

Dermira, Inc.  
Form S-3/A  
November 13, 2015  
[Table of Contents](#)

As filed with the Securities and Exchange Commission on November 13, 2015

Registration No. 333-207755

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

---

AMENDMENT NO. 1

TO

**FORM S-3**

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

---

**DERMIRA, INC.**

(Exact name of registrant as specified in its charter)

Edgar Filing: Dermira, Inc. - Form S-3/A

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard  
Industrial Classification  
Code Number)

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

---

**275 Middlefield Road, Suite 150**

**Menlo Park, CA 94025**

**(650) 421-7200**

(Address, including zip code, and telephone number, including  
area code of registrant's principal executive offices)

---

**Thomas G. Wiggins**  
**Chief Executive Officer and Chairman of the Board**  
**275 Middlefield Road, Suite 150**  
**Menlo Park, California 94025**  
**(650) 421-7200**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

**Douglas N. Cogen, Esq.**  
**Michael A. Brown, Esq.**  
**Robert A. Freedman, Esq.**  
**Fenwick & West LLP**  
**555 California Street, 12th Floor**  
**San Francisco, CA 94104**  
**(415) 875-2300**

**Andrew L. Guggenheimer**  
**Chief Operating Officer and**  
**Chief Financial Officer**  
**275 Middlefield Road, Suite 150**  
**Menlo Park, CA 94025**  
**(650) 421-7200**

---

**Approximate date of commencement of proposed sale to the public:**

**From time to time after the effective date of this Registration Statement.**

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

## Edgar Filing: Dermira, Inc. - Form S-3/A

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If this form is a registration statement filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a  
smaller reporting  
company)

Smaller reporting company

---

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

---

Table of Contents

**EXPLANATORY NOTE**

This registration statement contains two prospectuses:

- a prospectus, which covers the offering, issuance and sale by us of up to a maximum aggregate offering price of \$300,000,000 of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities, and/or units consisting of some or all of these securities; and
- a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75,000,000 of our common stock that may be issued and sold under a sales agreement with Cowen and Company, LLC.

The prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the prospectus will be specified in a prospectus supplement to the prospectus. The sales agreement prospectus immediately follows the prospectus. The \$75,000,000 of common stock that may be offered, issued and sold under the sales agreement prospectus is included in the \$300,000,000 of securities that may be offered, issued and sold by us under the prospectus.

---

Table of Contents

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to completion, dated November 13, 2015**

**PROSPECTUS**

**\$300,000,000**

**Common Stock, Preferred Stock,  
Debt Securities, Warrants, Subscription Rights and Units**

---

From time to time, we or selling security holders may offer our common stock or preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities, and/or units consisting of some or all of these securities, in any combination, together or separately, in one or more offerings, in amounts, at prices and on the terms that we will determine at the time of the offering and which will be set forth in a prospectus supplement and any related free writing prospectus. The applicable prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. The total amount of these securities will have an initial aggregate offering price of up to \$300,000,000.

You should read this prospectus, the information incorporated, or deemed to be incorporated, by reference in this prospectus, and any applicable prospectus supplement and related free writing prospectus carefully before you invest.

Our common stock is listed on The NASDAQ Global Select Market under the symbol **DERM**. The last reported sale price of our common stock on The NASDAQ Global Select Market on October 29, 2015 was \$27.12 per share. None of the other securities we may offer are currently traded on any securities exchange. The applicable prospectus supplement and any related free writing prospectus will contain information, where applicable, as to any other listing on The NASDAQ Global Select Market or any securities market or exchange of the securities covered by the

applicable prospectus supplement and any related free writing prospectus.

**Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading **Risk Factors** beginning on page 5 of this prospectus and in the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the documents incorporated by reference into this prospectus.**

The securities may be sold by us or selling security holders to or through underwriters or dealers, directly to purchasers or through agents designated from time to time, on a continuous or delayed basis. For additional information on the methods of sale, you should refer to the discussion under the heading **Plan of Distribution** in this prospectus. If any underwriters, dealers or agents are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters or agents and any applicable fees, discounts or commissions, details regarding over-allotment options, if any, and the net proceeds to us will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

---

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

---

**The date of this prospectus is                      , 2015.**

---

Table of Contents

TABLE OF CONTENTS

Prospectus

	<b>Page</b>
<u>About this Prospectus</u>	1
<u>Summary</u>	2
<u>Risk Factors</u>	5
<u>Special Note Regarding Forward-Looking Statements</u>	5
<u>Use of Proceeds</u>	6
<u>Ratio of Earnings to Fixed Charges</u>	6
<u>Plan of Distribution</u>	7
<u>Description of Capital Stock</u>	9
<u>Description of Debt Securities</u>	14
<u>Description of Warrants</u>	21
<u>Description of Subscription Rights</u>	23
<u>Description of Units</u>	24
<u>Legal Matters</u>	25
<u>Experts</u>	25
<u>Where You Can Find Additional Information</u>	25
<u>Incorporation of Certain Information by Reference</u>	26

Table of Contents

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf registration process, from time to time, we may sell any combination of the securities described in this prospectus in one or more offerings, up to an aggregate dollar amount of \$300,000,000. We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities under this shelf registration process, we will provide a prospectus supplement that will contain specific information about the terms of the offering. We may also add, update or change in the applicable prospectus supplement any of the information contained in this prospectus. To the extent there is a conflict between the information contained in this prospectus and the applicable prospectus supplement, you should rely on the information in the applicable prospectus supplement; provided that, if any statement in one of these documents is inconsistent with a statement in another document having a later date (for example, a document incorporated by reference in this prospectus or any applicable prospectus supplement), the statement in the document having the later date modifies or supersedes the earlier statement. You should read both this prospectus and any applicable prospectus supplement together with additional information described under the heading **Where You Can Find Additional Information**.

You should rely only on the information contained in or incorporated by reference into this prospectus or any applicable prospectus supplement. No dealer, salesperson or any other person is authorized to give any information or to make any representation other than the information and representations contained in or incorporated by reference into this prospectus or any applicable prospectus supplement. If different information is given or different representations are made, you may not rely on that information or those representations as having been authorized by us. You may not imply from the delivery of this prospectus and any applicable prospectus supplement, nor from a sale made under this prospectus and any applicable prospectus supplement, that our affairs are unchanged since the date of this prospectus and any applicable prospectus supplement or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus and any applicable prospectus supplement or any sale of a security. This prospectus and any applicable prospectus supplement may only be used where it is legal to sell the securities.

***THIS PROSPECTUS MAY NOT BE USED TO OFFER AND SELL SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.***

Unless the context indicates otherwise, as used in this prospectus, the terms **Company**, **Dermira**, **Registrant**, **we**, **us**, and **our** refer to Dermira, Inc., a Delaware corporation, and its sole subsidiary, taken as a whole, unless otherwise noted.

This prospectus and the information incorporated herein by reference may include trademarks, service marks and trade names owned by us or others. **Dermira** is a pending trademark in the United States and Canada and a registered trademark in some other countries. The Dermira logo and all product names are our common law trademarks. All other service marks, trademarks and tradenames appearing in this prospectus are the property of their respective owners.



Table of Contents

**SUMMARY**

*This summary highlights information contained in other parts of this prospectus or incorporated by reference in this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2014, and our other filings with the Securities and Exchange Commission listed in the section of the prospectus entitled *Incorporation of Certain Information by Reference*. This summary does not contain all of the information you should consider in making your investment decision. Before deciding to invest in our securities, you should read the entire prospectus, the applicable prospectus supplement and any related free writing prospectus, and the information incorporated by reference herein in their entirety. You should carefully consider, among other things, the matters discussed in the section entitled *Risk Factors* contained in the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See *Special Note Regarding Forward-Looking Statements*.*

**Our Company**

We are a specialty biopharmaceutical company focused on bringing innovative and differentiated products to dermatologists and their patients. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our strategy is to leverage this experience to in-license, acquire, develop and commercialize products that we believe can be successful in the dermatology marketplace. Our portfolio of five product candidates targets significant market opportunities and includes three late-stage product candidates: Cimzia (certolizumab pegol), which we are developing in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe plaque psoriasis; DRM04, which we are developing for the treatment of hyperhidrosis, or excessive sweating; and DRM01, which we are developing for the treatment of acne.

We are currently focused on the development of therapeutic solutions in medical dermatology to treat skin conditions, such as psoriasis, hyperhidrosis and acne. These diseases impact millions of people worldwide and can have significant, multidimensional effects on patients quality of life, including their physical, functional and emotional well-being. According to multiple published studies, patients report that medical dermatology conditions affect quality of life in ways comparable to other serious diseases, such as cancer, heart disease, diabetes, epilepsy, asthma and arthritis.

We believe that medical dermatology represents a particularly attractive segment of the biopharmaceutical industry for multiple reasons:

- Dermatology represents a large, growing, specialty market supported by strong patient demand.
- The dermatology market is ripe for innovation with significant commercial opportunities.

- The development of dermatology products can be relatively efficient in terms of time and cost.
- Dermatology products can be commercialized at relatively low cost.
- The needs of dermatologists and their patients have been underserved as a result of the significant consolidation of dermatology-focused companies.

We believe that these industry dynamics present an opportunity for us to establish our company as a leader in dermatology product development and commercialization, and we plan to capitalize on that opportunity for the benefit of patients and dermatologists.

Our three late-stage product candidates are:

- Cimzia, an injectable biologic tumor necrosis factor-alpha inhibitor, or TNF inhibitor, that is currently approved and marketed by UCB for the treatment of numerous inflammatory diseases spanning multiple medical specialties, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease, in multiple countries, including the United States. Biologic TNF inhibitors are a class of pharmaceutical products that are manufactured by biological processes and designed to exert their effect by inhibiting TNF, a naturally occurring molecule that plays an important role in promoting inflammation within the body, including in patients with psoriasis. We have entered into a development and commercialization agreement, or the UCB agreement, to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. Based on the results of two Phase 2 clinical trials conducted by UCB and our end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, we and UCB commenced a Phase 3 clinical program for Cimzia for the treatment of moderate-to-severe plaque psoriasis in December 2014. We expect topline results from the Phase 3 clinical program in 2017.

Table of Contents

- DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of hyperhidrosis. Anticholinergics are a class of pharmaceutical products that exert their effect by blocking the action of acetylcholine, a molecule that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. DRM04 is a topical formulation of a novel form of an anticholinergic agent that has been approved for systemic administration in other indications, and it is designed to inhibit sweat production by blocking the activation of sweat glands following topical administration. Based on the results of a Phase 2 program comprising three randomized, double-blind, vehicle-controlled clinical trials in 341 patients and our end-of-Phase 2 meeting with the FDA in April 2015, we commenced a Phase 3 clinical program for DRM04 in patients with primary axillary, or underarm, hyperhidrosis in July 2015. We expect topline results from the Phase 3 clinical program in the second half of 2016.
- DRM01, a novel, topical, small-molecule sebum inhibitor we are developing for the treatment of acne. Sebum is an oily substance made up of lipids produced by glands in the skin called sebaceous glands, and excessive sebum production is an important aspect of acne that is not addressed by available topical therapies. DRM01 is designed to exert its effect by inhibiting acetyl coenzyme A carboxylase, an enzyme that plays an important role in the synthesis of fatty acids, a type of lipid that represents an essential component of the majority of sebum lipids. Based on the results of a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial, we commenced a Phase 2b clinical program in April 2015. We expect topline results from the Phase 2b clinical program in the first half of 2016.

In addition, we have two early-stage product candidates in preclinical development for the treatment of inflammatory skin diseases and acne.

Dermira was founded by Thomas G. Wiggans, Eugene A. Bauer, M.D., Christopher M. Griffith and Luis C. Peña with the vision of building a leading dermatology company. Several members of our management team, including Mr. Wiggans, Dr. Bauer and Mr. Peña, have extensive experience within the dermatology field, including having served in executive roles at leading dermatology companies such as Connetics Corporation, Peplin, Inc. and Stiefel Laboratories, Inc., a GlaxoSmithKline LLC Company. This experience brings us significant insight into product and commercial opportunities, as well as a broad network of relationships with leaders within the industry and medical community.

### **The Securities We May Offer**

With this prospectus, we may offer common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities, and/or units consisting of some or all of these securities in any combination. The aggregate offering price of securities that we offer with this prospectus will not exceed \$300,000,000. Each time we offer securities with this prospectus, we will provide offerees with a prospectus supplement that will contain the specific terms of the securities being offered. The following is a summary of the securities we may offer with this prospectus.

*Common Stock*

We may offer shares of our common stock, par value \$0.001 per share.

Table of Contents

*Preferred Stock*

We may offer shares of our preferred stock, par value \$0.001 per share, in one or more series. Our board of directors or a committee designated by our board of directors will determine the rights, preferences and privileges of the series of shares of preferred stock being offered. The rights, preferences and privileges of each series of preferred stock will be more fully described in the applicable prospectus supplement.

*Debt Securities*

We may offer general obligations, which may be secured or unsecured, senior or subordinated and convertible into shares of our common stock or preferred stock. In this prospectus, we refer to the all debt securities together as the debt securities. Our board of directors or a committee designated by our board of directors will determine the terms of each series of debt securities being offered.

We will issue the debt securities under an indenture between us and a trustee. In this document, we have summarized general features of the debt securities from the indenture. We encourage you to read the indenture, which is an exhibit to the registration statement of which this prospectus is a part.

*Warrants*

We may offer warrants to purchase our common stock, preferred stock or debt securities. We may issue warrants independently or together with other securities. Our board of directors or a committee designated by our board of directors will determine the terms of the warrants.

*Subscription Rights*

We may offer subscription rights to purchase our common stock, preferred stock or debt securities. We may issue subscription rights independently or together with other securities. Our board of directors or a committee designated by our board of directors will determine the terms of the subscription rights.

*Units*

We may offer units consisting of some or all of the securities described above, in any combination, including common stock, preferred stock, warrants and/or debt securities. The terms of these units will be set forth in a prospectus supplement. The description of the terms of these units in the related prospectus supplement will not necessarily be complete. You should refer to the applicable form of unit and unit agreement for complete information with respect to these units.

#### **Corporate Information**

We were incorporated in the State of Delaware in August 2010 under the name Skintelligence, Inc. We changed our name to Dermira, Inc. in September 2011. Our principal executive offices are located at 275 Middlefield Road, Suite 150, Menlo Park, California 94025, and our telephone number is (650) 421-7200. Our website address is [www.dermira.com](http://www.dermira.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our securities.

Table of Contents

**RISK FACTORS**

An investment in our securities involves a high degree of risk. The prospectus supplement applicable to each offering of securities will contain a discussion of the risks applicable to an investment in our securities. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement and any free writing prospectus, together with all of the other information contained or incorporated by reference in the applicable prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under Part II, Item 1A, "Risk Factors," in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015, or September 2015 10-Q, which is incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the Securities and Exchange Commission, or SEC, in the future. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference herein contain forward-looking statements. All statements contained in this prospectus and the documents incorporated by reference herein other than statements of historical fact, including statements regarding our future consolidated results of operations and financial position, our business strategy and plans, market growth, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "potentially," "continue," "anticipate," "intend," "expect," "would," "project," "plan" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our consolidated financial condition, consolidated results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in our September 2015 10-Q, as well as those discussed in this prospectus, the documents incorporated by reference in this prospectus, the applicable prospectus supplement and any free writing prospectus. All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus and the documents incorporated by reference herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We undertake no obligation to update any of these forward-looking statements for any reason after the date of this prospectus, or in the case of documents referred to or incorporated by reference, the date of those documents, or to conform such statements to actual results or revised expectations. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

## Edgar Filing: Dermira, Inc. - Form S-3/A

You should read this prospectus, the documents incorporated by reference herein, the applicable prospectus supplement and any free writing prospectus, and the documents that we have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.



Table of Contents**USE OF PROCEEDS**

We will have broad discretion over the use of the net proceeds to us from the sale of our securities under this prospectus and investors will be relying on the judgment of our management regarding the application of the proceeds. Unless otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of securities under this prospectus to fund research and development of our product candidates, working capital, capital expenditures and other general corporate purposes. Additionally, we may use a portion of the net proceeds to us from the sale of our securities under this prospectus to expand our business by in-licensing or acquiring, as the case may be, commercial products, product candidates, technologies, compounds, other assets or complementary businesses. We will set forth in the applicable prospectus supplement our intended uses for the net proceeds received from the sale of any securities. Pending these uses, we intend to invest the net proceeds in investment-grade, interest-bearing securities such as money market funds, certificates of deposit, commercial paper, repurchase agreements, corporate debt and guaranteed obligations of the U.S. government.

**RATIO OF EARNINGS TO FIXED CHARGES**

The financial information provided in the table below should be read in conjunction with our financial statements and the related notes incorporated by reference into this prospectus. The following table shows our ratio of earnings to fixed charges for the periods indicated. As earnings are inadequate to cover the combined preference dividends and fixed charges, we have provided the deficiency amounts. For purposes of calculating this deficiency, earnings consist of loss from continuing operations before fixed charges. Fixed charges consist of interest expense and the portion of rent expense which we believe is representative of the interest component of rental expense. This table is qualified by the more detailed information appearing in the computation table set forth in Exhibit 12.1 to the registration statement, of which this prospectus is a part.

(in millions)	Year Ended December 31,			Nine Months Ended September 30,
	2012	2013	2014	2015
Ratio of earnings to fixed charges				
Deficiency of earnings to fixed charges	\$ (20.3)	\$ (22.4)	\$ (31.8)	\$ (47.2)

Table of Contents

**PLAN OF DISTRIBUTION**

We may sell the securities covered by this prospectus to one or more underwriters for public offering and sale by them, and may also sell the securities to investors directly or through agents. We will name any underwriter or agent involved in the offer and sale of securities in the applicable prospectus supplement. We have reserved the right to sell or exchange securities directly to investors on our own behalf in jurisdictions where we are authorized to do so. We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed from time to time;
- market prices prevailing at the time of sale;
- prices related to such prevailing market prices; or
- negotiated prices.

We may directly solicit offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time. We will name in any prospectus supplement any agent involved in the offer or sale of our securities. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis, and a dealer will purchase securities as a principal for resale at varying prices to be determined by the dealer.

If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale and we will provide the name of any underwriter in the applicable prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agent.

We will provide in the applicable prospectus supplement any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, or the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, and to reimburse them for certain expenses. We may grant underwriters who participate in the distribution of our securities under this prospectus an option to purchase additional securities to cover any over-allotments in connection with the distribution.

The securities we offer under this prospectus may or may not be listed through The NASDAQ Global Select Market or any other securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include short sales of the securities, which involves the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such short positions by making purchases in the open market or by exercising their option to purchase additional securities. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

We may engage in at-the-market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and they may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in these sale transactions will be an underwriter and will be identified in the applicable prospectus supplement. In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. The financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

Table of Contents

We will file a prospectus supplement to describe the terms of any offering of our securities covered by this prospectus. The applicable prospectus supplement will disclose:

- the terms of the offer;
  
- the name or names of any underwriters, including any managing underwriters, as well as any dealers or agents, and the amounts of securities underwritten or purchased by each of them;
  
- the purchase price of the securities from us;
  
- the net proceeds to us from the sale of the securities;
  
- any delayed delivery arrangements;
  
- the nature of the underwriters' obligations to take the securities;
  
- any over-allotment options under which underwriters, if any, may purchase additional securities from us;
  
- any underwriting discounts, commissions or other items constituting underwriters' compensation, and any commissions paid to agents;
  
- in a subscription rights offering, whether we have engaged dealer-managers to facilitate the offering or subscription, including their name or names and compensation;
  
- any securities exchanges or markets on which such securities may be listed;

- any public offering price; and
- other facts material to the transaction.

We will bear all or substantially all of the costs, expenses and fees in connection with the registration of our securities under this prospectus. The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business.

Table of Contents

**DESCRIPTION OF CAPITAL STOCK**

**General**

Our authorized capital stock consists of 500,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.001 par value per share. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation and restated bylaws, which are included as exhibits to the registration statement, of which this prospectus is a part, and to the applicable provisions of Delaware law.

Table of Contents

**Common Stock**

***Dividend Rights***

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. For more information about our dividend policy, see *Dividend Policy* in our Annual Report on Form 10-K for the year ended December 31, 2014, which is incorporated by reference in this prospectus.

***Voting Rights***

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation. Accordingly, holders of a majority of the shares of our common stock are able to elect all of our directors. We have a classified board of directors, divided into three classes with staggered three-year terms. Only one class of directors may be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

***No Preemptive or Similar Rights***

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

***Right to Receive Liquidation Distributions***

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

**Preferred Stock**

Our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board

## Edgar Filing: Dermira, Inc. - Form S-3/A

of directors can also increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

We will incorporate by reference into the registration statement, of which this prospectus is a part, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. This description of the preferred stock in the certificate of designation, any applicable prospectus supplement and any related free writing prospectus will describe, among other things, the following terms of the preferred stock:

- the number of shares in any series;
  
- the designation for any series by number, letter or title that shall distinguish the series from any other series of preferred stock;
  
- the dividend rate and whether dividends on that series of preferred stock will be cumulative, noncumulative or partially cumulative;
  
- the voting rights of that series of preferred stock, if any;
  
- the conversion provisions applicable to that series of preferred stock, if any;
  
- the redemption or sinking fund provisions applicable to that series of preferred stock, if any;
  
- the liquidation preference per share of that series of preferred stock, if any;
  
- the rank of that series of preferred stock relative to other series of preferred stock; and
  
- the terms of any other preferences or rights, if any, applicable to that series of preferred stock.

The description of preferred stock set forth above and in any description of the terms of a particular series of preferred stock in the related prospectus supplement and any related free writing prospectus will not be complete. You should refer to the applicable certificate of designation



Edgar Filing: Dermira, Inc. - Form S-3/A

for such series of preferred stock for complete information with respect to such preferred stock. The prospectus supplement will also contain a description of material U.S. federal income tax considerations relating to that series of preferred stock.

Table of Contents

**Registration Rights**

As of September 30, 2015, holders of an aggregate of no more than 14,085,307 outstanding shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act. These shares are referred to as registrable securities. These rights are provided under the terms of an amended and restated investors' rights agreement between us and the holders of these shares, which was entered into in connection with our preferred stock financings, and include demand registration rights, short-form registration rights and piggyback registration rights. In any registration made pursuant to such amended and restated investors' rights agreement, all fees, costs and expenses of underwritten registrations, including fees and disbursements of one special counsel to the selling stockholders not to exceed \$50,000, will be borne by us and all selling expenses, including estimated underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

The registration rights terminate October 2019 or, with respect to any particular stockholder, at such time as that stockholder holds less than one percent of our outstanding stock, we have completed this offering and such stockholder can sell all of its shares during any three-month period pursuant to Rule 144 promulgated under the Securities Act.

***Demand Registration Rights***

Under the terms of the amended and restated investors' rights agreement, if we receive a written request, at any time after 90 days following the effective date of this offering, from the holders of at least 66<sup>2</sup>/<sub>3</sub>% of the registrable securities then outstanding that we file a registration statement under the Securities Act covering the registration of outstanding registrable securities, then we will be required to use our reasonable best efforts to register, within 90 days of such written request, all of the shares requested to be registered for public resale, if the amount of registrable securities to be registered will have aggregate gross proceeds (before underwriting discounts and commissions) of at least \$10.0 million. We are required to effect only two registrations pursuant to this provision of the amended and restated investors' rights agreement. We may postpone the filing of a registration statement no more than once during any 12-month period for up to 120 days if our board of directors determines that the filing would be detrimental to us and our stockholders. We are not required to effect a demand registration under certain additional circumstances specified in the amended and restated investors' rights agreement.

***Form S-3 Registration Rights***

The holders of at least 30% of the registrable securities then outstanding can request that we register all or part of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least \$5.0 million. The stockholders may require us to effect at most two registration statements on Form S-3 in any 12-month period. We may postpone the filing of a registration statement on Form S-3 no more than once during any 12-month period for up to 120 days if our board of directors determines that the filing would be detrimental to us and our stockholders. We are not required to effect a registration on Form S-3 under certain additional circumstances specified in the amended and restated investors' rights agreement.

*Piggyback Registration Rights*

If we register any of our securities for public sale in an offering pursuant to this prospectus, holders of registrable securities will have the right to include their shares in the registration statement. However, this right does not apply to a demand registration, a registration relating to employee benefit plans, a registration relating to a corporate reorganization, or a registration on any registration form which does not permit secondary sales or does not include substantially the same information as would be required to be included in a registration statement covering the sale of registrable securities. The underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine in good faith that marketing factors require limitation, in which case the number of shares to be registered will be apportioned, first, to us for our own account and, second, pro rata among the holders of registrable securities requesting inclusion of their registrable securities in such registration statement, according to the total number of registrable securities held by each such holder. However, the number of shares to be registered by these holders cannot be reduced below 30% of the total shares covered by the registration statement.

Table of Contents

**Anti-Takeover Provisions**

The provisions of Delaware law, our restated certificate of incorporation and our restated bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

*Delaware Law*

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, regulating corporate takeovers. In general, DGCL Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 $\frac{2}{3}$ % of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that DGCL Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

*Restated Certificate of Incorporation and Restated Bylaws Provisions*

Our restated certificate of incorporation and our restated bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- ***Board of Directors Vacancies.*** Our restated certificate of incorporation and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.
- ***Classified Board.*** Our restated certificate of incorporation and restated bylaws provide that our board of directors is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors. See Proposal No. 1 Election of Directors appearing in our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 29, 2015, which is incorporated by reference in this prospectus.

Table of Contents

- ***Stockholder Action; Special Meetings of Stockholders.*** Our restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our lead independent director, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.
- ***Advance Notice Requirements for Stockholder Proposals and Director Nominations.*** Our restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.
- ***No Cumulative Voting.*** The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws do not provide for cumulative voting.
- ***Directors Removed Only for Cause.*** Our restated certificate of incorporation provides that stockholders may remove directors only for cause.
- ***Amendment of Charter Provisions.*** Any amendment of the above provisions in our restated certificate of incorporation would require approval by holders of at least two-thirds of our outstanding common stock.
- ***Issuance of Undesignated Preferred Stock.*** Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by merger, tender offer, proxy contest or other means.

- **Choice of Forum.** Our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

#### **Exchange Listing**

Our common stock is listed on The NASDAQ Global Select Market under the symbol **DERM**.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is (800) 937-5449.

Table of Contents

**DESCRIPTION OF DEBT SECURITIES**

**General**

We will issue the debt securities offered by this prospectus and any accompanying prospectus supplement under an indenture to be entered into between us and the trustee identified in the applicable prospectus supplement. The terms of the debt securities will include those stated in the indenture and those made part of the indenture by reference to the Trust Indenture Act of 1939, as in effect on the date of the indenture. We have filed a copy of the form of indenture as an exhibit to the registration statement, of which this prospectus is a part. The indenture will be subject to and governed by the terms of the Trust Indenture Act of 1939.

We may offer under this prospectus up to an aggregate principal amount of \$300,000,000 in debt securities, or if debt securities are issued at a discount, or in a foreign currency, foreign currency units or composite currency, the principal amount as may be sold for an aggregate public offering price of up to \$300,000,000. Unless otherwise specified in the applicable prospectus supplement, the debt securities will represent our direct, unsecured obligations and will rank equally with all of our other unsecured indebtedness.

We may issue the debt securities in one or more series with the same or various maturities, at par, at a premium, or at a discount. We will describe the particular terms of each series of debt securities in a prospectus supplement relating to that series, which we will file with the SEC. The applicable prospectus supplement relating to the particular series of debt securities being offered will specify the particular amounts, prices and terms of those debt securities. These terms may include:

- the title of the series;
- the aggregate principal amount, and, if a series, the total amount authorized and the total amount outstanding;
- the issue price or prices, expressed as a percentage of the aggregate principal amount of the debt securities;
- any limit on the aggregate principal amount;
- the date or dates on which principal is payable or the method for determining that date or dates;



- the interest rate or rates (which may be fixed or variable) or, if applicable, the method used to determine such rate or rates;
- the date or dates from which interest, if any, will be payable and any regular record date for the interest payable;
- the place or places where principal and, if applicable, premium and interest, is payable;
- the terms and conditions upon which we may, or the holders may require us to, redeem or repurchase the debt securities;
- the denominations in which such debt securities may be issuable, if other than denominations of \$1,000 or any integral multiple of that number;
- whether the debt securities are to be issuable in the form of certificated securities (as described below) or global securities (as described below);
- the portion of principal amount that will be payable upon declaration of acceleration of the maturity date if other than the principal amount of the debt securities;
- the currency of denomination;
- the designation of the currency, currencies or currency units in which payment of principal and, if applicable, premium and interest, will be made;

Table of Contents

- if payments of principal and, if applicable, premium or interest, on the debt securities are to be made in one or more currencies or currency units other than the currency of denomination, the manner in which the exchange rate with respect to such payments will be determined;
- if amounts of principal and, if applicable, premium and interest may be determined by reference to an index based on a currency or currencies or by reference to a commodity, commodity index, stock exchange index or financial index, then the manner in which such amounts will be determined;
- the provisions, if any, relating to any collateral provided for such debt securities;
- any addition to or change in the covenants and/or the acceleration provisions described in this prospectus or in the indenture;
- any events of default, if not otherwise described below under **Events of Default** ;
- the terms and conditions, if any, for conversion into or exchange for shares of our common stock or preferred stock;
- any depositaries, interest rate calculation agents, exchange rate calculation agents or other agents;
- the terms and conditions, if any, upon which the debt securities shall be subordinated in right of payment to our other indebtedness;
- the applicable CUSIP number; and
- any other terms specific to the debt securities.

## Edgar Filing: Dermira, Inc. - Form S-3/A

We may issue discount debt securities that provide for an amount less than the stated principal amount to be due and payable upon acceleration of the maturity of such debt securities in accordance with the terms of the indenture. We may also issue debt securities in bearer form, with or without coupons. If we issue discount debt securities or debt securities in bearer form, we will describe material U.S. federal income tax considerations and other material special considerations which apply to these debt securities in the applicable prospectus supplement.

We may issue debt securities denominated in or payable in a foreign currency or currencies or a foreign currency unit or units. If we do, we will describe the restrictions, elections, and general tax considerations relating to the debt securities and the foreign currency or currencies or foreign currency unit or units in the applicable prospectus supplement.

Debt securities offered under this prospectus and any prospectus supplement will be subordinated in right of payment to our senior indebtedness. In addition, we will seek the consent of the holders of any such senior indebtedness prior to issuing any debt securities under this prospectus to the extent required by the agreements evidencing such senior indebtedness.

### **Registrar and Paying Agent**

The debt securities may be presented for registration of transfer or for exchange at the corporate trust office of the security registrar or at any other office or agency that we maintain for those purposes. In addition, the debt securities may be presented for payment of principal, interest and any premium at the office of the paying agent or at any office or agency that we maintain for those purposes.

Table of Contents

**Conversion or Exchange Rights**

Debt securities may be convertible into or exchangeable for shares of our common stock or preferred stock. The terms and conditions of conversion or exchange will be stated in the applicable prospectus supplement. The terms will include, among others, the following:

- the conversion or exchange price;
- the conversion or exchange period;
- provisions regarding the convertibility or exchangeability of the debt securities, including who may convert or exchange;
- events requiring adjustment to the conversion or exchange price;
- provisions affecting conversion or exchange in the event of our redemption of the debt securities; and
- any anti-dilution provisions, if applicable.

**Registered Global Securities**

If we decide to issue debt securities in the form of one or more global securities, then we will register the global securities in the name of the depositary for the global securities or the nominee of the depositary, and the global securities will be delivered by the trustee to the depositary for credit to the accounts of the holders of beneficial interests in the debt securities.

The applicable prospectus supplement will describe the specific terms of the depositary arrangement for debt securities of a series that are issued in global form. None of us, the trustee, any payment agent or the security registrar will have any responsibility or liability for any aspect of the records relating to or payments made on account of beneficial ownership interests in a global debt security or for maintaining, supervising or reviewing any records relating to these beneficial ownership interests.

### **No Protection in the Event of Change of Control**

The indenture does not have any covenants or other provisions providing for a put or increased interest or otherwise that would afford holders of our debt securities additional protection in the event of a recapitalization transaction, a change of control or a highly leveraged transaction. If we offer any covenants or provisions of this type with respect to any debt securities covered by this prospectus, we will describe them in the applicable prospectus supplement.

### **Covenants**

Unless otherwise indicated in this prospectus or the applicable prospectus supplement, our debt securities will not have the benefit of any covenants that limit or restrict our business or operations, the pledging of our assets or the incurrence by us of indebtedness. We will describe in the applicable prospectus supplement any material covenants in respect of a series of debt securities.

### **Merger, Consolidation or Sale of Assets**

The form of indenture provides that we will not consolidate with or merge into any other person or convey, transfer, sell or lease our properties and assets substantially as an entirety to any person, unless:

- the person formed by the consolidation or into or with which we are merged or the person to which our properties and assets are conveyed, transferred, sold or leased, is a corporation organized and existing under the laws of the United States, any state or the District of Columbia or a corporation or comparable legal entity organized under the laws of a foreign jurisdiction and, if we are not the surviving person, the surviving person has expressly assumed all of our obligations, including the payment of the principal of and, premium, if any, and interest on the debt securities and the performance of the other covenants under the indenture; and
- immediately before and immediately after giving effect to the transaction, no event of default, and no event which, after notice or lapse of time or both, would become an event of default, has occurred and is continuing under the indenture.

Table of Contents

**Events of Default**

Unless otherwise specified in the applicable prospectus supplement, the following events will be events of default under the indenture with respect to debt securities of any series:

- we fail to pay any principal or premium, if any, when it becomes due;
  
- we fail to pay any interest within 30 days after it becomes due; however, if we extend an interest payment under the terms of the debt securities, the extension will not be a failure to pay interest;
  
- we fail to observe or perform any other covenant in the debt securities or the indenture for 60 days after written notice specifying the failure from the trustee or the holders of not less than 25% in aggregate principal amount of the outstanding debt securities of that series;
  
- certain events involving bankruptcy, insolvency or reorganization of us or any of our significant subsidiaries;  
and
  
- any other event of default provided in the applicable resolution of our board of directors or the supplemental indenture under which we issue debt securities.

The trustee may withhold notice to the holders of the debt securities of any series of any default, except in payment of principal of or premium, if any, or interest on the debt securities of a series, if the trustee considers it to be in the best interest of the holders of the debt securities of that series to do so.

If an event of default (other than an event of default resulting from certain events of bankruptcy, insolvency or reorganization) occurs, and is continuing, then the trustee or the holders of not less than 25% in aggregate principal amount of the outstanding debt securities of any series may accelerate the maturity of the debt securities. If this happens, the entire principal amount, plus the premium, if any, of all the outstanding debt securities of the affected series plus accrued interest to the date of acceleration will be immediately due and payable. At any time after the acceleration, but before a judgment or decree based on such acceleration is obtained by the trustee, the holders of a majority in aggregate principal amount of outstanding debt securities of such series may rescind and annul such acceleration if:

## Edgar Filing: Dermira, Inc. - Form S-3/A

- all events of default (other than nonpayment of accelerated principal, premium or interest) have been cured or waived;
- all lawful interest on overdue interest and overdue principal has been paid; and
- the rescission would not conflict with any judgment or decree.

In addition, if the acceleration occurs at any time when we have outstanding indebtedness that is senior to the debt securities, the payment of the principal amount of outstanding debt securities may be subordinated in right of payment to the prior payment of any amounts due under the senior indebtedness, in which case the holders of debt securities will be entitled to payment under the terms prescribed in the instruments evidencing the senior indebtedness and the indenture.

If an event of default resulting from certain events of bankruptcy, insolvency or reorganization occurs, the principal, premium and interest amount with respect to all of the debt securities of any series will be due and payable immediately without any declaration or other act on the part of the trustee or the holders of the debt securities of that series.

The holders of a majority in principal amount of the outstanding debt securities of a series will have the right to waive any existing default or compliance with any provision of the indenture or the debt securities of that series and to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, subject to certain limitations specified in the indenture.

No holder of any debt security of a series will have any right to institute any proceeding with respect to the indenture or for any remedy under the indenture, unless:

- the holder gives to the trustee written notice of a continuing event of default;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of the affected series make a written request and offer reasonable indemnity to the trustee to institute a proceeding as trustee;
- the trustee fails to institute a proceeding within 60 days after such request; and
- the holders of a majority in aggregate principal amount of the outstanding debt securities of the affected series do not give the trustee a direction inconsistent with such request during such 60-day period.





Table of Contents

These limitations do not, however, apply to a suit instituted for payment on debt securities of any series on or after the due dates expressed in the debt securities.

We will periodically deliver certificates to the trustee regarding our compliance with our obligations under the indenture.

**Modification and Waiver**

From time to time, we and the trustee may, without the consent of holders of the debt securities of one or more series, amend the indenture or the debt securities of one or more series, or supplement the indenture, for certain specified purposes, including:

- to provide that the surviving entity following a change of control permitted under the indenture will assume all of our obligations under the indenture and debt securities;
- to provide for certificated debt securities in addition to uncertificated debt securities;
- to comply with any requirements of the SEC under the Trust Indenture Act of 1939;
- to provide for the issuance of and establish the form and terms and conditions of debt securities of any series as permitted by the indenture;
- to cure any ambiguity, defect or inconsistency, or make any other change that does not materially and adversely affect the rights of any holder; and
- to appoint a successor trustee under the indenture with respect to one or more series.

From time to time we and the trustee may, with the consent of holders of at least a majority in principal amount of an outstanding series of debt securities, amend or supplement the indenture or the debt securities series, or waive compliance in a particular instance by us with any provision of the indenture or the debt securities. We may not, however, without the consent of each holder affected by such action, modify or supplement the indenture or the debt securities or waive compliance with any provision of the indenture or the debt securities in order to:

- reduce the amount of debt securities whose holders must consent to an amendment, supplement, or waiver to the indenture or such debt security;
- reduce the rate of or change the time for payment of interest or reduce the amount of or postpone the date for payment of sinking fund or analogous obligations;
- reduce the principal of or change the stated maturity of the debt securities;
- make any debt security payable in money other than that stated in the debt security;
- change the amount or time of any payment required or reduce the premium payable upon any redemption, or change the time before which no such redemption may be made;
- waive a default in the payment of the principal of, premium, if any, or interest on the debt securities or a redemption payment;
- waive a redemption payment with respect to any debt securities or change any provision with respect to redemption of debt securities; or
- take any other action otherwise prohibited by the indenture to be taken without the consent of each holder affected by the action.

Table of Contents

**Defeasance of Debt Securities and Certain Covenants in Certain Circumstances**

The indenture permits us, at any time, to elect to discharge our obligations with respect to one or more series of debt securities by following certain procedures described in the indenture. These procedures will allow us either:

- to defease and be discharged from any and all of our obligations with respect to any debt securities except for the following obligations (which discharge is referred to as legal defeasance):

1. to register the transfer or exchange of such debt securities;
2. to replace temporary or mutilated, destroyed, lost or stolen debt securities;
3. to compensate and indemnify the trustee;
4. to maintain an office or agency in respect of the debt securities and to hold monies for payment in trust; or

- to be released from our obligations with respect to the debt securities under certain covenants contained in the indenture, as well as any additional covenants which may be contained in the applicable supplemental indenture (which release is referred to as covenant defeasance).

In order to exercise either defeasance option, we must deposit with the trustee or other qualifying trustee, in trust for that purpose:

- money;
- U.S. Government Obligations (as described below) or Foreign Government Obligations (as described below) that through the scheduled payment of principal and interest in accordance with their terms will provide money; or

- a combination of money and/or U.S. Government Obligations and/or Foreign Government Obligations sufficient in the written opinion of a nationally-recognized firm of independent accountants to provide money;

that, in each case specified above, provides a sufficient amount to pay the principal of, premium, if any, and interest, if any, on the debt securities of the series, on the scheduled due dates or on a selected date of redemption in accordance with the terms of the indenture.

In addition, defeasance may be effected only if, among other things:

- in the case of either legal or covenant defeasance, we deliver to the trustee an opinion of counsel, as specified in the indenture, stating that as a result of the defeasance neither the trust nor the trustee will be required to register as an investment company under the Investment Company Act of 1940;
- in the case of legal defeasance, we deliver to the trustee an opinion of counsel stating that we have received from, or there has been published by, the Internal Revenue Service a ruling to the effect that, or there has been a change in any applicable federal income tax law with the effect that (and the opinion shall confirm that), the holders of outstanding debt securities will not recognize income, gain or loss for U.S. federal income tax purposes solely as a result of such legal defeasance and will be subject to U.S. federal income tax on the same amounts, in the same manner, including as a result of prepayment, and at the same times as would have been the case if legal defeasance had not occurred;
- in the case of covenant defeasance, we deliver to the trustee an opinion of counsel to the effect that the holders of the outstanding debt securities will not recognize income, gain or loss for U.S. federal income tax purposes as a result of covenant defeasance and will be subject to U.S. federal income tax on the same amounts, in the same manner and at the same times as would have been the case if covenant defeasance had not occurred; and
- certain other conditions described in the indenture are satisfied.

If we fail to comply with our remaining obligations under the indenture and applicable supplemental indenture after a covenant defeasance of the indenture and applicable supplemental indenture, and the debt securities are declared due and payable because of the occurrence of any undefeased event of default, the amount of money and/or U.S. Government Obligations and/or Foreign Government Obligations on deposit with the trustee could be insufficient to pay amounts due under the debt securities of the affected series at the time of acceleration. We will, however, remain liable in respect of these payments.

Table of Contents

The term "U.S. Government Obligations" as used in the above discussion means securities that are direct obligations of or non-callable obligations guaranteed by the United States of America for the payment of which obligation or guarantee the full faith and credit of the United States of America is pledged.

The term "Foreign Government Obligations" as used in the above discussion means, with respect to debt securities of any series that are denominated in a currency other than U.S. dollars, (1) direct obligations of the government that issued or caused to be issued such currency for the payment of which obligations its full faith and credit is pledged or (2) obligations of a person controlled or supervised by or acting as an agent or instrumentality of such government the timely payment of which is unconditionally guaranteed as a full faith and credit obligation by that government, which in either case under clauses (1) or (2), are not callable or redeemable at the option of the issuer.

**Regarding the Trustee**

We will identify the trustee with respect to any series of debt securities in the applicable prospectus supplement relating to the applicable debt securities. You should note that if the trustee becomes a creditor of ours, the indenture and the Trust Indenture Act of 1939 limit the rights of the trustee to obtain payment of claims in certain cases, or to realize on certain property received in respect of any such claim, as security or otherwise. The trustee and its affiliates may engage in, and will be permitted to continue to engage in, other transactions with us and our affiliates. If, however, the trustee acquires any "conflicting interest" within the meaning of the Trust Indenture Act of 1939, it must eliminate such conflict or resign.

The holders of a majority in principal amount of the then outstanding debt securities of any series may direct the time, method and place of conducting any proceeding for exercising any remedy available to the trustee. If an event of default occurs and is continuing, the trustee, in the exercise of its rights and powers, must use the degree of care and skill of a prudent person in the conduct of his or her own affairs. Subject to that provision, the trustee will be under no obligation to exercise any of its rights or powers under the indenture at the request of any of the holders of the debt securities, unless they have offered to the trustee reasonable indemnity or security.

**No Individual Liability of Incorporators, Stockholders, Officers or Directors**

Each indenture provides that no incorporator and no past, present or future stockholder, officer or director of our company or any successor corporation in those capacities will have any individual liability for any of our obligations, covenants or agreements under the debt securities or such indenture.

**Governing Law**

The indentures and the debt securities will be governed by, and construed in accordance with, the laws of the State of New York.



Table of Contents

**DESCRIPTION OF WARRANTS**

**General**

We may issue warrants for the purchase of our common stock, preferred stock, debt securities or any combination thereof. Warrants may be issued independently or together with our debt securities, preferred stock or common stock and may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with the warrants. The warrant agent will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the applicable prospectus supplement for that series of warrants and the warrant agreement for that particular series.

**Debt Warrants**

The applicable prospectus supplement relating to a particular issue of warrants to purchase debt securities will describe the terms of the debt warrants, including the following:

- the title of the debt warrants;
- the offering price for the debt warrants, if any;
- the aggregate number of the debt warrants;
- the designation and terms of the debt securities, including any conversion rights, purchasable upon exercise of the debt warrants;
- if applicable, the date from and after which the debt warrants and any debt securities issued with them will be separately transferable;

Edgar Filing: Dermira, Inc. - Form S-3/A

- the principal amount of debt securities that may be purchased upon exercise of a debt warrant and the exercise price for the warrants, which may be payable in cash, securities or other property;
- the dates on which the right to exercise the debt warrants will commence and expire;
- if applicable, the minimum or maximum amount of the debt warrants that may be exercised at any one time;
- whether the debt warrants represented by the debt warrant certificates or debt securities that may be issued upon exercise of the debt warrants will be issued in registered or bearer form;
- information with respect to book-entry procedures, if any;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, a discussion of material U.S. federal income tax considerations;
- the antidilution provisions of the debt warrants, if any;
- the redemption or call provisions, if any, applicable to the debt warrants;
- any provisions with respect to the holder's right to require us to repurchase the debt warrants upon a change in control or similar event; and
- any additional terms of the debt warrants, including procedures and limitations relating to the exchange, exercise and settlement of the debt warrants.

Debt warrant certificates will be exchangeable for new debt warrant certificates of different denominations. Debt warrants may be exercised at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement. Prior to the exercise of their debt warrants, holders of debt warrants will not have any of the rights of holders of the debt securities purchasable upon exercise and will not be entitled to payment of principal or any premium, if any, or interest on the debt securities purchasable upon exercise.





Table of Contents

**Equity Warrants**

The applicable prospectus supplement relating to a particular series of warrants to purchase our common stock or preferred stock will describe the terms of the warrants, including the following:

- the title of the warrants;
- the offering price for the warrants, if any;
- the aggregate number of warrants;
- the designation and terms of the common stock or preferred stock that may be purchased upon exercise of the warrants;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each security;
- if applicable, the date from and after which the warrants and any securities issued with the warrants will be separately transferable;
- the number of shares of common stock or preferred stock that may be purchased upon exercise of a warrant and the exercise price for the warrants;
- the dates on which the right to exercise the warrants shall commence and expire;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

Edgar Filing: Dermira, Inc. - Form S-3/A

- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- if applicable, a discussion of material U.S. federal income tax considerations;
- the antidilution provisions of the warrants, if any;
- the redemption or call provisions, if any, applicable to the warrants;
- any provisions with respect to a holder's right to require us to repurchase the warrants upon a change in control or similar event; and
- any additional terms of the warrants, including procedures and limitations relating to the exchange, exercise and settlement of the warrants.

Holders of equity warrants will not be entitled:

- to vote, consent or receive dividends;
- receive notice as stockholders with respect to any meeting of stockholders for the election of our directors or any other matter; or
- exercise any rights as stockholders.

Table of Contents

**DESCRIPTION OF SUBSCRIPTION RIGHTS**

We may issue subscription rights to purchase our common stock, preferred stock or debt securities. These subscription rights may be offered independently or together with any other security offered hereby and may or may not be transferable by the stockholder receiving the subscription rights in such offering. In connection with any offering of subscription rights, we may enter into a standby arrangement with one or more underwriters or other purchasers pursuant to which the underwriters or other purchasers may be required to purchase any securities remaining unsubscribed for after such offering.

The applicable prospectus supplement relating to any subscription rights we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the price, if any, for the subscription rights;
  
- the exercise price payable for our common stock, preferred stock or debt securities upon the exercise of the subscription rights;
  
- the number of subscription rights to be issued to each stockholder;
  
- the number and terms of our common stock, preferred stock or debt securities which may be purchased per each subscription right;
  
- the extent to which the subscription rights are transferable;
  
- any other terms of the subscription rights, including the terms, procedures and limitations relating to the exchange and exercise of the subscription rights;
  
- the date on which the right to exercise the subscription rights shall commence, and the date on which the subscription rights shall expire;

- the extent to which the subscription rights may include an over-subscription privilege with respect to unsubscribed securities or an over-allotment privilege to the extent the securities are fully subscribed; and
- if applicable, the material terms of any standby underwriting or purchase arrangement which may be entered into by us in connection with the offering of subscription rights.

The description in the applicable prospectus supplement of any subscription rights we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable subscription rights certificate, which will be filed with the SEC if we offer subscription rights. We urge you to read the applicable subscription rights certificate and any applicable prospectus supplement in their entirety.

Table of Contents

**DESCRIPTION OF UNITS**

We may issue units consisting of some or all of the securities described above, in any combination, including common stock, preferred stock, warrants and/or debt securities. The terms of these units will be set forth in a prospectus supplement. The description of the terms of these units in the related prospectus supplement will not necessarily be complete. You should refer to the applicable form of unit and unit agreement for complete information with respect to these units.

Table of Contents

**LEGAL MATTERS**

The validity of the securities offered by this prospectus will be passed upon for us by Fenwick & West LLP, San Francisco, California, which beneficially owns an aggregate of 43,103 shares of our common stock, representing approximately 0.14% of our outstanding shares of capital stock as of September 30, 2015. Additional legal matters may be passed upon for us or any underwriters, dealers or agents by counsel that we will name in the applicable prospectus supplement.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our consolidated financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to file annual, quarterly and other reports, proxy statements and other information with the SEC. You may inspect and copy these reports, proxy statements and other information at the public reference facilities maintained by the SEC in Washington, DC, 100 F Street N.E., Washington, DC 20549. Copies of such materials can be obtained from the SEC's public reference section at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at (800) SEC-0330. Additionally, the SEC maintains an Internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and various other information about us. You may also inspect the documents described herein at our principal executive offices, 275 Middlefield Road, Suite 150, Menlo Park, CA 94025, during normal business hours.

Information about us is also available at our website at [www.dermira.com](http://www.dermira.com). However, the information on our website is not a part of this prospectus and is not incorporated by reference into this prospectus.

Table of Contents

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-36668) or may file with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of any offering of securities made by this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 25, 2015;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015 and filed with the SEC on May 12, 2015, August 13, 2015 and November 10, 2015, respectively;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2014 from our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 29, 2015;
- our Current Reports on Form 8-K, filed with the SEC on June 16, 2015, September 30, 2015 and October 1, 2015;
- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on September 29, 2014 under Section 12 of the Exchange Act, including any amendment or report filed for the purpose of updating such description; and
- filings we make with the SEC pursuant to the Exchange Act after the date of the initial registration statement, of which this prospectus is a part, and prior to the effectiveness of the registration statement.



## Edgar Filing: Dermira, Inc. - Form S-3/A

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Dermira, Inc., 275 Middlefield Road, Suite 150, Menlo Park, CA 94025. Copies of the above reports may also be accessed from our website at [www.investor.dermira.com](http://www.investor.dermira.com). We do not incorporate the information from our website into this prospectus or any supplement to this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus or any supplement to this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus or any supplement to this prospectus). See the section of this prospectus entitled "Where You Can Find Additional Information" for information concerning how to read and obtain copies of materials that we file with the SEC at the SEC's public offices.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus, will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

Table of Contents

**\$300,000,000**

**Common Stock**

**Preferred Stock**

**Debt Securities**

**Warrants**

**Subscription Rights**

**Units**



**PROSPECTUS**

---

---

Table of Contents

**The information in this prospectus supplement and the accompanying prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus supplement and accompanying prospectus are not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to completion, dated November 13, 2015**

**PROSPECTUS SUPPLEMENT**

**Up to \$75,000,000**

**Common Stock**

---

We have entered into a sales agreement with Cowen and Company, LLC, or Cowen, relating to shares of our common stock offered by this prospectus supplement. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$75,000,000 from time to time through Cowen acting as our agent.

Our common stock is listed on The NASDAQ Global Select Market under the symbol **DERM**. The last reported sale price of our common stock on The NASDAQ Global Select Market on October 29, 2015 was \$27.12 per share.

Sales of our common stock, if any, under this prospectus supplement may be made in sales deemed to be at-the-market equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through The NASDAQ Global Select Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions. Cowen will act as sales agent on a best efforts basis and will use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us,

consistent with its normal trading and sales practices, on mutually agreed terms between Cowen and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cowen will be entitled to compensation at a fixed commission rate of up to 3.0% of the gross sales price per share sold through it as agent under the sales agreement. In connection with the sale of our common stock on our behalf, Cowen will be deemed to be an underwriter within the meaning of the Securities Act and the compensation of Cowen will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Cowen with respect to certain liabilities, including liabilities under the Securities Act.

---

**Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page S-6 of this prospectus supplement and the accompanying prospectus, any related free writing prospectus and under similar headings in the documents incorporated by reference into this prospectus supplement.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

---

**Cowen and Company**

The date of this prospectus supplement is \_\_\_\_\_, 2015.

---

Table of Contents

**TABLE OF CONTENTS**

**Prospectus Supplement**

	<b>Page</b>
<u>About this Prospectus Supplement</u>	S-1
<u>Prospectus Supplement Summary</u>	S-2
<u>Risk Factors</u>	S-6
<u>Special Note Regarding Forward-Looking Statements</u>	S-45
<u>Use of Proceeds</u>	S-46
<u>Dilution</u>	S-47
<u>Plan of Distribution</u>	S-48
<u>Legal Matters</u>	S-49
<u>Experts</u>	S-49
<u>Where You Can Find Additional Information</u>	S-49
<u>Incorporation of Certain Information by Reference</u>	S-49

**Prospectus**

	<b>Page</b>
<u>About this Prospectus</u>	1
<u>Summary</u>	2
<u>Risk Factors</u>	5
<u>Special Note Regarding Forward-Looking Statements</u>	5
<u>Use of Proceeds</u>	6
<u>Ratio of Earnings to Fixed Charges</u>	6
<u>Plan of Distribution</u>	7
<u>Description of Capital Stock</u>	9
<u>Description of Debt Securities</u>	14
<u>Description of Warrants</u>	21
<u>Description of Subscription Rights</u>	23
<u>Description of Units</u>	24
<u>Legal Matters</u>	25
<u>Experts</u>	25
<u>Where You Can Find Additional Information</u>	25
<u>Incorporation of Certain Information by Reference</u>	26

Table of Contents

**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is this prospectus supplement, including the documents incorporated by reference herein, which describes the specific terms of this offering and updates the information contained in the accompanying prospectus. The second part, the accompanying prospectus, including the documents incorporated by reference therein, provides general information. The prospectus and prospectus supplement are part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under this shelf registration process, we may from time to time sell shares of our common stock having an aggregate offering price of up to \$300,000,000 under this prospectus at prices and on terms to be determined by market conditions at the time of the offering.

Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus supplement, the accompanying prospectus and any free writing prospectus and all of the information incorporated by reference herein and therein, as well as the additional information described under the headings **Where You Can Find Additional Information** and **Incorporation of Certain Information by Reference**. These documents contain important information that you should consider when making your investment decision.

To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference herein filed prior to the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date (for example, a document incorporated by reference in this prospectus), the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus, and any related free writing prospectus filed by us with the SEC. We have not, and Cowen has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement does not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in this prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus supplement, the accompany prospectus, the documents incorporated by reference herein and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus supplement and/or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless the context indicates otherwise, as used in this prospectus, the terms **Company**, **Dermira**, **Registrant**, **we**, **us** and **our** refer to Dermira, Inc., a Delaware corporation, and its sole subsidiary, taken as a whole, unless otherwise noted. When we refer to **you**, we mean the holders of our common stock.

## Edgar Filing: Dermira, Inc. - Form S-3/A

This prospectus supplement and the information incorporated herein by reference may include trademarks, service marks and trade names owned by us or others. Dermira is a pending trademark in the United States and Canada and a registered trademark in some other countries. The Dermira logo and all product names are our common law trademarks. All other service marks, trademarks and tradenames appearing in this prospectus supplement are the property of their respective owners.

S-1

---



Table of Contents

**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights information contained in other parts of this prospectus supplement or incorporated by reference from our Annual Report on Form 10-K for the year ended December 31, 2014, and our other filings with the Securities and Exchange Commission listed in the section of the prospectus supplement entitled Incorporation of Certain Information by Reference. This summary does not contain all of the information you should consider in making your investment decision. Before deciding to invest in our common stock, you should read the entire prospectus, this prospectus supplement, the accompanying prospectus, any related free writing prospectus and the information incorporated by reference herein in their entirety. You should carefully consider, among other things, the matters discussed in the section entitled Risk Factors contained in this prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference in this prospectus supplement. Some of the statements in this prospectus supplement constitute forward-looking statements that involve risks and uncertainties. See Special Note Regarding Forward-Looking Statements.*

**Company Overview**

We are a specialty biopharmaceutical company focused on bringing innovative and differentiated products to dermatologists and their patients. Our portfolio of five product candidates targets significant market opportunities and includes three late-stage product candidates: Cimzia (certolizumab pegol), which we are developing in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe plaque psoriasis; DRM04, which we are developing for the treatment of hyperhidrosis, or excessive sweating; and DRM01, which we are developing for the treatment of acne.

We are currently focused on the development of therapeutic solutions in medical dermatology to treat skin conditions, such as psoriasis, hyperhidrosis and acne. These diseases impact millions of people worldwide and can have significant, multidimensional effects on patients quality of life, including their physical, functional and emotional well-being. According to multiple published studies, patients report that medical dermatology conditions affect quality of life in ways comparable to other serious diseases, such as cancer, heart disease, diabetes, epilepsy, asthma and arthritis.

We believe that medical dermatology represents a particularly attractive segment of the biopharmaceutical industry for multiple reasons:

- Dermatology represents a large, growing, specialty market supported by strong patient demand.
- The dermatology market is ripe for innovation with significant commercial opportunities.
- The development of dermatology products can be relatively efficient in terms of time and cost.

- Dermatology products can be commercialized at relatively low cost.
- The needs of dermatologists and their patients have been underserved as a result of the significant consolidation of dermatology-focused companies.

We believe that these industry dynamics present an opportunity for us to establish our company as a leader in dermatology product development and commercialization, and we plan to capitalize on that opportunity for the benefit of patients and dermatologists.

Our three late-stage product candidates are:

- Cimzia, an injectable biologic tumor necrosis factor-alpha inhibitor, or TNF inhibitor, that is currently approved and marketed by UCB for the treatment of numerous inflammatory diseases spanning multiple medical specialties, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease, in multiple countries, including the United States. Biologic TNF inhibitors are a class of pharmaceutical products that are manufactured by biological processes and designed to exert their effect by inhibiting TNF, a naturally occurring molecule that plays an important role in promoting inflammation within the body, including in patients with psoriasis. We have entered into a development and commercialization agreement, or the UCB agreement, to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. Based on the results of two Phase 2 clinical trials conducted by UCB and our end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, we and UCB commenced a Phase 3 clinical program for Cimzia for the treatment of moderate-to-severe plaque psoriasis in December 2014. We expect topline results from the Phase 3 clinical program in 2017.

Table of Contents

- DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of hyperhidrosis. Anticholinergics are a class of pharmaceutical products that exert their effect by blocking the action of acetylcholine, a molecule that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. DRM04 is a topical formulation of a novel form of an anticholinergic agent that has been approved for systemic administration in other indications, and it is designed to inhibit sweat production by blocking the activation of sweat glands following topical administration. Based on the results of a Phase 2 program comprising three randomized, double-blind, vehicle-controlled clinical trials in 341 patients and our end-of-Phase 2 meeting with the FDA in April 2015, we commenced a Phase 3 clinical program for DRM04 in patients with primary axillary, or underarm, hyperhidrosis in July 2015. We expect topline results from the Phase 3 clinical program in the second half of 2016.
- DRM01, a novel, topical, small-molecule sebum inhibitor we are developing for the treatment of acne. Sebum is an oily substance made up of lipids produced by glands in the skin called sebaceous glands, and excessive sebum production is an important aspect of acne that is not addressed by available topical therapies. DRM01 is designed to exert its effect by inhibiting acetyl coenzyme A carboxylase, an enzyme that plays an important role in the synthesis of fatty acids, a type of lipid that represents an essential component of the majority of sebum lipids. Based on the results of a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial, we commenced a Phase 2b clinical program in April 2015. We expect topline results from the Phase 2b clinical program in the first half of 2016.

In addition, we have two early-stage product candidates in preclinical development for the treatment of inflammatory skin diseases and acne.

Dermira was founded by Thomas G. Wiggans, Eugene A. Bauer, M.D., Christopher M. Griffith and Luis C. Peña with the vision of building a leading dermatology company. Several members of our management team, including Mr. Wiggans, Dr. Bauer and Mr. Peña, have extensive experience within the dermatology field, including having served in executive roles at leading dermatology companies such as Connetics Corporation, Peplin, Inc. and Stiefel Laboratories, Inc., a GlaxoSmithKline LLC Company. This experience brings us significant insight into product and commercial opportunities, as well as a broad network of relationships with leaders within the industry and medical community.

#### **Key Developments**

Following is a summary of selected key developments affecting our business:

- ***Completed patient enrollment for first Cimzia Phase 3 clinical trial in psoriasis program.*** In September 2015, we completed patient enrollment for the global CIMPASI-2 clinical trial of Cimzia in adult patients with moderate-to-severe chronic plaque psoriasis. Completion of patient enrollment for this Phase 3 study

triggered a milestone payment of \$7.3 million payable by UCB to us.

- **Phase 3 program for DRM04 in patients with axillary hyperhidrosis.** In July 2015, we dosed the first patients in a Phase 3 program for DRM04 in patients with axillary hyperhidrosis. The DRM04 Phase 3 program consists of two identical, randomized, double-blind, vehicle-controlled studies, ATMOS-1 and ATMOS-2, each enrolling approximately 330 patients. The program is designed to assess the safety and efficacy of DRM04 compared to vehicle to support a potential New Drug Application, or NDA, submission to the FDA. A total of 660 adult and adolescent, or ages nine and older, patients with primary axillary hyperhidrosis will be enrolled in two identical Phase 3 trials being conducted at approximately 60 sites in the United States and Germany. Subjects will be randomized into two separate arms evaluating DRM04 compared to vehicle. In each trial, 220 patients will receive DRM04 and 110 patients will receive vehicle. Patients are instructed to apply the study product to each axilla once daily for four weeks using topical wipes containing either DRM04 or vehicle only. The DRM04 dose being evaluated in the Phase 3 program is a 3.75% concentration of our novel form of the reference agent, which was evaluated in Study DRM04-HH02 and corresponds to the 3% dosage formulation of the reference agent evaluated in both Phase 2b studies. The co-primary endpoints will be the average absolute change from baseline in gravimetrically-measured sweat production and the proportion of patients who achieve at least a four-point improvement from baseline in disease severity as measured by the Axillary Sweating Daily Diary, or ASDD, the company's proprietary patient-reported outcome, or PRO, instrument. Each of these endpoints will be measured at the end of the four-week treatment period. Based on discussions with the FDA, we developed and validated the ASDD instrument in accordance with the 2009 FDA guidance document for PRO measures. The ASDD endpoint, a 4-point change on an 11-point scale, was selected based on analyses of data generated in the second Phase 2b Study, DRM04-HH02, and feedback from the FDA. Secondary efficacy endpoints will measure the proportion of subjects who have at least a two-grade improvement from baseline as measured by the Hyperhidrosis Disease Severity Scale, or HDSS, wherein patients rate the severity of their disease on a four-point scale, and the proportion of subjects with at least a 50% reduction from baseline in gravimetrically-measured sweat production, each as measured at the end of the four-week treatment period. The Phase 3 program also will include an open-label study, ARIDO, assessing the long-term safety of DRM04, in which patients from either of the Phase 3 studies will be permitted to continue to receive treatment for up to an additional 44 weeks.

Table of Contents

- **Phase 2b program for DRM01 in patients with acne.** In April 2015, we announced the dosing of the first patient in a Phase 2b dose-ranging trial for DRM01 in patients with facial acne vulgaris. The randomized, multi-center, double-blind, parallel-group, vehicle-controlled study is designed to assess the safety and efficacy of DRM01 compared to vehicle. The goal of the study is to establish the optimal dose for a potential Phase 3 program. In the Phase 2b trial, approximately 400 adult patients with moderate-to-severe facial acne vulgaris will be randomized into five separate arms evaluating different DRM01 dosing regimens compared to vehicle. Approximately 300 patients will receive DRM01 with 100 patients in each of three arms consisting of DRM01 gel at concentrations of 7.5% once a day, 7.5% twice a day and 4% once a day, and approximately 100 will receive vehicle, with 50 patients receiving vehicle once a day and 50 patients receiving vehicle twice a day. Consistent with the preceding Phase 2a trial and in accordance with the published FDA draft guidance for the development of acne drugs, the primary endpoints are the absolute changes from baseline in inflammatory and non-inflammatory lesion counts and the proportion of patients achieving at least a two-point improvement from baseline in the five-point Investigator's Global Assessment, or IGA, score. Each endpoint will be measured at the end of the 12-week treatment period. The trial will be conducted at approximately 30 sites in the U.S. and Canada. Pending the successful completion of the Phase 2b trial and all applicable non-clinical work, we expect to include both adult and adolescent patients in a Phase 3 program.

- **U.S. patents covering DRM01 and DRM04 and patent portfolio.** U.S. Patent No. 8,884,034 issued in November 2014 and includes claims covering DRM01, pharmaceutical compositions and methods of its use. U.S. Patent Nos. 8,859,610 and 9,006,462 issued in October 2014 and April 2015, respectively, and include claims covering pharmaceutical solutions, topical solutions and absorbent pads comprising DRM04 and methods of its use. As of September 30, 2015, we own or have an exclusive license to 27 issued U.S. patents and 90 issued foreign patents, which include granted European patent rights that have been validated in various EU member states, and 12 pending U.S. patent applications and 34 pending foreign patent applications.

**Corporate Information**

We were incorporated in the State of Delaware in August 2010 under the name Skintelligence, Inc. We changed our name to Dermira, Inc. in September 2011. Our principal executive offices are located at 275 Middlefield Road, Suite 150, Menlo Park, California 94025, and our telephone number is (650) 421-7200. Our website address is [www.dermira.com](http://www.dermira.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock.

Table of Contents

<b>The Offering</b>		
Common stock offered by us		Shares having an aggregate offering price of up to \$75,000,000.
Common stock to be outstanding after this offering		Up to 32,684,315 shares (as more fully described in the notes following this table), assuming sales of 2,765,486 shares of our common stock in this offering at an offering price of \$27.12 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on October 29, 2015. The actual number of shares issued will vary depending on the sales price under this offering.
Manner of offering		At-the-market offerings that may be made from time to time through our sales agent, Cowen and Company, LLC. See <u>Plan of Distribution</u> on page S-48.
Use of proceeds		We currently intend to use the net proceeds from this offering to fund research and development of our product candidates, working capital, capital expenditures and other general corporate purposes. See <u>Use of Proceeds</u> on page S-46.
Risk factors		You should read the <u>Risk Factors</u> section of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ symbol		DERM
<p>The number of shares of common stock to be outstanding after this offering is based on 29,918,829 shares of common stock outstanding as of September 30, 2015 and excludes:</p> <ul style="list-style-type: none"> <li>• 3,718,828 shares of our common stock issuable upon the exercise of outstanding options under our 2010 Equity Incentive Plan and 2014 Equity Incentive Plan as of September 30, 2015, with a weighted-average exercise price of \$8.53 per share; and</li> <li>• 1,795,617 shares of our common stock reserved and available for future issuance under our equity compensation plans, consisting of (1) 1,275,551 shares of common stock reserved for issuance under the 2014 Equity Incentive Plan as of September 30, 2015 and (2) 520,066 shares of common stock reserved and available for issuance under the 2014 Employee Stock Purchase Plan as of September 30, 2015.</li> </ul>		

Edgar Filing: Dermira, Inc. - Form S-3/A

Unless otherwise noted, the information in this prospectus supplement reflects and assumes the following:

- no exercise of outstanding options subsequent to September 30, 2015; and
- an assumed public offering price of \$27.12 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on October 29, 2015.

s-5

---

Table of Contents

**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below together with all of the risks, uncertainties and assumptions discussed under Part II, Item 1A, Risk Factors, in our Quarterly Report on Form 10-Q for the quarter period ended September 30, 2015, or September 2015 10-Q, which is incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the Securities and Exchange Commission, or SEC, in the future, before deciding whether to invest in shares of our common stock. The risks and uncertainties described below and incorporated by reference herein are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In that event, the market price of our stock could decline, and you could lose part or all of your investment.*

**Risks Related to Development, Regulatory Approval and Commercialization**

*Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, primarily Cimzia, which we are developing in collaboration with UCB Pharma S.A., DRM04 and DRM01.*

Our portfolio of five product candidates includes three late-stage product candidates: Cimzia (certolizumab pegol), an injectable biologic tumor necrosis factor-alpha inhibitor, or TNF inhibitor, for the treatment of moderate-to-severe plaque psoriasis; DRM04, a topical treatment for hyperhidrosis, or excessive sweating; and DRM01, a topical sebum inhibitor for the treatment of acne. We are also developing DRM02, a topical treatment targeting phosphodiesterase-4 for inflammatory skin diseases, and DRM05, a topical photodynamic therapy for acne. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our late-stage product candidates. The successful development and commercialization of Cimzia is subject to a number of risks under our development and commercialization agreement with UCB, or the UCB agreement. For more information about these risks, see Risks Related to Our Collaboration with UCB. In the future, we may also become dependent on one or more of our early-stage product candidates or any future product candidates that we may in-license, acquire or develop. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
  
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
  
- whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;



- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;

Table of Contents

- a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates;
- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and
- our ability to in-license or acquire additional product candidates or commercial-stage products that we believe can be successfully developed and commercialized.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business.

***We have had significant and increasing operating expenses and we will require substantial additional financing to achieve our goals, which we may not be able to obtain when needed and on acceptable terms, or at all. We have a history of losses and may not be able to achieve or maintain profitability, which could cause our business and operating results to suffer.***

We are a clinical-stage specialty biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred losses in each year since we commenced operations in August 2010. We have incurred net losses of \$16.1 million and \$7.8 million for the three months ended September 30, 2015 and 2014, respectively, and \$47.2 million and \$25.1 million for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had an accumulated deficit of \$129.9 million.

We have financed our operations primarily through the sale of equity securities and convertible debt securities. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any. Revenue from our current and potential future collaborations is uncertain because milestones or other contingent payments under our agreements may not be achieved or received.

As of September 30, 2015, we had capital resources consisting of cash and cash equivalents and investments of \$232.5 million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, manufacturing and supply, as well as marketing and selling any products approved for sale. In particular, our Phase 3 clinical programs for our product candidates will require substantial funds to complete. We plan to finance the development and commercialization of Cimzia in part through milestone payments made by UCB under the UCB agreement. In addition, other unanticipated costs may arise. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates.

Table of Contents

As of September 30, 2015, we believe that existing cash and cash equivalents and investments are sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Our currently anticipated expenditures for the development and potential commercialization of our lead product candidates, Cimzia, DRM04 and DRM01, exceed our existing cash and cash equivalents and investments. We will need to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities. We have substantial contractual obligations to UCB. In the event we are unable to raise sufficient capital to fund our development and commercialization obligations to UCB, we will face significant contractual liability.

The amount and timing of our future funding requirements will depend on many factors, including:

- the timing, rate of progress and cost of any preclinical and clinical trials and other product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our product candidates in the United States and any foreign countries;
- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;

- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including post-grant challenges or opposition to third-party patent claims;
- costs associated with prosecuting or defending any litigation that we may become involved in and any damages payable by us that result from such litigation;
- costs associated with any product recall that could occur;
- costs of operating as a public company;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses; and
- personnel, facilities and equipment requirements.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Our current loan and security agreement contains negative covenants that restrict our ability to obtain additional debt financing. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans.

In order to fund the development and potential commercialization of our product candidates, we may also need to enter into collaboration agreements with pharmaceutical and biotechnology companies. Our ability to establish and maintain these collaborations is highly uncertain and subject to a number of variables. Under these arrangements, we may be responsible for substantial costs in connection with the clinical development, regulatory approval or the commercialization of a partnered product candidate. Furthermore, the payments we could receive from our potential collaboration partners may be subject to numerous conditions and may ultimately be insufficient to cover the cost of this development and commercialization.



Table of Contents

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts, or other aspects of our business plan. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

***The UCB agreement requires us to pay substantial development costs in order for UCB to seek approval of Cimzia for the treatment of moderate-to-severe plaque psoriasis from the FDA, the European Medicines Agency and the Canadian federal department for health. Our inability to fund our obligations under the UCB agreement would harm our business and operating results.***

The UCB agreement requires us to pay all development costs in order for UCB to seek approval of Cimzia for the treatment of moderate-to-severe plaque psoriasis from the FDA, the European Medicines Agency, or the EMA, as established by Regulation (EC) 2309/93 and Regulation (EC) 726/2004, and the Canadian federal department for health, or Health Canada, up to a specified amount greater than \$75.0 million and less than \$95.0 million, with any development costs in excess of this amount to be shared equally by us and UCB. Delays in the commencement, enrollment and completion of clinical trials, including as a result of regulatory requirements, could substantially increase our product development costs. We do not know whether our planned clinical trials will begin on time or will be completed on budget or on schedule, or at all. While UCB is obligated to pay us if certain development and regulatory approval milestones are met, these milestone payments will not increase even if our development costs increase, so we would be required to bear a greater portion of any increased costs, which would adversely impact our financial position. The costs associated with product development can increase for a variety of reasons, including:

- the terms of agreements with prospective contract research organizations, or CROs, and trial sites, which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and other third-party contractors;
- identification and maintenance of a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to obtain institutional review board, or IRB, approval to conduct a clinical trial at prospective sites;
- increase in the time and expense required to conduct clinical trials due to difficulties in recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the treatment of psoriasis; and

Edgar Filing: Dermira, Inc. - Form S-3/A

- inability to retain patients in clinical trials due to the treatment protocol, length of treatment period, personal issues, side effects from the therapy or lack of efficacy, particularly for those patients receiving placebo.

In addition, a clinical trial may be suspended or terminated by us, UCB, the FDA, the EMA, Health Canada or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failed inspection of the clinical trial operations or trial sites by the FDA, the EMA, Health Canada or other regulatory authorities;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- inability to fully enroll clinical trials; and
- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties or other reasons.



Table of Contents

*Clinical drug development for our product candidates is very expensive, time-consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.*

Clinical drug development for our product candidates is very expensive, time-consuming and difficult to design and implement, and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. Our product candidates are in various stages of development. We expect that clinical trials for these product candidates will continue for several years, but may take significantly longer than expected to complete. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, such as psoriasis, or clinical trials for indications for which patients do not as commonly seek treatment, such as hyperhidrosis;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- difficulty in obtaining IRB approval for studies to be conducted at each site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;

- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;  
or
- insufficient data to support regulatory approval.

Table of Contents

In the case of our topical product candidates, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient, or API, through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect. As a result, safety and efficacy can be difficult to establish. The topical route of administration may involve new dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays. For example, the dosage form for DRM04 is an API-saturated wipe, and we are not aware of previous FDA approvals of prescription drug wipes. In addition, it is possible that the FDA may require more short-term exposure of individuals to DRM04 than we currently anticipate collecting in our safety database. If we are required to expose additional individuals to DRM04 in order to establish a safety database sufficient for approval, approval of DRM04, if at all, could be delayed and our costs could increase.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed. In particular, for Cimzia, if we experience delays in the completion of, or if we terminate, clinical trials, our ability to receive development-, regulatory- or sales-based milestone payments and royalties under the UCB agreement will be reduced, delayed or prevented.

***We may be unable to obtain regulatory approval for Cimzia, DRM04, DRM01 or our early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.***

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current product candidates in the United States until we receive approval of a new drug application, or NDA, or biologics license application, or BLA, or other applicable regulatory filing from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries.

To gain approval to market a biologic product such as Cimzia or a new drug such as DRM04 or DRM01, the FDA and foreign regulatory authorities must receive preclinical, clinical and chemistry, manufacturing and controls data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the product for the intended indication applied for in an NDA, BLA or other applicable regulatory filing. The development and approval of biologic and new drug products involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct. For example, in the Phase 2 clinical trial for Cimzia in moderate-to-severe plaque psoriasis, a six-point physical global assessment, or PGA, scale was used, and in our Phase 3 clinical trials, we are using a five-point PGA scale similar to the scale that was used to support the approval of Cosentyx. As a result, data from our Phase 2 clinical trial may not accurately predict Phase 3 results. For DRM04, the results of our Phase 2 clinical trials may not accurately predict results in our Phase 3 clinical trials, which will have larger numbers of patients and will use a different tool to measure our patient-reported outcomes than that used as the primary endpoint in our Phase 2 trials. In addition, for DRM04, the FDA commented that it believes that we may not have identified the optimal dose and concentration for use in our Phase 3 trials. If the FDA determines that we have not provided sufficient dose response information to select the dose to study in our Phase 3 trials, then approval of DRM04, if at all, could be delayed and our costs could increase. Even for a drug such as Cimzia that has been approved for multiple

indications, regulatory review processes are lengthy and uncertain.

S-11

---

Table of Contents

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, including:

- the FDA or the applicable foreign regulatory body may disagree with the design or implementation of one or more clinical trials;
  
- the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
  
- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials, including the number of subjects in the safety database, sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
  
- the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;
  
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other applicable regulatory filing;
  
- the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials;
  
- the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, manufacturing, quality control, labeling or specifications of our current or future product candidates;
  
- the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;

- the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials;
- the FDA or the applicable foreign regulatory agency also may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
- the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract;
- the FDA or the applicable foreign regulatory body may not approve or grant marketing clearance of a device intended to be used in combination with our product candidates, such as an auto-injector with Cimzia or light source with DRM05; or
- the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. For example, the FDA may not agree with our Phase 3 clinical trial protocols for Cimzia. In addition, our product candidates may not be approved by the FDA or applicable foreign regulatory agencies even though they meet specified endpoints in our clinical trials. The FDA or applicable foreign regulatory agencies may ask us to conduct additional costly and time-consuming clinical trials in order to obtain marketing approval or approval to enter into an advanced phase of development, or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials. In our collaboration with UCB, we are required to pursue development in support of UCB seeking approval from each of the FDA, the EMA and Health Canada, although we have the right to abandon pursuit of regulatory approval in Canada. If UCB is unable to obtain and retain regulatory approval for the marketing of Cimzia for psoriasis, we could lose our ability to receive royalties and regulatory- and sales-based milestone payments, which would adversely affect our financial position and business.

Table of Contents

Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would harm our business, financial condition, operating results and prospects.

***UCB substantially controls the governance of our collaboration, and may make decisions regarding product development, regulatory strategy and commercialization that may not be in our best interests.***

To oversee the parties' activities in the collaboration, the UCB agreement provides for the establishment of a joint steering committee, joint development team, joint development committee, joint commercialization team and joint commercialization committee on which we each have representation, and while the parties have agreed to make committee decisions by consensus, UCB has final decision-making authority for the overall regulatory, development and commercialization strategy for Cimzia, market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales and safety and pharmacovigilance.

In exercising its final decision-making authority, UCB may make decisions regarding product development or regulatory strategy based on its determination of how to best preserve and extend regulatory approvals for Cimzia in indications other than psoriasis, which may delay or prevent achieving regulatory approval for Cimzia for the treatment of psoriasis.

If Cimzia does receive regulatory approval for the treatment of psoriasis in the United States or Canada, UCB could use its final decision-making authority to direct our market access, promotional or medical affairs activities to dermatologists in ways that would adversely impact sales attributable to dermatologists, including due to a concern that such activities could adversely impact sales of Cimzia attributable to physicians other than dermatologists, for which UCB is not required to pay us royalties or milestone payments. If such limitations resulted in reduced sales of Cimzia to dermatologists, the royalties and sales-based milestone payments we could receive under the UCB agreement would be adversely affected, negatively impacting our financial performance.

***We have never completed a Phase 3 clinical trial, and may be unable to successfully do so for any of our product candidates.***

The conduct of a Phase 3 clinical trial is a complicated process. Although our employees have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company have not completed a Phase 3 clinical trial, and as a result may require more time and incur greater costs than we anticipate. For example, we commenced the Phase 3 clinical program for Cimzia in December 2014 and commenced the Phase 3 clinical program for DRM04 in July 2015. Failure to commence or complete, or delays in, our planned Phase 3 clinical trials would prevent us from or delay us in obtaining regulatory approval of and commercializing our product candidates and could prevent us from or delay us in receiving development- or regulatory-based milestone payments and commercializing Cimzia for the treatment of psoriasis and DRM04 for hyperhidrosis, which would adversely impact our financial performance.

***Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.***

## Edgar Filing: Dermira, Inc. - Form S-3/A

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our product candidates may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;



Table of Contents

- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- in the case of hyperhidrosis, patients' perception of the condition as one for which medical treatment may be appropriate and a prescription therapy may be available;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or REMS;

- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

According to Decision Resources, Enbrel, Humira and Stelara, injectable biologics for the treatment of moderate-to-severe plaque psoriasis, achieved aggregate worldwide sales of \$5.1 billion in 2013 and we are uncertain whether this market, including off-label use of other injectable biologics for the treatment of psoriasis, has peaked or may still grow and whether we could displace any existing market share if Cimzia is approved for the treatment of moderate-to-severe plaque psoriasis. In particular, Cimzia's administration schedule may not be perceived as advantageous and its theoretical advantages may not lead to a perception of Cimzia being safer or comparably effective to Humira or Enbrel. Even if approved for moderate-to-severe plaque psoriasis, we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia relative to other TNF inhibitors or biologics in our marketing materials and may not be able to promote any theoretical advantages that are not in our approved product labeling.

***Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.***

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of health care products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including over-the-counter treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

Table of Contents

Many pharmaceutical companies currently offer products, and continue to develop additional alternative product candidates and technologies, for indications similar to those targeted by our product candidates, including AbbVie Inc., Allergan plc, Amgen Inc., Anacor Pharmaceuticals, Inc., Anterios, Inc., Astellas Pharma US, Inc., Bayer HealthCare AG (formerly Intendis, Inc.), Brickell Biotech, Inc., Celgene International, Eisai Co., Ltd., Galderma S.A., GlaxoSmithKline LLC, or GSK, Janssen Biotech, Inc., Johnson & Johnson, LEO Pharma A/S, Eli Lilly and Company, Maruho Co., Ltd., Merck & Co., Inc., Miramar Labs, Inc., Mitsubishi Tanabe Pharma Corporation, Mylan Inc., Novartis International AG, Pfizer Inc., Regeneron Pharmaceuticals, Inc., Revance Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Teva Pharmaceutical Industries Ltd. and Valeant Pharmaceuticals International. The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States.

***Cimzia faces intense competition and most of our competitors have significantly greater resources than we do.***

If approved for the treatment of psoriasis, Cimzia will face direct competition from numerous other injectable products such as Cosentyx, Enbrel, Humira, Remicade and Stelara, and the existence of these products may limit the market size for Cimzia. In addition, Cimzia will compete against oral systemic treatments for psoriasis, which include acitretin, apremilast, methotrexate and cyclosporine, and against a number of approved topical treatments for psoriasis, including branded drugs and generic versions where available. There are a number of other treatments used for psoriasis, including light-based treatments, topical corticosteroids and non-prescription topical treatments. Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles.

Additional products and treatments, including numerous injectable biological products currently in clinical trials, may also receive regulatory approval in one or more territories in which we compete, and these existing and new products may be more effective, more widely used and less costly than ours, which may reduce the sales on which we receive royalties and sales-based milestone payments under the UCB agreement. Even if a generic product or an over-the-counter product is less effective than our product candidates, a less effective generic or over-the-counter product may be more quickly adopted by health insurers, physicians and patients than our competing product candidates based upon cost or convenience.

***Cimzia may face competition from biosimilars, which may have an adverse impact on future sales.***

Even if Cimzia for the treatment of psoriasis achieves regulatory approval, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are demonstrated to be highly similar, or biosimilar, to or interchangeable with an FDA-approved biological product. This new pathway could allow

## Edgar Filing: Dermira, Inc. - Form S-3/A

competitors to reference the FDA's prior determinations regarding innovative biological products and to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period runs from the initial approval of the innovator product and not from approval of a new indication. In addition, the 12-year exclusivity period does not prevent another company from developing a product that is highly similar to the innovative product, generating all the data necessary for a full BLA and seeking approval. Exclusivity only assures that another company cannot rely on the FDA's prior determinations in approving a BLA for an innovator's biological product to support the biosimilar product's approval. Further, under the FDA's current interpretation, it is possible that a biosimilar applicant could obtain approval for one or more of the indications approved for the innovator product by extrapolating clinical data from one indication to support approval for the other indications. In his proposed budget for fiscal year 2014, President Obama proposed to

s-15

---

Table of Contents

reduce this 12-year period of exclusivity to seven years and proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." It is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity. The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for Cimzia. If competitors are able to obtain marketing approval for biosimilars referencing Cimzia or other branded biologic products against which Cimzia competes, Cimzia may become subject to competition from such biosimilars. Such competition could lead to off-label use of the biosimilar for psoriasis or reduced market share and contribute to downward pressure on pricing and reduced profit margins.

***We expect to face generic competition for our product candidates, which could adversely affect our business, financial condition, operating results and prospects.***

Upon the expiration or loss of any patent protection for any of our product candidates that are approved, or upon the at-risk launch, despite pending patent infringement litigation against the generic product, by a generic competitor of a generic version of any of our product candidates that are approved, which may be sold at significantly lower prices than our approved product candidates, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects. In particular, our DRM04 product candidate faces competition from currently marketed generic oral and compounded topical anticholinergic agents. In addition, we may be subject to additional competition from third parties pursuing topical formulations of other anticholinergic agents for hyperhidrosis.

***Use of subjective assessments of efficacy by patients, including patient-reported outcome assessments, or PROs, in our DRM04 clinical trials may delay the development of DRM04 or increase our development costs.***

Due to the difficulty of objectively measuring the symptoms of hyperhidrosis, subjective assessments of efficacy by patients are expected to have an important role in the development and regulatory approval of our DRM04 product candidate. Subjective assessments, such as PROs, involve patients' subjective assessments of efficacy, and this subjectivity increases the uncertainty of determining clinical endpoints. Such assessments can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, from patient to patient and from site to site within a clinical trial. Furthermore, in our Phase 2 clinical program, we have used an existing tool, the Hyperhidrosis Disease Severity Scale, or HDSS, which the FDA has determined is not a validated PRO, and a new PRO, the Axillary Sweating Daily Diary, or ASDD, which was validated in our Phase 2 clinical program to assess efficacy in a subjective manner. We are using the new ASDD PRO, along with an objective measure, sweat production, for the primary assessment of efficacy in our planned Phase 3 clinical program for DRM04. The FDA may not agree with our endpoints or that we have demonstrated that our objective endpoint of sweat production is a clinically meaningful endpoint, potentially making additional clinical trials necessary which would delay the development of DRM04 and increase our costs.

***Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review.***

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or other REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to,

## Edgar Filing: Dermira, Inc. - Form S-3/A

among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and with the FDA's good clinical practice, or GCP, requirements and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

Table of Contents

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;

- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

***We have conducted, are conducting and may in the future conduct clinical trials for our product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials.***

We have conducted, are conducting and may in the future choose to conduct, one or more of our clinical trials outside the United States, including in Canada and Europe. For example, in December 2014, we commenced our Phase 3 clinical program for Cimzia in multiple countries. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.



Table of Contents

***Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action.***

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. For example, if we obtain regulatory approval for Cimzia for the treatment of moderate-to-severe plaque psoriasis, we expect that regulatory authorities will require us to include the same box warning regarding increased risk of serious infections that may lead to hospitalization or death and a potential association with increased cancer risk in TNF inhibitors, of which Cimzia is one, that is currently included in labeling for Cimzia for the treatment of other indications. Results of clinical trials could reveal a high and unacceptable severity and prevalence of one or more of these side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. In addition, the FDA recently created a Tracked Safety Issue, or TSI, for all TNF inhibitors, including Cimzia, based on a potential signal of psychiatric and nervous system disorders including: anxiety, hallucination, paranoia, psychotic disorder, cognitive impairment, depression, and suicide/suicidal ideation. This TSI may have an impact on our development program or the labeling for Cimzia. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;

- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

*We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.*

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

Table of Contents

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- decreased enrollment rates of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- or
- loss of revenue.

We have obtained product liability insurance coverage for clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

***If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.***

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. For example, if Cimzia is approved for use in the United States for the treatment of moderate-to-severe plaque psoriasis, due to the design of our Phase 3 clinical trial comparing Cimzia to Enbrel, the prescribing information may not include data comparing the clinical performance of Cimzia and Enbrel and we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia to Enbrel in our marketing materials. Similarly, although our DRM04 product candidate, if approved, may appeal to individuals who have not been diagnosed with hyperhidrosis, we will only be able to promote DRM04 for its approved indication. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion.

Table of Contents

If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

***We may choose not to continue developing or commercializing any of our product candidates other than Cimzia at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.***

At any time, we may decide to discontinue the development of any of our product candidates other than Cimzia or not to continue commercializing one or more of our approved product candidates other than Cimzia for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. We are, however, required to develop and commercialize Cimzia in accordance with our obligations to UCB regardless of our potential return on our investment with respect to Cimzia.

***We or our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.***

We or our current and prospective partners may be subject to product recalls, withdrawals or seizures if any of our product candidates, if approved for marketing, fail to meet specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to the manufacture, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

***If the FDA does not conclude that certain of our product candidates satisfy the requirements under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or Section 505(b)(2), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

We are currently developing one product candidate, DRM04, for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. DRM04 is a topical formulation of a novel form of an anticholinergic agent that has been approved for systemic administration in other indications. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference. Reliance on safety findings made by the FDA in approving the anticholinergic agent we intend to reference in our NDA could expedite the development program for our product candidates by potentially decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval. DRM04 differs from the approved product we intend to reference in chemical structure, route of administration, dosage form and indication, and if we are unable to demonstrate an acceptable clinical bridge through comparative pharmacokinetic data between DRM04 and the approved product the FDA may not permit us to use the Section 505(b)(2) pathway for regulatory approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, or if the Section 505(b)(2) regulatory

Table of Contents

pathway fails to significantly decrease the amount of testing we must conduct, we may need to conduct additional preclinical or clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for DRM04, or any other product candidate for which we seek approval pursuant to the Section 505(b)(2) regulatory pathway in the future, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved referenced product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

***If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.***

For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. In addition, certain currently approved therapies for the treatment of hyperhidrosis have received limited or no reimbursement coverage by insurers and, accordingly, coverage for DRM04, if approved, may not be available. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.



Table of Contents

***Healthcare reform measures could hinder or prevent the commercial success of our products and product candidates.***

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of any partner with which we may collaborate. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, in March 2010, President Obama signed one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which are expected to impact existing government healthcare programs and result in the development of new programs. The Affordable Care Act, among other things, (1) increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, (2) established annual fees on manufacturers of certain branded prescription drugs and (3) enacted a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals and imaging centers.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

***We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.***

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights, among other topics, are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

Table of Contents

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

***Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

The manufacturing activities of our third-party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party suppliers and manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

Table of Contents

***Our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

**Risks Related to Our Collaboration with UCB**

***The UCB agreement is terminable by UCB if we consummate a change of control with a significant number of competitor companies, which may adversely impact the likelihood that we will be acquired.***

If we consummate a change of control with a third party that is clinically developing or commercializing a biologic TNF inhibitor, UCB has the right to terminate the UCB agreement. If such termination occurs prior to the grant of regulatory approval for Cimzia for the treatment of psoriasis, we would be obligated to pay the remaining costs for which we would be responsible under the agreed development plan reduced by the amount of development milestone payments that would have been payable upon achievement of applicable development milestones if and when such milestones are achieved. This could make an acquisition of us by any such company economically unattractive, potentially prohibitively so. Among the companies that we are aware are currently clinically developing or commercializing biologic TNF inhibitors are AbbVie, Allergan, Amgen, Baxter International Inc., Boehringer Ingelheim, Biogen Idec Inc., Eisai, GSK, Hospira, Inc., Johnson & Johnson, Merck, Mitsubishi Tanabe Pharma Corporation, Mylan, Novartis AG, Pfizer, Ranbaxy Laboratories Limited, Sandoz Inc., Stiefel Laboratories, Inc., a GSK Company, Takeda and Teva. Additional companies may develop or commercialize a biologic TNF inhibitor in the future. The resulting unlikelihood of an acquisition of us by these companies may reduce our future strategic options and the likelihood of our stockholders participating in a company sale transaction that could be financially attractive to them.

In addition, UCB has the right to terminate the UCB agreement with the same economic consequences if we consummate a change of control with a company that is not clinically developing or commercializing a biologic TNF inhibitor but that otherwise does not meet all of the following requirements:

- the company either (1) is engaged in the development or commercialization of a pharmaceutical product or (2) will maintain us as an operating entity and will maintain at least 50% of our executive management team for at least 12 months;
- the company has sufficient working capital to continue and complete our development obligations under the UCB agreement (taking into consideration any milestone payments to be made by UCB) and has the ability to obtain sufficient funding to perform the commercial and medical affairs activities and other obligations for which we are responsible under the UCB agreement; and
- if the change of control occurs prior to the date of the grant of first regulatory approval for Cimzia for the treatment of psoriasis in the United States, Canada or the European Union, the company agrees in writing to complete such development obligations.

It is therefore possible that other potential acquirors, even though not developing or commercializing a biologic TNF inhibitor, would not meet one or more of these criteria, making an acquisition of us by such a company unlikely, further reducing the ability of our stockholders to participate in a transaction that could be financially attractive to them.

Table of Contents

***We could have significant disputes with UCB over our collaboration, which could adversely impact our ability to obtain any of its intended benefits.***

We cannot ensure that UCB will fulfill its obligations under the UCB agreement. We may assert that UCB has not fulfilled its obligations, which UCB may dispute. UCB may assert that we have not fulfilled our obligations under the UCB agreement, which we may dispute. If UCB asserts that we have materially breached the UCB agreement and seeks to terminate the UCB agreement, our ability to realize the anticipated or any benefits from this collaboration would be adversely affected. Any disputes we have with UCB could lead to delays in, or termination of, the development and commercialization of Cimzia for the treatment of psoriasis and time-consuming and expensive arbitration. In any such dispute, UCB will have considerably more resources than we will to pursue such dispute, which may make it less likely that we will prevail in any such dispute, regardless of the relative merit of our position.

***We are dependent on UCB for product supply.***

Under the UCB agreement, UCB is solely responsible for supplying sufficient quantities of Cimzia as well as the comparator drugs and placebo to be used in our Phase 3 clinical trials and any post-approval studies that are conducted. We are not permitted to obtain these materials from any other source. If we experience any interruption in product supply, potentially due to UCB's own dependencies on its suppliers, or due to damage to or destruction of its or its suppliers' facilities or equipment or noncompliance with regulatory requirements, or if we incorrectly forecast our product supply requirements or UCB incorrectly plans its manufacturing production, or if UCB were to allocate supplies of Cimzia to its commercial sales rather than to our development program, it could impact our ability to timely supply our clinical sites, and cause potentially serious delays in the timing of our clinical studies and substantially increased costs if studies need to be adjusted or re-performed.

UCB is also solely responsible for and controls all aspects of the manufacture, distribution and supply of Cimzia for commercialization, including providing any product samples that we may use in our marketing and promotion activities as well as the product that will be sold from which we would derive royalties and any sales-based milestone payments. If UCB experiences any interruption in product supply for any of the reasons described in the prior paragraph, or if UCB were to allocate its supplies of Cimzia to commercial sales attributable to physicians other than dermatologists, it could adversely impact the sales from which we derive such royalties and payments, and our financial results.

***We have agreed with UCB to a scope of exclusivity that will prevent us from developing and commercializing a material category of products, which could harm our current and future business prospects, including the likelihood that we will be acquired.***

We have agreed that, during the term of the UCB agreement, except in limited circumstances, we and our affiliates will not clinically develop, seek regulatory approval for or commercialize a biologic TNF inhibitor other than Cimzia, or promote any other biologic TNF inhibitor to any dermatologist in the United States or Canada. If, during the term of the UCB agreement, we acquire or are acquired by a third party that is clinically developing or commercializing a biologic TNF inhibitor, in addition to UCB's termination rights described above, we have agreed to either cease such clinical development or commercialization or divest such product candidate. These exclusivity obligations may inhibit our business opportunities by excluding an important class of products, TNF inhibitors, from potential development or commercialization by us. In addition, any acquirer of us would also be subject to these exclusivity obligations, which will potentially exclude companies that are or would consider developing or commercializing TNF inhibitors from acquiring us, which may reduce the likelihood of our being acquired in a transaction that could be beneficial to our stockholders.

*UCB may determine that further development of Cimzia for the treatment of psoriasis poses a significant safety risk and terminate the UCB agreement, which would adversely affect our business.*

The UCB agreement is terminable by UCB if it determines that a validated safety signal is established, the magnitude of which UCB determines constitutes a significant patient risk so that the development or commercialization of Cimzia should cease. In such event, while UCB would be obligated to reimburse us for certain costs we have incurred by paying to us royalties on sales of Cimzia in the United States and Canada, such reimbursement will likely take years, and if sales of Cimzia cease in all indications, we will likely never recoup such costs. In any event, if the UCB agreement were to be terminated for safety reasons, we would not be able to develop a dermatology-focused sales force using Cimzia as our initial commercial product or realize any royalties or sales-based milestones, and therefore our principal strategic and financial objectives in pursuing this collaboration would not be achieved.



Table of Contents

***UCB has made very limited disclosures, representations, warranties and indemnities to us regarding its ownership of and the validity of the intellectual property related to Cimzia, and that its and our activities in our collaboration will not infringe the intellectual property rights of third parties.***

In the UCB agreement, UCB has made very limited disclosures, representations, warranties and indemnities to us that the development of Cimzia for the treatment of psoriasis and the sale and promotion of Cimzia for the treatment of psoriasis and psoriatic arthritis will not infringe a patent or other intellectual property right of a third party, or that UCB's intellectual property related to Cimzia is valid. If third parties bring claims that the intellectual property relevant to the collaboration and Cimzia infringes the intellectual property rights of such third party, we or UCB could be enjoined from performing our activities under the UCB agreement, exposed to substantial damages or required to pay royalties to such third party, or any combination of these adverse effects. Any third-party royalties that would need to be paid in connection with the activities under our collaboration would be included in our cost of goods and therefore could reduce the financial benefits that we receive from sales of Cimzia. In addition, if a claim is made against us in connection with our collaboration, UCB may control the defense of such claim, and may make different decisions than we would make, potentially exposing us to increased liability.

**Risks Related to Our Dependence on Third Parties other than UCB**

***We have in the past relied and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials and other aspects of product development. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates when expected or at all.***

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our clinical trials and other aspects of product development. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP and GLP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites in a timely manner, or do so on commercially reasonable terms or at all. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity

of the data generated at the applicable clinical trial site may be questioned by the FDA.

***We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.***

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products.

Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

Table of Contents

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs for production of both APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all.

We also rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. UCB is solely responsible for and controls all aspects of the manufacture, distribution and supply of Cimzia. For more information about risks related to the manufacture of Cimzia, see [Risks Related to Our Collaboration with UCB](#). Some of the APIs and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier fails to supply product on a timely basis or in the requested amount, supplies product that fails to meet regulatory requirements, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases we may be required to get regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely. In particular, we are dependent on our current suppliers of the nonwoven material and foil in our DRM04 finished product, and any need to find and qualify new suppliers for these materials would adversely affect our business. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

In addition, these contract manufacturers are engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

To date, our drug substances and product candidates have been manufactured in small quantities for preclinical studies and early-stage clinical trials. As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our drug substances and product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any of such drug substance and product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product.



Table of Contents

If our third-party contractors are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers continue to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third-party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our product candidates may be delayed or interrupted. In addition, third-party suppliers and manufacturers may have the ability to increase the price payable by us for the supply of the APIs and other substances and materials used in our product candidates, in some cases without our consent.

Additionally, any damage to or destruction of our third-party manufacturers or suppliers facilities or equipment may significantly impair our ability to have our product candidates manufactured on a timely basis. Furthermore, if a contract manufacturer or supplier becomes financially distressed or insolvent, or discontinues our relationship beyond the term of any existing agreement for any other reason, this could result in substantial management time and expense to identify, qualify and transfer processes to alternative manufacturers or suppliers, and could lead to an interruption in clinical or commercial supply.

Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

***Manufacturing and supply of the APIs and other substances and materials used in our product candidates and finished drug products is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.***

Manufacturing and supply of APIs, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price and successful delivery of our product candidates and can impede, delay, limit or prevent the successful development and commercialization of our product candidates. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include:

- failure of our manufacturers to follow cGMP requirements or mishandling of product while in production or in preparation for transit;
- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency and stability;
- difficulty in establishing optimal production, storage, packaging and shipment methods and processes;
- challenges in designing effective drug delivery substances and techniques;
- transportation and import/export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of product;
- natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and
- latent defects that may become apparent after product has been released and which may result in recall and destruction of product.

Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our products, which could harm our business, financial condition, operating results and prospects.

Table of Contents

*If we are not able to establish and maintain collaborations, we may have to alter our development and commercialization plans.*

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. In order to fund further development of our product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and experience, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

Collaborations typically impose detailed obligations on each party, such as those required under the UCB agreement. If we were to breach our obligations, we may face substantial consequences, including potential termination of the collaboration, and our rights to our partners' product candidates, in which we have invested substantial time and money, would be lost.

We may not be successful in our efforts to implement collaborations or other alternative arrangements for the development of our product candidates. When we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish to the third party some or all of the control over the future success of that product candidate. Our collaboration partner may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a partnered product candidate or research program, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Table of Contents

**Risks Related to Our Business and Financial Operations**

*We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.*

Our management, personnel, systems and facilities currently in place are not adequate to support our business plan and future growth. We will need to further expand our scientific, medical affairs, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners;
- manage our preclinical and clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and



- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

***If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.***

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including: our Chief Executive Officer and Chairman of the Board, Thomas G. Wiggans; our Chief Medical Officer and a member of our board of directors, Eugene A. Bauer, M.D.; our Chief Operating Officer and Chief Financial Officer, Andrew L. Guggenime; our Executive Vice President, Product Development, Luis C. Peña; and our Vice President, Corporate Development and Strategy, Christopher M. Griffith. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

Table of Contents

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

***We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.***

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products from prior employment at other companies, we as a company have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. To commercialize Cimzia, we also intend to leverage the commercial infrastructure of our partner UCB in selected areas such as managed care and patient access, which will provide us with resources and expertise in these areas that are greater than we could initially build ourselves. If we are unable to utilize UCB's resources and expertise in this way, the cost, time and complexity involved in developing our own commercial infrastructure will likely increase. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. The inability to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results and prospects.

***Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.***

We intend to in-license, acquire, develop and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

## Edgar Filing: Dermira, Inc. - Form S-3/A

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

s-31

---

Table of Contents

*We intend to in-license and acquire product candidates and may in-license and acquire commercial-stage products or engage in other strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management.*

Our strategy is to in-license and acquire product candidates and we may in-license and acquire commercial-stage products or engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and

- inability to retain our key employees or those of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects. We have no current plan, commitment or obligation to enter into any transaction described above.

Table of Contents

*Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.*

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. From time to time, we may enter into collaboration agreements and license agreements with other companies that include development funding and significant upfront and milestone expenditures and payments, and we expect that amounts earned from or paid pursuant to these agreements will be a significant source of our capital expenditures and an important source of our revenue. Accordingly, our revenue and profitability will depend on development funding and the achievement of development and clinical milestones under the UCB agreement, as well as any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
  
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
  
- any delays in regulatory review and approval of product candidates in clinical development;
  
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
  
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
  
- our ability to obtain additional funding to develop our product candidates;

Edgar Filing: Dermira, Inc. - Form S-3/A

- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;

- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

s-33

---



Table of Contents

***Our operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn.***

Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary medical products and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider certain of our product candidates to be discretionary, and if full reimbursement for such products is not available, demand for these products may be tied to the discretionary spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for certain of our products and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to risk.

***Our ability to utilize our net operating loss, or NOL, carryforwards and research and development income tax credit carryforwards may be limited.***

As of December 31, 2014, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes of \$61.5 million, \$44.5 million and \$3.5 million, respectively. If not utilized, the federal and California NOL carryforwards will begin expiring during the year ending December 31, 2030 and the Canadian NOL carryforwards will begin expiring during the year ending December 31, 2028. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an ownership change, generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have experienced at least one ownership change since inception and our utilization of NOL carryforwards will therefore be subject to annual limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

***We may be adversely affected by natural disasters and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our corporate headquarters are located in Menlo Park, California, near major earthquake and fire zones. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers and suppliers facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners or manufacturers disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates, our business, financial condition, operating results and prospects would suffer.



Table of Contents

***Our business and operations would suffer in the event of failures in our internal computer systems.***

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

**Risks Related to Our Intellectual Property**

***We may not be able to obtain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.***

Our success with respect to our product candidates and technologies will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents.

Our patent portfolio includes patents and patent applications in the United States and foreign jurisdictions where we believe there is a market opportunity for our products. The covered technology and the scope of coverage vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our technologies. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use or sell products identical to or substantially similar to, our product candidates.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable if challenged in post-grant proceedings or by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. In particular, due to the extensive prior art relating to anticholinergic agents to control hyperhidrosis and because DRM04 is a form of a generic anticholinergic agent, the patent protection available for DRM04 may not prevent competitors from developing and commercializing similar products. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates.

Table of Contents

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable or provide us with a competitive advantage.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. The issued U.S. patents relating to DRM01 and DRM04 will expire between 2020 and 2034. The issued U.S. patents relating to Cimzia will expire in 2024.

## Edgar Filing: Dermira, Inc. - Form S-3/A

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

Table of Contents

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a first-to-file system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. Patent and Trademark Office, or USPTO, after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.



Table of Contents

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

***If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.***

We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects..

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot assure you that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such

technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents.

Table of Contents

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we rely on certain third-party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some of our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results.

*We may become involved in lawsuits or other adverse proceedings to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.*

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings such as inter partes review, post-grant review and reexamination brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Table of Contents

*We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.*

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome.

**Risks Related to this Offering, the Securities Markets and Ownership of Our Common Stock**

*The stock price of our common stock has been, and is likely to continue to be, volatile and may decline and you may not be able to resell your shares at or above the offering price.*

Prior to our initial public offering in October 2014, there had not been a public market for our common stock. The price of our common stock in this offering will be determined through negotiations between the underwriters and us and may vary from the market price of our common stock prior to or following this offering. If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the offering price. An active or liquid market in our common stock may not be sustainable. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- the development status of our product candidates, including whether any of our product candidates receive regulatory approval;
- regulatory or legal developments in the United States and foreign countries;
- the results of our clinical trials and preclinical studies;
- the clinical results of our competitors or potential competitors;

Edgar Filing: Dermira, Inc. - Form S-3/A

- the success of, and fluctuations in, the commercial sales of products approved for commercialization, if any;
- the execution of our partnering and manufacturing arrangements;
- our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- variations in the level of expenses related to our commercialization activities, if any product candidates are approved;
- the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;
- overall performance of the equity markets;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- the public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;

- FDA or foreign regulatory actions affecting us or our industry;
- changes in the structure of healthcare payment systems;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- ratings downgrades by any securities analysts who follow our common stock;
- the development and sustainability of an active trading market for our common stock;
- the size of our market float;
- the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;
- recruitment or departure of key personnel;
- changes in accounting principles;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- any other factors discussed herein.





Table of Contents

In addition, the stock markets, and in particular The NASDAQ Global Select Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

Since January 1, 2015 through October 29, 2015, the closing sale price of our common stock on The NASDAQ Global Select Market ranged from \$14.34 to \$31.37 per share. Because our stock price has been volatile, investing in our common stock is risky.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. Ineffective internal control could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with the fiscal year ending December 31, 2015. However, for as long as we are an emerging growth company under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***We incur significantly increased costs as a result of and devote substantial management time to operating as a public company.***

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and The NASDAQ Global Select Market, including the establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices and required filing of annual, quarterly and current reports with respect to our business and operating results. Compliance with these requirements has increased and will continue to increase our legal and financial compliance costs and has made and will increasingly make some activities more time-consuming and costly. In addition, our management and other personnel need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We also need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.



Table of Contents

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Prior to our initial public offering in October 2014, there had not been a public market for our common stock and we did not have research coverage by securities and industry analysts. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

***Future sales of our common stock or securities convertible into our common stock may depress our stock price.***

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of September 30, 2015, we had approximately 29.9 million shares of common stock outstanding.

If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital. Certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangements described in Description of Capital Stock in the accompanying prospectus. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***Our directors and executive officers, together with their affiliates, will continue to exert significant influence over us after this offering and could impede a change of corporate control.***

As of September 30, 2015, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 17% of our outstanding common stock (assuming no sale of shares under this prospectus supplement). As a result, these stockholders, acting together, would have the ability to exert significant influence on matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or

- discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of us.

*Delaware law and provisions in our restated certificate of incorporation and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.*

The anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change of control by prohibiting us from engaging in a business combination with stockholders owning in excess of 15% of our outstanding voting stock for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- our board of directors is classified into three classes of directors with staggered three-year terms, with directors removable from office only for cause, so that not all members of our board of directors are elected at one time;
- only our board of directors has the right to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

Table of Contents

- only our chairman of our board of directors, our chief executive officer, our president or a majority of our board of directors are authorized to call a special meeting of stockholders;
- certain litigation against us can only be brought in Delaware;
- our restated certificate of incorporation authorizes the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval, and which may include rights superior to the rights of the holders of common stock;
- all stockholder actions must be taken at meetings of our stockholders, and may not be taken by written consent;
- our board of directors is expressly authorized to make, alter or repeal our bylaws; and
- advance notice requirements apply for stockholders to nominate candidates for elections to our board of directors or to bring matters that can be acted upon by stockholders at stockholder meetings.

These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing so as to cause us to take certain corporate actions you desire.

***We are an emerging growth company as defined in the JOBS Act and cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an emerging growth company as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements and exemption from the auditor's attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenue of \$1 billion or more, (2) the last day of 2019, (3) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

***Because management has broad discretion as to the use of the net proceeds from this offering, you may not agree with how we use them, and such proceeds may not be applied successfully.***

Our management will have broad discretion over the use of proceeds from this offering. We currently intend to use the net proceeds from this offering to fund research and development of our product candidates, working capital, capital expenditures and other general corporate purposes. Additionally, we may use a portion of the net proceeds to us from the sale of our securities under this prospectus to expand our business by in-licensing or acquiring, as the case may be, commercial products, product candidates, technologies, compounds, other assets or complementary businesses. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock, or that you otherwise do not agree with. You will be relying on the judgment of our management concerning these uses and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The failure of our management to apply these funds effectively could, among other things, result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

***If you purchase shares of common stock sold in this offering, you will incur immediate and substantial dilution.***

If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share after giving effect to this offering, based on the assumed public offering price of \$27.12 per share, which is the last reported sale price of our common stock on The NASDAQ Global Select Market on October 29, 2015, because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the offering price when they purchased shares of our capital stock. You will experience additional dilution upon exercise of the outstanding stock options and other equity awards that may be granted under our equity incentive plans, and when we otherwise issue additional shares of our common stock. For more information, see Dilution.

Table of Contents

*We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.*

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. In addition, the terms of our loan and security agreement currently restrict our ability to pay dividends. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

*The actual number of shares we will issue under the sales agreement, at any one time or in total, is uncertain.*

Subject to certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a sales notice to Cowen at any time throughout the term of the sales agreement. The number of shares that are sold by Cowen after delivering a sales notice will fluctuate based on the market price of the common shares during the sales period and limits we set with Cowen. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued.

*The common stock offered hereby will be sold in at-the-market offerings, and investors who buy shares at different times will likely pay different prices.*

Investors who purchase shares in this offering at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience a decline in the value of their shares as a result of share sales made at prices lower than the prices they paid.

Table of Contents

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement and the documents incorporated by reference herein contain forward-looking statements. All statements contained in this prospectus supplement and the documents incorporated by reference herein other than statements of historical fact, including statements regarding our future consolidated results of operations and financial position, our business strategy and plans, market growth, and our objectives for future operations, are forward-looking statements. The words believe, may, will, estimate, potentially, continue, anticipate, intend, could, would, project, plan and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our consolidated financial condition, consolidated results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading Risk Factors in our September 2015 10-Q, as well as those discussed in this prospectus supplement, the documents incorporated by reference in this prospectus supplement and any free writing prospectus. All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus and the documents incorporated by reference herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We undertake no obligation to update any of these forward-looking statements for any reason after the date of this prospectus supplement, or in the case of documents referred to or incorporated by reference herein or in the accompanying prospectus, the date of those documents, or to conform such statements to actual results or revised expectations. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

You should read this prospectus supplement, the accompanying prospectus, any free writing prospectus and the documents incorporated by reference herein with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.



Table of Contents

**USE OF PROCEEDS**

We may issue and sell shares of our common stock having aggregate sale proceeds of up to \$75,000,000 from time to time. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement with Cowen as a source of financing. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We currently intend to use any net proceeds from the sale of securities under this prospectus supplement primarily to fund research and development of our product candidates, working capital, capital expenditures and other general corporate purposes. Additionally, we may use a portion of the net proceeds from this offering to expand our current business by in-licensing or acquiring, as the case may be, commercial products, product candidates, technologies, compounds, other assets or complementary businesses, using cash or shares of our common stock. However, we have no current commitments or obligations to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our clinical trials and other development efforts and other factors described under **Risk Factors** in this prospectus supplement and the documents incorporated by reference herein, as well as the amount of cash used in our operations. As a result, our management will have broad discretion over the uses of the net proceeds, if any, we receive in connection with securities offered pursuant to this prospectus supplement and investors will be relying on the judgment of our management regarding the application of the proceeds. Pending these uses, we intend to invest the net proceeds in investment-grade, interest-bearing securities such as money market funds, certificates of deposit, commercial paper, repurchase agreements, corporate debt and guaranteed obligations of the U.S. government.

Table of Contents**DILUTION**

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after our public offering.

As of September 30, 2015, our net tangible book value was \$210.5 million, or \$7.03 per share of common stock. Net tangible book value per share represents the amount of our tangible assets less our liabilities divided by the total number of shares of our common stock outstanding.

Our as adjusted net tangible book value as of September 30, 2015 would be \$283.3 million, or \$8.67 per share of common stock. As adjusted net tangible book value per share reflects the sale by us of shares of our common stock in the full aggregate amount of \$75,000,000 in this offering, at an assumed offering price of \$27.12 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on October 29, 2015, after deducting the estimated commissions and estimated offering expenses payable by us. This represents an immediate increase in as adjusted net tangible book value of \$1.64 per share to existing stockholders and immediate dilution of \$18.45 per share to new investors purchasing shares in the offering.

The following table illustrates this per share dilution to new investors:

Assumed offering price per share		\$	27.12
Net tangible book value per share as of September 30, 2015, before giving effect to this offering	\$	7.03	
Increase in as adjusted net tangible book value per share after giving effect to this offering		1.64	
As adjusted net tangible book value per share, after giving effect to this offering			8.67
Dilution per share to investors purchasing shares in this offering	\$		18.45

The shares sold in this offering, if any, will be sold from time to time at various prices. An increase of \$1.00 per share in the price at which the shares are sold from the assumed offering price of \$27.12 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$75,000,000 is sold at that price, would increase our as adjusted net tangible book value per share after the offering to \$8.69 per share and would increase the dilution in net tangible book value per share to new investors to \$19.43 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of \$1.00 per share in the price at which the shares are sold from the assumed offering price of \$27.12 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$75,000,000 is sold at that price, would decrease our as adjusted net tangible book value per share after the offering to \$8.64 per share and would decrease the dilution in net tangible book value per share to new investors to \$17.48 per share, after deducting commissions and estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

To the extent that outstanding options are exercised or outstanding restricted stock units vest, investors purchasing our common stock in this offering will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The number of shares of common stock to be outstanding after this offering is based on 29,918,829 shares of common stock outstanding as of September 30, 2015 and excludes the following:

- 3,718,828 shares of our common stock issuable upon the exercise of outstanding options under our 2010 Equity Incentive Plan and 2014 Equity Incentive Plan as of September 30, 2015 with a weighted-average exercise price of \$8.53 per share; and
- 1,795,617 shares of our common stock reserved and available for future issuance under our equity compensation plans, consisting of (1) 1,275,551 shares of common stock reserved and available for issuance under the 2014 Equity Incentive Plan as of September 30, 2015 and (2) 520,066 shares of common stock reserved for issuance under the 2014 Employee Stock Purchase Plan as of September 30, 2015.

Table of Contents

**PLAN OF DISTRIBUTION**

We have entered into a sales agreement with Cowen, under which we may issue and sell from time to time up to \$75,000,000 of our common stock through Cowen as our sales agent. Sales of our common stock, if any, will be made at market prices by any method that is deemed to be an at-the-market offering as defined in Rule 415 under the Securities Act, including sales made directly on The NASDAQ Global Select Market or any other trading market for our common stock, or sales to or through a market maker other than on an exchange. If authorized by us in writing, Cowen may also sell shares of our common stock by any other method permitted by law, including privately negotiated transactions, and Cowen may also purchase shares of our common stock as principal.

Cowen will offer our common stock subject to the terms and conditions of the sales agreement on a daily basis or as otherwise agreed upon by us and Cowen. We will designate the maximum amount of common stock to be sold through Cowen subject to the terms and conditions of the sales agreement as specified by us in a placement notice. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. We may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by us in any such instruction. Cowen or we may suspend the offering of our common stock being made through Cowen under the sales agreement upon written notice to the other party. Cowen and we each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party's sole discretion at any time.

The aggregate compensation payable to Cowen as sales agent equals a mutually agreed percentage, not to exceed 3.0%, of the gross sales price of the shares sold through it pursuant to the sales agreement. We have also agreed to reimburse Cowen up to a mutually agreed amount, not to exceed \$50,000, of Cowen's actual outside legal expenses incurred by Cowen in connection with this offering. We estimate that the total expenses of the offering payable by us, excluding commissions payable to Cowen under the sales agreement, will be approximately \$400,000.

Cowen will provide written confirmation to us following the close of trading on The NASDAQ Global Select Market on each day in which our common stock is sold through it as sales agent under the sales agreement. Each confirmation will include the number of shares of our common stock sold through it as sales agent on that day, the volume-weighted average price of the shares sold, the percentage of the daily trading volume and the net proceeds payable to us.

We will report at least quarterly the number of shares of common stock sold through Cowen under the sales agreement, the net proceeds to us and the compensation paid by us to Cowen in connection with the sales of our common stock.

Settlement for sales of our common stock will occur, unless the parties agree otherwise, on the third business day that is also a trading day following the date on which any sales were made in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sales of our common stock on our behalf, Cowen will be deemed to be an underwriter within the meaning of the Securities Act, and the compensation paid to Cowen will be deemed to be underwriting commissions or discounts. We have agreed in the sales agreement to provide indemnification and contribution to Cowen against certain liabilities, including liabilities under the Securities Act. As sales agent, Cowen will not engage in any transactions that stabilizes our common stock.

Edgar Filing: Dermira, Inc. - Form S-3/A

Our common stock is listed on The NASDAQ Global Select Market and trades under the symbol DERM. The transfer agent of our common stock is American Stock Transfer and Trust Company, LLC.

Cowen and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees.

s-48

---

Table of Contents

**LEGAL MATTERS**

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Fenwick & West LLP, San Francisco, California, which beneficially owns an aggregate of 43,103 shares of our common stock, representing approximately 0.14% of our outstanding shares of capital stock as of September 30, 2015. Cowen is being represented in connection with this offering by Cooley LLP, New York, New York.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014, as set forth in their report, which is incorporated by reference in this prospectus supplement and elsewhere in the registration statement. Our consolidated financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-3 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus supplement, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the common stock offered hereby, reference is made to the accompanying prospectus and registration statement of which it is a part and the exhibits filed therewith. Statements contained in this prospectus supplement regarding the contents of any contract or any other document that is filed as an exhibit to the accompanying prospectus and the registration statement of which it is a part are not necessarily complete, and in each instance we refer you to the copy of such contract or other document filed as an exhibit to the registration statement or the exhibits to the reports or other documents incorporated by reference in this prospectus for a copy of such contract or other document.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are required to file annual, quarterly and other reports, proxy statements and other information with the SEC. You may inspect and copy these reports, proxy statements and other information at the public reference facilities maintained by the SEC at 100 F Street N.E., Washington, DC 20549. Copies of such materials can be obtained from the SEC's public reference section at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at (800) SEC-0330. Additionally, the SEC maintains an Internet site ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and various other information about us. You may also inspect the documents described herein at our principal executive offices, 275 Middlefield Road, Suite 150, Menlo Park, CA 94025, during normal business hours.

Information about us is also available at our website at [www.dermira.com](http://www.dermira.com). However, the information on our website is not a part of this prospectus and is not incorporated by reference into this prospectus.

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

## Edgar Filing: Dermira, Inc. - Form S-3/A

The SEC allows us to incorporate by reference information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus. Information in this prospectus supplement supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus supplement.

We incorporate by reference into this prospectus and the registration statement of which this prospectus supplement and accompanying prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-36668) or may file with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of any offering of securities made by this prospectus supplement and accompanying prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 25, 2015;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015 and filed with the SEC on May 12, 2015, August 13, 2015 and November 10, 2015, respectively;

Table of Contents

- the information specifically incorporated by reference into our Annual Report on Form 10-K for the year ended December 31, 2014 from our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 29, 2014;
- our Current Reports on Form 8-K, filed with the SEC on June 16, 2015, September 30, 2015 and October 1, 2015; and
- the description of our common stock contained in our registration statement on Form 8-A filed with the SEC on September 29, 2014 under Section 12 of the Exchange Act, including any amendment or report filed for the purpose of updating such description.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Dermira, Inc., 275 Middlefield Road, Suite 150, Menlo Park, CA 94025. Copies of the above reports may also be accessed from our website at [www.investor.dermira.com](http://www.investor.dermira.com). We do not incorporate the information from our website into this prospectus supplement and you should not consider any information on, or that can be accessed through, our website as part of this prospectus supplement. See the section of this prospectus supplement entitled "Where You Can Find Additional Information" for information concerning how to read and obtain copies of materials that we file with the SEC at the SEC's public offices.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus supplement, will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus supplement modifies, supersedes or replaces such statement.



Table of Contents

**Up to \$75,000,000**

**Common Stock**

---

**PROSPECTUS SUPPLEMENT**

---

**Cowen and Company**

, 2015

---

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth estimated expenses in connection with the issuance and distribution of the securities being registered. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee.

SEC registration fee	\$	30,210
FINRA filing fee		45,500
NASDAQ listing fee		*
Printing and engraving		*
Legal fees and expenses		*
Accounting fees and expenses		*
Transfer agent and registrar fees and expenses		*
Trustee fees and expenses		*
Miscellaneous expenses		*
Total	\$	*

\* These fees are calculated based on the type of securities offered and the number of issuances and accordingly, cannot be estimated at this time.

**Item 15. Indemnification of Officers and Directors**

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the Delaware General Corporation Law are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended.

As permitted by the Delaware General Corporation Law, the Registrant's restated certificate of incorporation contains provisions that eliminate the personal liability of its directors for monetary damages for any breach of fiduciary duties as a director, except liability for the following:

- any breach of the director's duty of loyalty to the Registrant or its stockholders;

Edgar Filing: Dermira, Inc. - Form S-3/A

- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (regarding unlawful dividends and stock purchases); or
- any transaction from which the director derived an improper personal benefit.

As permitted by the Delaware General Corporation Law, the Registrant's restated bylaws provide that:

- the Registrant is required to indemnify its directors and executive officers to the fullest extent permitted by the Delaware General Corporation Law, subject to very limited exceptions;
- the Registrant may indemnify its other employees and agents as set forth in the Delaware General Corporation Law;
- the Registrant is required to advance expenses, as incurred, to its directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to very limited exceptions; and
- the rights conferred in the restated bylaws are not exclusive.

The Registrant has entered into indemnity agreements with each of its current directors and executive officers to provide these directors and executive officers additional contractual assurances regarding the scope of the indemnification set forth in the Registrant's restated certificate of incorporation and restated bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of the Registrant for which indemnification is sought. The indemnification provisions in the Registrant's restated certificate of incorporation, restated bylaws and the indemnity agreements entered into between the Registrant and each of its directors and executive officers may be sufficiently broad to permit indemnification of the Registrant's directors and executive officers for liabilities arising under the Securities Act.

Table of Contents

The Registrant currently carries liability insurance for its directors and officers.

Three of the Registrant's directors (Fred B. Craves, Wende S. Hutton and Jake R. Nunn) are also indemnified by their employers with regard to their service on the Registrant's board of directors.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

Description of Document	Exhibit Number
Sales Agreement, dated as of November 2, 2015, by and between Dermira, Inc. and Cowen and Company, LLC.	1.2
Restated Certificate of Incorporation.	3.1
Restated Bylaws.	3.2
Amended and Restated Investors Rights Agreement dated August 15, 2014, by and among the Registrant and certain of its stockholders.	4.2

**Item 16. Exhibits**

The exhibits listed in the accompanying Exhibit Index are incorporated by reference herein and are filed (except where otherwise indicated) as part of this registration statement.

**Item 17. Undertakings.**

(a) The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no

## Edgar Filing: Dermira, Inc. - Form S-3/A

more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*Provided, however,* that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Table of Contents

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(6) That, for the purpose of determining liability of the Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such

## Edgar Filing: Dermira, Inc. - Form S-3/A

securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(e) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report, to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X is not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



Table of Contents

(j) The undersigned Registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act, or the Act, in accordance with the rules and regulations prescribed by the SEC under section 305(b)(2) of the Act.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 1 to Registration Statement on Form S-3 and has duly caused this Amendment No. 1 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Menlo Park, State of California, on this 13th day of November, 2015.

**DERMIRA, INC.**

By: */s/ THOMAS G. WIGGANS*  
 Thomas G. Wiggans  
*Chief Executive Officer and Chairman of the Board*

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to Registration Statement on Form S-3 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
<i>/s/ THOMAS G. WIGGANS</i> Thomas G. Wiggans	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	November 13 , 2015
<i>/s/ ANDREW L. GUGGENHIME</i> Andrew L. Guggenhime	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	November 13, 2015
* Eugene A. Bauer	Chief Medical Officer and Director	November 13, 2015
* David E. Cohen	Director	November 13, 2015
* Fred B. Craves	Director	November 13, 2015
* Matthew K. Fust	Director	November 13, 2015
* Wende S. Hutton	Director	November 13, 2015

Table of Contents

* Mark D. McDade	Director	November 13, 2015
* Jake R. Nunn	Director	November 13, 2015
* William R. Ringo	Director	November 13, 2015
* Kathleen Sebelius	Director	November 13, 2015
* By: /s/ Andrew L. Guggenime Andrew L. Guggenime	Attorney-in-fact	November 13, 2015

Table of Contents**EXHIBIT INDEX**

Exhibit Number	Description of Document	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
1.1*	Form of Underwriting Agreement.					
1.2	Sales Agreement, dated as of November 2, 2015, by and between the Registrant and Cowen and Company, LLC.	S-3	333-207755	1.2	11/2/2015	
3.1	Restated Certificate of Incorporation.	10-Q	001-36668	3.1	11/12/2014	
3.2	Restated Bylaws.	10-Q	001-36668	3.2	11/12/2014	
4.1	Form of Common Stock Certificate.	S-1	333-198410	4.1	8/27/2014	
4.2	Amended and Restated Investors Rights Agreement, dated August 15, 2014, by and among the Registrant and certain of its stockholders.	S-1	333-198410	4.2	8/27/2014	
4.3*	Form of Preferred Stock Certificate.					
4.4	Form of Debt Security.	S-3	333-207755	4.4	11/2/2015	
4.5	Form of Indenture.	S-3	333-207755	4.5	11/2/2015	
4.6*	Form of Warrant.					
4.7*	Form of Warrant Agreement.					
4.8*	Form of Subscription Rights Certificate.					
4.9*	Form of Unit.					
4.10*	Form of Unit Agreement.					
5.1	Opinion of Fenwick & West LLP.	S-3	333-207755	5.1	11/2/2015	
12.1	Statement of Computation of Ratio of Earnings to Fixed Charges.					X
23.1	Consent of independent registered public accounting firm.					X
23.2	Consent of Fenwick & West LLP.	S-3	333-207755	5.1	11/2/2015	
24.1	Power of Attorney.	S-3	333-207755	24.1	11/2/2015	
25.1**	Form T-1 Statement of Eligibility of Trustee for Senior Indenture under The Trust Indenture Act of 1939.					

Edgar Filing: Dermira, Inc. - Form S-3/A

25.2\*\* Form T-1 Statement of Eligibility of Trustee for  
Subordinated Indenture under The Trust  
Indenture Act of 1939.

---

\* To be filed by amendment or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934, as amended, and incorporated herein by reference.

\*\* To be filed in accordance with the requirements of Section 305(b)(2) of the Trust Indenture Act of 1939 and Rule 5b-3 thereunder.