45 million upon the first commercial sale of lebrikizumab in the European Union;
  - up to $1.25 billion in payments based on the achievement of certain thresholds for annual net sales of lebrikizumab in Europe ranging from $86 million to $3 billion, with each such potential milestone payment representing between approximately 7% and 15% of the applicable net sales threshold; and
  - royalty payments based on a range of percentages of tiers of corresponding ranges of annual net sales of lebrikizumab in Europe, where such percentages begin in the low double-digits for the first annual net sales tier and increases up to the low twenties for the highest net sales tier.
- Royalty payment obligations with respect to a given country in Europe will commence on the date of the first commercial sale of lebrikizumab in such country and end on the later of the date that is (a) ten (10) years after the date of the first commercial sale of the product in such country, (b) the expiration of the last to expire valid claim within the licensed Dermira patents in such country covering the use, import, offering for sale, or sale of lebrikizumab in such country, or (c) the expiration of the last to expire regulatory exclusivity conferred by the applicable regulatory authority in such country for lebrikizumab.
- Upon written request from Almirall and subject to certain conditions, Dermira will be required to supply to Almirall all drug product required by Almirall for development and commercialization under the Agreement for purchase at Dermira's cost.
- Almirall will be subject to a noncompetition provision for a period of five (5) years following the Effective Date, subject to applicable laws, which precludes it and its affiliates and sublicensees from developing or commercializing in Europe any monoclonal antibody product for the treatment or prevention of dermatology indications for which (a) a Phase 3 Trial has been initiated, and (b) a mechanism of action of such product is through blocking of interleukin-13.
- Following the Effective Date, and subject to earlier termination as described below, the Agreement will remain in effect until (a) if Almirall does not exercise the option during the option exercise period, the expiration of the option exercise period, and (b) if Almirall exercises the option during the

option exercise period, the date when Almirall ceases development and commercialization activities under the Agreement.

- Subject to certain conditions and limitations: (a) either party may terminate the Agreement in the event of an uncured breach of material obligations by, or certain insolvency events of, the other party; and (b) following Almirall's receipt of topline results from all of the Phase 3 Trials, Almirall may terminate the Agreement at any time, upon six (6) months' prior written notice to Dermira.
- Neither party may assign the Agreement or any part thereof without the prior written consent of the other party except, subject to certain notice requirements, in connection with the sale or other transfer of all or substantially all of the assets of the business to which the Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction); provided that any permitted successor or assignee of rights or obligations under the Agreement expressly assumes in writing the performance of such rights or obligations.
- If Dermira undergoes a change of control (as defined in the Agreement, "Change of Control") with a third party that is, as of the date such Change of Control transaction is consummated, developing or commercializing in moderate-to-severe atopic dermatitis in the United States and in Europe a monoclonal antibody for which (i) a Phase 3 trial has been initiated in moderate-to-severe atopic dermatitis and (ii) the mechanism of action is through binding to interleukin-13, and
  - (a) such third party does not within twelve (12) months after the closing of the Change of Control transaction either (i) transfer to another third party all of its (1) rights to commercialize such product in moderate-to-severe atopic dermatitis in the United States and in Europe or (2) rights to develop and commercialize lebrikizumab in moderate-to-severe atopic dermatitis in the United States and in Europe (in this case upon Almirall's prior consent), or (ii) cease such development and commercialization, and
  - (b) such third party does not expressly assume in writing the performance of Dermira's obligations under the Agreement and Dermira thereafter materially breaches without cure such obligations, then

Almirall may, at its sole cost and expense, elect to perform such obligations under the development plan and, to the extent permissible, to perform Dermira's obligations to supply drug product to Almirall. In such event, subject to certain agreed limitations, Almirall will be entitled to reimbursement from Dermira of payment obligations made to third parties on behalf of Dermira, which may be credited against milestone or royalty payments to Dermira, provided that Dermira's milestone and royalty payments due to Roche under the agreement under which Dermira licensed its rights to lebrikizumab from Roche with respect to activities under this Agreement will apply as a floor for any such credit.

- Each of Dermira and Almirall shall indemnify the other party for losses arising out of: (a) the breach by the indemnifying party of any warranty, representation, covenant, or agreement made by it in the Agreement; (b) the negligence, gross negligence or willful misconduct of the indemnifying party or its affiliates; and (c) the failure to comply with applicable law by or on behalf of the indemnifying party or its affiliates or subcontractors in connection with the development plan or the Agreement, except to the extent such losses arise directly or indirectly from the negligence, gross negligence, or willful misconduct of an indemnitee or the breach by the other party of any warranty, representation or covenant made by it in the Agreement.
- The Agreement contains customary representations and warranties made by both parties.

The foregoing summary of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the Agreement, which will be filed as an exhibit to Dermira's Quarterly Report on Form 10-Q for the quarter ending March 31, 2019.

Item 8.01 Other Events.

On February 11, 2019, Dermira issued a press release announcing its entry into the Agreement. The press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.
(d)Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press release dated February 11, 2019.

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 12, 2019 By: /s/ Andrew L. Guggenhime
Andrew L. Guggenhime
Chief Financial Officer