

Dermira, Inc.  
Form S-1/A  
August 04, 2015

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As filed with the Securities and Exchange Commission on August 4, 2015

Registration No. 333-205907

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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AMENDMENT NO. 1  
TO

**FORM S-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**DERMIRA, INC.**

(Exact name of registrant as specified in its charter)

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

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

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**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)

# Edgar Filing: Dermira, Inc. - Form S-1/A

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### Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

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 check the following box.

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 statement 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 statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) 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.

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 the 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

Smaller reporting company

(Do not check if a  
smaller reporting company)

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### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee(3)
Common Stock, \$0.001 par value per share	4,312,500	\$22.43	\$96,729,375	\$11,240

(1) Estimated pursuant to Rule 457(a) under the Securities Act of 1933, as amended. Includes additional shares that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of calculating the amount of the registration fee and is based on the last reported sale price per share of Registrant's common stock as reported on The NASDAQ Global Select Market on August 3, 2015.

(3) The Registrant previously paid \$11,359 in connection with a prior filing of this Registration Statement. No additional registration fee is being paid in connection with this amendment to the Registration Statement.

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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.

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**The information in this preliminary 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 preliminary 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 August 4, 2015**

**PRELIMINARY PROSPECTUS**

**3,750,000 SHARES OF COMMON STOCK**

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Dermira, Inc. is offering 3,750,000 shares of its common stock.

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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 August 3, 2015 was \$22.43 per share.

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We are an "emerging growth company" under applicable Securities and Exchange Commission rules and are eligible for reduced public company disclosure requirements.

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**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 13 of this prospectus.**

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	<b>Per Share</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

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(1) We refer you to "Underwriting" beginning on page 90 for additional information regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days to purchase up to 562,500 additional shares of common stock.

**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.**

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The underwriters expect to deliver the shares of common stock to purchasers on or about \_\_\_\_\_, 2015, through the book-entry facilities of The Depository Trust Company.

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**Leerink Partners**

**Cowen and Company**

**Guggenheim Securities**

**Needham & Company**

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

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We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Persons who come into possession of this prospectus and any applicable free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

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**SUMMARY**

*This summary highlights information contained in other parts of this prospectus 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 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 shares of our common stock, you should read the entire prospectus, the registration statement of which this prospectus is a part, 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" included elsewhere in this prospectus and the matters discussed in the sections entitled "Selected Consolidated Financial Data," our consolidated financial statements and the accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case, 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.

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





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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.

**Our Product Candidates**

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.

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.

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**Our Strategy**

Our strategy is to in-license, acquire, develop and commercialize innovative and differentiated products that we believe can be successful in the dermatology marketplace. The key components of our strategy are to:

***Rapidly develop our late-stage product candidates.*** We commenced our Phase 3 clinical program for Cimzia within 10 months of establishing our collaboration with UCB, produced positive Phase 2b clinical trial results within nine months of initiating our first clinical trial of DRM04 and produced positive Phase 2a clinical trial results within one year of initiating our first clinical trial of DRM01. We believe that our team's expertise in designing and executing product development programs in dermatology, combined with the relative efficiencies of dermatology product development, will enable us to rapidly develop our late-stage product candidates.

***Efficiently establish proof-of-concept for our early-stage product candidates and advance promising candidates into late-stage development.*** In developing our early-stage product candidates, we focus on translating advances in the understanding of skin disease biology into innovative solutions for unmet needs in dermatology. We seek to rapidly and efficiently establish proof-of-concept for these product candidates. Using this approach, our experienced management team is able to efficiently determine whether and how to advance product candidates into the next stages of development, which we believe increases our ability to direct resources to promising programs and enhances our likelihood of successfully developing and commercializing our product candidates.

***In-license and acquire new product candidates and, potentially, commercial-stage products.*** Since our founding in 2010, we have executed three transactions resulting in a portfolio of five product candidates. We intend to continue to identify, evaluate, in-license and acquire product candidates from a number of sources by leveraging the insights, network and experience of our management team. Our objective is to maintain a well-balanced portfolio by in-licensing or acquiring additional product candidates across various stages of development. We also may seek to in-license and acquire dermatology products that have received regulatory approval for marketing in order to accelerate our entry into the market or expand the portfolio of products we can market to dermatologists.

***Build a medical affairs organization and specialized sales and marketing organization of highly experienced professionals who can effectively communicate the benefits of our approved products and support dermatologists and their patients.*** We believe that we can compete effectively in the dermatology market by having a medical affairs organization and specialized sales and marketing organization focused solely on dermatologists and their patients. To commercialize any approved products we may successfully develop or acquire, we intend to build a medical affairs organization and specialized sales and marketing organization that will provide high levels of customer support and scientific expertise to dermatologists and their patients.

***Maximize the value of our portfolio by commercializing our approved products ourselves where we can effectively do so and partnering with other companies to help us reach new markets.*** We currently hold worldwide rights to all of our product candidates with the exception of Cimzia. We currently plan to commercialize our approved products in the United States and Canada by deploying a specialized sales force targeting dermatologists in these countries. We may partner with third parties to help us reach other geographic markets or medical specialties. We have an exclusive license to market Cimzia to dermatologists in the United States and Canada following regulatory approval of Cimzia for the treatment of psoriasis in these countries. We plan to leverage the infrastructure of our partner, UCB, to support our marketing of Cimzia in the United States and Canada.

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*Continue to build a team of committed, experienced employees and leverage our relationships with members of the dermatology community.* We believe that the field of dermatology offers an exceptional opportunity to build relationships with opinion leaders, advocacy groups and medical practitioners. We believe that consolidation in the dermatology industry has resulted in an enhanced opportunity for a dermatology-focused company to build relationships with these stakeholders and has made available a large and growing talent pool of experienced employees who can make significant contributions to our company.

**Key Markets for Our Product Candidates**

***The Moderate-to-Severe Plaque Psoriasis Market***

Psoriasis is a chronic, complex, immune-mediated disease that requires long-term treatment. It is commonly considered the most prevalent autoimmune disease in the world. According to Decision Resources, the diagnosed prevalence of psoriasis in the United States was approximately 9.3 million people, or approximately 2.9% of the population, in 2013.

According to Decision Resources, in 2013, U.S. sales of psoriasis prescriptions accounted for \$4.4 billion and U.S. sales of biologic therapies for moderate-to-severe plaque psoriasis were \$3.7 billion, of which \$2.8 billion were from TNF inhibitors. According to data provided by IMS Health National Prescription Audit, or IMS NPA, and IMS National Sales Perspectives, or IMS NSP, between 2010 and 2013, sales of biologic therapies attributable to U.S. dermatologists grew at a compounded annual growth rate of 19% and sales of TNF inhibitors attributable to U.S. dermatologists grew at a compounded annual growth rate of 12%.

We believe that there is a substantial opportunity for continued expansion of the market for biologic psoriasis therapies. According to an analysis of survey data collected by the National Psoriasis Foundation published in JAMA Dermatology, roughly half of moderate-to-severe plaque psoriasis patients remain unsatisfied with their treatment options. Even with the significant recent growth in the market, penetration of biologics into the addressable population of moderate-to-severe plaque psoriasis patients remains relatively low, particularly in comparison to other large biologics markets. In the United States in 2012, according to Decision Resources, only 10.5% of treated moderate-to-severe psoriasis patients received biologics and 21.7% of treated rheumatoid arthritis patients received biologics. We believe that penetration into the psoriasis patient population may continue to increase as dermatologists become more familiar with available biologic therapies, particularly the established safety record of TNF inhibitors, and as new biologic products reach the market. Decision Resources projects that U.S. sales of branded, systemic psoriasis therapies will increase from approximately \$3.9 billion in 2013 to \$5.9 billion by 2023.

***The Hyperhidrosis Market***

Hyperhidrosis is a condition of excessive sweating beyond what is physiologically required to maintain normal thermal regulation. Primary hyperhidrosis, which is excessive sweating without a known cause, can affect the underarms, palms of the hands, soles of the feet, face and other areas. Several studies have demonstrated that excessive sweating often impedes normal daily activities and can result in occupational, emotional, psychological, social and physical impairment. In the United States, based on the most recent data available, the prevalence of hyperhidrosis was estimated in 2003 to be 2.8% of the population, or roughly 7.8 million people. According to published studies, approximately half of hyperhidrosis sufferers have axillary hyperhidrosis.

The market for products to control sweating is large and highly underpenetrated by prescription pharmaceutical products. Despite the limited efficacy of over-the-counter, or OTC, antiperspirants for the alleviation of hyperhidrosis symptoms, according to a 2003 survey, only 38% of hyperhidrosis patients had discussed their condition with a healthcare professional. We believe that this is largely a

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result of the lack of effective, well-tolerated, convenient prescription treatment options. Patients who seek treatment from a physician most commonly receive prescription topical antiperspirants. According to data provided by IMS NPA, these topical antiperspirants generated approximately 490,000 prescriptions in the United States in 2014. However, their use is limited by modest efficacy and skin irritation, particularly in patients with more severe disease. We believe that the market opportunity for a new, effective, well-tolerated, topical hyperhidrosis treatment is substantially larger than the current market for prescription topical antiperspirants because such a therapy could further penetrate the segment of patients who seek treatment from a physician and encourage more patients to seek treatment.

***The Acne Market***

Acne is one of the most common skin diseases. It is characterized by clogging of the pores and associated local skin lesions. Acne lesions are believed to result from an interaction of multiple pathogenic, or contributing, factors, including excessive sebum production. Acne can significantly impact patients' quality of life, resulting in social, psychological and emotional impairments that are comparable to those reported by patients with epilepsy, asthma, diabetes or arthritis. According to widely-cited data, it is estimated that acne affected more than 85% of teenagers globally in 1994, 150 million people globally as of 2008 and 40 to 50 million Americans as of 1998. Acne is one of the most common reasons for visiting a dermatologist. According to GfK Custom Research, LLC, in 2007, acne represented about one-fourth of U.S. dermatologists' patient volume.

According to IMS MIDAS, products to treat acne accounted for over \$4.0 billion in global pharmaceutical sales in 2013. In the same year, according to data provided by IMS NSP and IMS NPA, products to treat acne accounted for approximately \$3.5 billion in U.S. pharmaceutical sales and each of the three major prescription pharmaceutical product classes that are predominantly used to treat acne generated between approximately \$580 million and \$2.1 billion in U.S. sales. These three product classes have been available for over 30 years, and we believe that growth in this market recently has been significantly limited by a lack of innovation in new product development.

We believe that there is a substantial unmet need and commercial opportunity for a topical acne therapy that targets sebum production. Acne treatment guidelines published by the Global Alliance to Improve Outcomes in Acne recommend that acne treatment be directed toward as many pathogenic factors as possible. Accordingly, patients are often treated with combination regimens that incorporate agents with complementary mechanisms of action targeting different pathogenic factors. The vast majority of acne patients are treated with topical therapies, and all of the four primary pathogenic factors except for excessive sebum production can be targeted with available topical treatments. While systemic therapies may be used to effectively inhibit sebum production, their use is limited by significant, systemic side effects. As a result, we believe that the introduction of a topical acne treatment that targets sebum production could establish a new product class and expand the acne market.

**Key Developments**

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

***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

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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.

***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.

***End-of-Phase 2 meeting with FDA for DRM04.*** In April 2015, we held an end-of-Phase 2 meeting with the FDA for DRM04. Based on feedback from the FDA and the results of the Phase 2 program comprising three randomized, double-blind, vehicle-controlled clinical trials in 341 patients, we are finalizing the design of a Phase 3 program for DRM04 in axillary hyperhidrosis and plan to initiate the program in the second half of 2015.

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***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 June 30, 2015, we own or have an exclusive license to 27 issued U.S. patents and 87 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.

***Cash and cash equivalents and investments balance.*** As of June 30, 2015, we had \$143.8 million in cash and cash equivalents and investments.

**Selected Risks Associated with Our Business**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

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, DRM04 and DRM01.

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.

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.

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.

Clinical drug development for our product candidates is 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.

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.

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.

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

We have in the past relied and expect to continue to rely on third-party contract research organizations and other third parties to conduct and oversee our clinical trials and other aspects

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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 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.

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.

**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.

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.

We have registered the trademark "Dermira" in Australia, the European Union, Japan and Switzerland and have a trademark application for the trademark "Dermira" pending with the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office. 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. Solely for convenience, the trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

**Implications of Being an Emerging Growth Company**

As a company with less than \$1.0 billion in revenue during our most recently completed fiscal year, we qualify as an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

reduced disclosure of financial information in this prospectus, including two years of audited financial information and two years of selected financial information;

an exemption from compliance with the auditor attestation requirement on the effectiveness of our internal control over financial reporting;

an exemption from compliance with any requirement that the Public Company Accounting Oversight Board may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

reduced disclosure about our executive compensation arrangements; and





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exemptions from the requirements to obtain a non-binding advisory vote on executive compensation or a stockholder approval of any golden parachute arrangements.

We may take advantage of some or all of these exemptions until we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of: the last day of the fiscal year in which we have more than \$1.0 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of 2019. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

However, we have irrevocably elected to not avail ourselves of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards applicable to public companies and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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**The Offering**

Shares of common stock offered by us	3,750,000 shares
Option to purchase additional shares offered by us	562,500 shares
Shares of common stock to be outstanding immediately after this offering	28,420,911 shares (28,983,411 shares if the underwriters' option to purchase additional shares is exercised in full)
Use of proceeds	We currently intend to use the net proceeds from this offering for external research and development expenses associated with the development of our Cimzia, DRM04 and DRM01 product candidates, with the balance primarily used to fund internal research and development expenses associated with all of our product candidates, working capital, capital expenditures and other general corporate purposes. See "Use of Proceeds."
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ symbol	"DERM"

The number of shares of common stock to be outstanding after this offering is based on 24,670,911 shares of common stock outstanding as of March 31, 2015 and excludes:

3,446,904 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 March 31, 2015, with a weighted-average exercise price of \$7.23 per share; and

2,140,459 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 1,592,449 shares of common stock reserved for issuance under the 2014 Equity Incentive Plan as of March 31, 2015 and (2) 548,010 shares of common stock reserved for issuance under the 2014 Employee Stock Purchase Plan as of March 31, 2015.

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

no exercise of outstanding options subsequent to March 31, 2015; and

no exercise of the underwriters' option to purchase additional shares.

Table of Contents**Summary Consolidated Financial Data**

The following tables summarize our consolidated financial data. We derived our summary consolidated statements of operations data for the years ended December 31, 2012, 2013 and 2014 from our audited consolidated financial statements incorporated by reference in this prospectus from our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, or our 2014 Annual Report, and we have derived the following statements of operations data for the three months ended March 31, 2014 and 2015 and the balance sheet data as of March 31, 2015 from our unaudited interim financial statements incorporated by reference in this prospectus from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, or our March 2015 Quarterly Report. Our unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles on the same basis as our audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, that are necessary for the fair presentation of our consolidated financial position as of March 31, 2015 and our consolidated results of operations for the three months ended March 31, 2014 and 2015. Our historical results are not necessarily indicative of the results to be expected in the future, and the results for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for the full year or any other period. You should read this data together with our financial statements and related notes, as well as the information under the captions "Selected Consolidated Financial Data" appearing in our 2014 Annual Report, which is incorporated by reference herein, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing in our 2014 Annual Report and our March 2015 Quarterly Report, which are incorporated by reference herein.

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands, except share and per share amounts)				
	(unaudited)				
<b>Consolidated Statements of Operations Data:</b>					
Collaboration revenue from a related party	\$	\$	\$ 7,300	\$	\$
Operating expenses:					
Research and development	17,055	17,937	30,710	6,685	10,088
General and administrative	3,148	4,366	8,288	1,812	4,146
Total operating expenses	20,203	22,303	38,998	8,497	14,234
Loss from operations	(20,203)	(22,303)	(31,698)	(8,497)	(14,234)
Interest and other income (expense), net	(51)	(38)	7	(9)	237
Interest expense		(9)	(153)	(33)	(38)
Loss before taxes	(20,254)	(22,350)	(31,844)	(8,539)	(14,035)
Provision for income taxes			31		
Net loss	\$ (20,254)	\$ (22,350)	\$ (31,875)	\$ (8,539)	\$ (14,035)
Net loss per share, basic and diluted(1)	\$ (27.99)	\$ (27.03)	\$ (4.96)	\$ (9.56)	\$ (0.57)
Weighted-average common shares used to compute net loss per share, basic and diluted(1)	723,607	826,757	6,426,022	893,542	24,655,011

(1)

For an explanation of the calculations of our basic and diluted net loss per share, see (a) Note 2 to our audited financial statements included in our 2014 Annual Report incorporated by reference

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herein and (b) Note 2 to our financial statements included in our March 2015 Quarterly Report incorporated by reference herein.

## As of March 31, 2015

Actual                      As Adjusted(1)(2)  
(in thousands)  
(unaudited)

**Balance Sheet Data:**

Cash and cash equivalents and investments	\$ 158,144	\$ 236,660
Working capital	112,494	191,010
Total assets	165,611	244,127
Bank term loan, current and non-current	1,940	1,940
Additional paid-in capital	237,550	316,063
Accumulated deficit	(96,684)	(96,684)
Total stockholders' equity	140,859	219,375

(1)

The as adjusted column in the summary consolidated balance sheet data above reflects the effect of the issuance and sale by us of 3,750,000 shares of our common stock in this offering, at an assumed public offering price of \$22.43 per share, which is the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2)

Each \$1.00 increase (decrease) in the assumed public offering price of \$22.43 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, would increase (decrease) each of cash and cash equivalents and investments, working capital, total assets and total stockholders' equity by approximately \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) each of cash and cash equivalents and investments, working capital, total assets and total stockholders' equity by approximately \$21.1 million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including the consolidated financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2014, or 2014 Annual Report, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, or March 2015 Quarterly Report, that are incorporated by reference into this prospectus before deciding whether to invest in shares of our common stock. The risks and uncertainties described below 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;

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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;

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 \$14.0 million and \$8.5 million for the three months ended March 31, 2015 and 2014, respectively. As of March 31, 2015, we had an accumulated deficit of \$96.7 million.



## Edgar Filing: Dermira, Inc. - Form S-1/A

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,

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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 March 31, 2015 and June 30, 2015, we had capital resources consisting of cash and cash equivalents and investments of \$158.1 million and \$143.8 million, respectively. 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.

We believe that the net proceeds from this offering and our existing cash and cash equivalents and investments, together with interest thereon, will be sufficient to fund our operations through 2017. 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 the net proceeds from this offering and our existing cash and cash equivalents and investments. We will need to raise additional capital following this offering to fund our operations and continue to support our planned research and development and commercialization activities. We have substantial contractual obligations to UCB. For more information about our collaboration with UCB, see "Business Collaborations and License Agreements Collaboration with UCB" in our 2014 Annual Report, which is incorporated by reference in this prospectus. 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;

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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.

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

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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

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.

***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.***

## Edgar Filing: Dermira, Inc. - Form S-1/A

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

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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;

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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.



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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

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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 and will use a different tool to measure our patient reported outcomes than that used as the primary endpoint in our Phase 2 program. 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 studies. 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. In addition, for DRM04, the results of our Phase 2a and Phase 2b clinical trials may not accurately predict results in our Phase 3 clinical trials that will have larger numbers of patients. Even for a drug such as Cimzia that has been approved for multiple indications, regulatory review processes are lengthy and uncertain.

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;



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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.

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

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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.***

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;

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;

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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;

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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.

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

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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. For more information about the competition we face, see "Business Competition" in our 2014 Annual Report, which is incorporated by reference in this prospectus.

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 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



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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 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 both tools, along with an objective measure, sweat production, to assess 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.

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*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, 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.

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;



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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.

***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 side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or

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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.



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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



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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. 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

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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 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

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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.

***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

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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;

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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;

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

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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.

***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.

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**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.

*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

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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 acquiror 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-



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based milestones, and therefore our principal strategic and financial objectives in pursuing this collaboration would not be achieved.

***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.

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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.

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

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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. 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

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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;

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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.

***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

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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.

**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



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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. Guggenhime; 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.

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



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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.

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.

***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;

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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.

***The terms of our credit facility place restrictions on our operating and financial flexibility and if we fail to comply with the covenants and other obligations under our credit facility, the lenders may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.***

At any time when we have the ability to obtain a term loan or we have outstanding borrowings under our loan and security agreement, as amended, with Square 1 Bank, we will be required to maintain certain deposit accounts with Square 1 Bank and we will be prohibited from engaging in significant business transactions without the prior consent of Square 1 Bank, including a change of control, the acquisition by us of another company, incurring additional indebtedness or engaging in new business activities other than those reasonably related or incidental to our current business activities. These restrictions could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders. As part of the credit facility, we granted to Square 1 Bank a first priority lien on all our assets other than our intellectual property, subject to certain limited exceptions. In addition, in the event of a default under this agreement, our repayment obligations may be accelerated in full and, in the event that we do not have sufficient capital to repay the amounts then owed, Square 1 Bank may foreclose on the assets securing our obligations under the credit facility. In addition, the terms of our loan and security agreement restrict our ability to pay dividends. Furthermore, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***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



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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;

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;

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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;

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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.

***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

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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.

***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

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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.

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.



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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.

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.

***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

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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

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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.

***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. For more information about these license arrangements, see "Business Collaborations and License Agreements" in our 2014 Annual Report, which is incorporated by reference in this prospectus.

***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.

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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.

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

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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 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.

***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

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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;

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;

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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 Securities and Exchange Commission, or the SEC, and

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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.

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.



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Since January 1, 2015 through August 3, 2015, the closing sale price of our common stock on The NASDAQ Global Select Market ranged from \$14.34 to \$24.91 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

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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.

***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

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price of our common stock. As of June 30, 2015, we had approximately 24.7 million shares of common stock outstanding.

As a result of the lock-up agreements described in "Shares Eligible for Future Sale" and "Underwriting," shares will be available for sale in the public market at various times as follows, subject to the provisions of Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act:

beginning on the date of this prospectus, all of the shares sold in this offering will be immediately available for sale in the public market without restriction;

11,829,918 shares will become eligible for sale in the public market beginning on the 91<sup>st</sup> day following the date of this prospectus pursuant to the lock-up agreements entered into in connection with this offering; provided, however, that Leerink Partners LLC may permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the end of the lock-up period; and

12,900,544 shares that are already issued and outstanding are immediately available for sale in the public market subject to securities laws and our insider trading policy.

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 "Shares Eligible for Future Sale" and "Underwriting." 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 promulgated 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.***

Upon completion of this offering, our directors and executive officers, together with their affiliates, will beneficially own, in the aggregate, approximately 17.0% of our outstanding common stock (assuming no exercise of the underwriters' option to purchase additional shares). 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.

See "Principal Stockholders" for more information regarding the ownership of our outstanding stock by our directors and executive officers, together with their affiliates, and holders of more than 5% of our common stock.

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***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;

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.



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***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 considerable discretion over the use of proceeds from this offering. We currently intend to use the net proceeds from this offering for external research and development expenses associated with the development of our Cimzia, DRM04 and DRM01 product candidates, with the balance primarily used to fund internal research and development expenses associated with all of our product candidates, working capital, capital expenditures and other general corporate purposes. In addition, a portion of the net proceeds may also be used to acquire or in-license, as applicable, 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 of \$14.86 per share as of March 31, 2015, at an assumed public offering price of \$22.43 per share, which is the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 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."

***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.

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**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," "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 in the "Risk Factors" 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 to conform these statements to actual results or revised expectations.

You should read this prospectus, the documents incorporated by reference herein, 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.

**INDUSTRY AND MARKET DATA**

Unless otherwise indicated, information contained in this prospectus and the documents incorporated by reference herein concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources, including independent industry publications. Any information in this prospectus attributed to GfK Custom Research, LLC, or GfK, is from GfK's 2007 Therapeutic Class Dynamics Physician Study in Acne © 2007 GfK Market Measures. Any information in this prospectus provided by IMS Health Incorporated, or IMS, is an estimate derived from the use of information under license from the following IMS Health Information services: IMS Health National Prescription Audit and National Sales Perspectives and IMS MIDAS. IMS expressly reserves all rights, including rights of copying, distribution and republication.

In presenting this information, we have also made assumptions based on such data and other similar sources, and on our knowledge of, and our experience to date in, the markets for our products. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications that is included in this prospectus and the documents incorporated by reference herein is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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**USE OF PROCEEDS**

We estimate that the net proceeds from our sale of 3,750,000 shares of our common stock in this offering, at an assumed public offering price of \$22.43 per share, which is the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$78.5 million. If the underwriters' option to purchase additional shares is exercised in full, we estimate that we will receive additional net proceeds of \$11.9 million. Each \$1.00 increase (decrease) in the assumed public offering price of \$22.43 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, would increase (decrease) the net proceeds to us from this offering by approximately \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$21.1 million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

As of June 30, 2015, we had \$143.8 million in cash and cash equivalents and investments. We currently intend to use the net proceeds we receive from this offering, together with our existing cash and cash equivalents and investments, as follows:

approximately \$40.0 million to fund external research and development expenses associated with the development of our Cimzia product candidate, net of development milestone payments we expect to receive from our partner UCB Pharma S.A.;

approximately \$30.0 million to fund external research and development expenses associated with the development of our DRM04 product candidate;

approximately \$45.0 million to fund external research and development expenses associated with the development of our DRM01 product candidate; and

the balance used to fund internal research and development expenses associated with all 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.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and investments, will be sufficient to meet our anticipated cash requirements through 2017, including for the completion of and topline results from our Phase 2b clinical trial for DRM01, our Phase 3 clinical program for DRM04 and our Phase 3 clinical program for Cimzia. This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We cannot specify with certainty all of the particular uses of the net proceeds that we will receive from this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures will depend on numerous factors, including the ongoing status of and results from clinical trials and other studies, as well as any strategic collaborations that we may enter into with third parties for our product candidates, any in-licensing transactions or acquisitions, any unforeseen cash needs and the performance of our investments.

We will have broad discretion over the uses of the net proceeds of this offering 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**PRICE RANGE OF COMMON STOCK**

Our common stock has been publicly traded on The NASDAQ Global Select Market under the symbol "DERM" since October 3, 2014. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sale prices per share for our common stock on The NASDAQ Global Select Market for the periods indicated:

	<b>High</b>	<b>Low</b>
<b>2014</b>		
Fourth Quarter (beginning October 3, 2014)	\$ 22.94	\$ 12.68
<b>2015</b>		
First Quarter	\$ 21.27	\$ 14.57
Second Quarter	\$ 18.01	\$ 14.20
Third Quarter (through August 3, 2015)	\$ 25.24	\$ 17.50

On August 3, 2015, the last reported sale price of our common stock on The NASDAQ Global Select Market was \$22.43 per share. As of June 30, 2015, we had approximately 38 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Table of Contents**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and investments and capitalization as of March 31, 2015:

on an actual basis; and

on an as adjusted basis to reflect the issuance and sale by us of 3,750,000 shares of our common stock in this offering, assuming the underwriters' option to purchase additional shares is not exercised, at an assumed public offering price of \$22.43 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our consolidated financial statements and related notes and the information under the captions "Selected Consolidated Financial Data" appearing in our 2014 Annual Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations," appearing in our 2014 Annual Report, and our March 2015 Quarterly Report, which are incorporated by reference in this prospectus.

	As of March 31, 2015	
	Actual (in thousands, except share and per share data)	As Adjusted(1)
	(unaudited)	
Cash and cash equivalents and investments	\$ 158,144	\$ 236,660
Bank term loan, current and non-current	1,940	1,940
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized, actual and as adjusted; no shares issued and outstanding, actual and as adjusted		
Common stock, \$0.001 par value per share; 500,000,000 shares authorized, actual and as adjusted; 24,670,911 shares issued and outstanding, actual; 28,420,911 shares issued and outstanding, as adjusted	25	28
Additional paid-in capital	237,550	316,063
Accumulated other comprehensive loss	(32)	(32)
Accumulated deficit	(96,684)	(96,684)
Total stockholders' equity	140,859	219,375
Total capitalization	\$ 142,799	\$ 221,315

(1)

Each \$1.00 increase (decrease) in the assumed public offering price of \$22.43 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, would increase (decrease) each of cash and cash equivalents and investments, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) each of cash and cash equivalents and investments, additional paid-in capital, total stockholders' equity and total capitalization by approximately

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\$21.1 million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted

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information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of common stock to be outstanding after this offering is based on 24,670,911 shares of common stock outstanding as of March 31, 2015 and excludes the following:

3,446,904 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 March 31, 2015 with a weighted-average exercise price of \$7.23 per share; and

2,140,459 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 1,592,449 shares of common stock reserved for issuance under the 2014 Equity Incentive Plan as of March 31, 2015 and (2) 548,010 shares of common stock reserved for issuance under the 2014 Employee Stock Purchase Plan as of March 31, 2015.

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 pro forma as adjusted net tangible book value per share of our common stock immediately after our public offering.

As of March 31, 2015, our net tangible book value was \$136.6 million, or \$5.54 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 March 31, 2015 would be \$215.1 million, or \$7.57 per share of common stock. As adjusted net tangible book value per share reflects the sale by us of 3,750,000 shares of our common stock in this offering, assuming the underwriters' option to purchase additional shares is not exercised, at an assumed public offering price of \$22.43 per share, which was the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This represents an immediate increase in as adjusted net tangible book value of \$2.03 per share to existing stockholders and immediate dilution of \$14.86 per share to new investors purchasing shares in the offering.

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

Assumed public offering price per share		\$22.43
Net tangible book value per share as of March 31, 2015, before giving effect to this offering	\$	5.54
Increase in as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering		2.03
As adjusted net tangible book value per share, after giving effect to this offering		7.57
Dilution per share to investors purchasing shares in this offering		\$14.86

Each \$1.00 increase (decrease) in the assumed public offering price of \$22.43 per share, the last reported sale price of our common stock on The NASDAQ Global Select Market on August 3, 2015, would increase (decrease) our as adjusted net tangible book value, after giving effect to this offering, by approximately \$3.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) the dilution to investors purchasing shares in this offering by approximately \$21.1 million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional shares in full, our as adjusted net tangible book value per share, after giving effect to this offering, would be \$7.83 per share, and the dilution in net tangible book value per share to investors purchasing shares in this offering would be \$14.60 per share.

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The number of shares of common stock to be outstanding after this offering is based on 24,670,911 shares of common stock outstanding as of March 31, 2015 and excludes the following:

3,446,904 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 March 31, 2015 with a weighted-average exercise price of \$7.23 per share; and

2,140,459 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 1,592,449 shares of common stock reserved for issuance under the 2014 Equity Incentive Plan as of March 31, 2015 and (2) 548,010 shares of common stock reserved for issuance under the 2014 Employee Stock Purchase Plan as of March 31, 2015.

Table of Contents**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

The following is a summary of transactions since January 1, 2012 to which we have been or will be a participant, in which the amount involved in the transaction exceeds or will exceed \$120,000 and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest, other than compensation arrangements that are described under the section of our 2015 Definitive Proxy Statement on Schedule 14A, or 2015 Proxy, captioned "Proposal No. 1 Election of Directors Director Compensation" and "Executive Compensation," which are incorporated by reference in this prospectus.

**Participation in Our Initial Public Offering**

Certain of our principal stockholders purchased shares of our common stock from the underwriters in our initial public offering at the initial public offering price, including entities affiliated with Bay City Capital, New Enterprise Associates 13, Limited Partnership and Canaan VIII L.P., for the number of shares and in the aggregate amounts set forth in the table below. The terms of these purchases were the same for all purchasers of our common stock in our initial public offering. Please refer to the section titled "Principal Stockholders" for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Common Stock	Total Purchase Price
Entities affiliated with Bay City Capital(1)	69,112	\$ 1,105,792
New Enterprise Associates 13, Limited Partnership(2)	69,112	1,105,792
Canaan VIII L.P.(3)	49,276	788,416

- (1) Consists of shares purchased by Bay City Capital Fund V, L.P. and Bay City Capital Fund V Co-Investment Fund, L.P. Fred B. Craves, a member of our board of directors, is a managing director of Bay City Capital.
- (2) Jake R. Nunn, a member of our board of directors, is a partner of New Enterprise Associates.
- (3) Wende S. Hutton, a member of our board of directors, is a member and manager of Canaan Partners VIII LLC, the general partner of Canaan VIII L.P.

**Series C Convertible Preferred Stock Financing**

In August 2014, we sold an aggregate of 5,297,041 shares of our Series C convertible preferred stock at a purchase price of \$9.628 per share for an aggregate purchase price of approximately \$51.0 million. Each share of our Series C convertible preferred stock converted automatically into one share of our common stock at the completion of our initial public offering in October 2014.

The purchasers of our Series C convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of Capital Stock Registration Rights." The following table summarizes the Series C convertible preferred stock purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock. The terms of these

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purchases were the same for all purchasers of our Series C convertible preferred stock. Please refer to the section titled "Principal Stockholders" for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series C Convertible Preferred Stock	Total Purchase Price
Entities affiliated with Fidelity Investments	1,038,636	\$ 9,999,999
UCB S.A.(1)	778,977	7,500,000
Entities affiliated with Bay City Capital(2)	382,840	3,685,992
New Enterprise Associates 13, Limited Partnership(3)	382,840	3,685,992
Canaan VIII L.P.(4)	272,955	2,628,014
Wiggans Living Trust dated 5/14/02(5)	25,965	249,999

- (1) Mark D. McDade, a member of our board of directors, is Executive Vice President, Chief Operating Officer of UCB Pharma S.A.
- (2) Consists of shares purchased by Bay City Capital Fund V, L.P. and Bay City Capital Fund V Co-Investment Fund, L.P. Fred B. Craves, a member of our board of directors, is a managing director of Bay City Capital.
- (3) Jake R. Nunn, a member of our board of directors, is a partner of New Enterprise Associates.
- (4) Wende S. Hutton, a member of our board of directors, is a manager of Canaan Partners VIII LLC, the general partner of Canaan VIII L.P.
- (5) Thomas G. Wiggans is a co-trustee of the Wiggans Living Trust dated 5/14/02. Mr. Wiggans is our Chief Executive Officer and Chairman of the Board.

**Series B Convertible Preferred Stock Financing**

In two closings in March 2013 and April 2014, we sold an aggregate of 3,561,040 shares of our Series B convertible preferred stock at a purchase price of \$8.4245 per share for an aggregate purchase price of approximately \$30.0 million. Each share of our Series B convertible preferred stock converted automatically into one share of our common stock at the completion of our initial public offering in October 2014.

The purchasers of our Series B convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of Capital Stock Registration Rights." The following table summarizes the Series B convertible preferred stock purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock. The terms of these



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purchases were the same for all purchasers of our Series B convertible preferred stock. Please refer to the section titled "Principal Stockholders" for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series B Convertible Preferred Stock	Total Purchase Price
New Enterprise Associates 13, Limited Partnership(1)	655,321	\$ 5,520,754
Entities affiliated with Bay City Capital(2)	655,320	5,520,755
UCB S.A.(3)	593,507	5,000,000
Canaan VIII L.P.(4)	469,878	3,958,492

- (1) Jake R. Nunn, a member of our board of directors, is a partner of New Enterprise Associates.
- (2) Consists of shares purchased by Bay City Capital Fund V, L.P. and Bay City Capital Fund V Co-Investment Fund, L.P. Fred B. Craves, a member of our board of directors, is a managing director of Bay City Capital.
- (3) Mark D. McDade, a member of our board of directors, is Executive Vice President, Chief Operating Officer of UCB Pharma S.A.
- (4) Wende S. Hutton, a member of our board of directors, is a manager of Canaan Partners VIII LLC, the general partner of Canaan VIII L.P.

**Series A Convertible Preferred Stock Financing**

In two closings in August 2011 and August 2012, we sold an aggregate of 6,572,625 shares of our Series A convertible preferred stock for an aggregate purchase price of approximately \$34.0 million, consisting of (1) 5,792,619 shares purchased in cash for a price of \$5.365 per share and (2) 780,006 shares purchased pursuant to the conversion of secured convertible promissory notes at a price of \$3.7555 per share, a 30% discount on the cash price per share of the Series A convertible preferred stock. Each share of our Series A convertible preferred stock converted automatically into one share of our common stock at the completion of our initial public offering in October 2014.

The purchasers of our Series A convertible preferred stock are entitled to specified registration rights. For additional information, see "Description of Capital Stock Registration Rights." The following table summarizes the Series A convertible preferred stock purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock. Other than with respect to the discounted price per share for shares purchased upon conversion of promissory notes, as set forth in the preceding paragraph, the terms of these purchases were the same for all purchasers of our

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Series A convertible preferred stock. Please refer to the section titled "Principal Stockholders" for more details regarding the shares held by these entities.

Name of Stockholder	Shares of Series A Convertible Preferred Stock	Total Purchase Price
Entities affiliated with New Enterprise Associates(1)	2,382,135	\$ 12,218,181
Entities affiliated with Bay City Capital(2)	2,382,135	12,218,181
Canaan VIII L.P.(3)	1,708,040	9,163,636
Thomas G. Wiggans(4)	82,043	330,616
Eugene A. Bauer(5)	18,272	76,123

- (1) Consists of (a) 2,029,243 shares purchased by New Enterprise Associates 13, Limited Partnership for cash, (b) 349,165 shares purchased by New Enterprise Associates 13, Limited Partnership upon conversion of a convertible promissory note and (c) 3,727 shares purchased by NEA Ventures 2011, Limited Partnership for cash. Jake R. Nunn, a member of our board of directors, is a partner of New Enterprise Associates.
- (2) Consists of (a) 1,994,954 shares purchased by Bay City Capital Fund V, L.P. for cash, (b) 342,636 shares purchased by Bay City Capital Fund V, L.P. upon conversion of convertible promissory notes, (c) 38,016 shares purchased by Bay City Capital Fund V Co-Investment Fund, L.P. for cash and (d) 6,529 shares purchased by Bay City Capital Fund V Co-Investment Fund, L.P. upon conversion of convertible promissory notes. Fred B. Craves, a member of our board of directors, is a managing director of Bay City Capital.
- (3) Consists of 1,708,040 shares purchased for cash. Wende S. Hutton, a member of our board of directors, is a manager of Canaan Partners VIII LLC, the general partner of Canaan VIII L.P.
- (4) Consists of (a) 13,979 shares purchased by Thomas G. Wiggans for cash and (b) 68,064 shares purchased by Mr. Wiggans upon conversion of a convertible promissory note. Mr. Wiggans is our Chief Executive Officer and Chairman of the Board.
- (5) Consists of (a) 4,660 shares purchased by Eugene A. Bauer for cash and (b) 13,612 shares purchased by Dr. Bauer upon conversion of a convertible promissory note. Dr. Bauer is our Chief Medical Officer and is a member of our board of directors.

**Transactions with UCB**

In March 2014, we entered into a development and commercialization agreement with UCB Pharma S.A., or UCB, pursuant to which we will develop Cimzia in order for UCB to seek regulatory approval from the U.S. Food and Drug Administration, the European Medicines Agency and the Canadian federal department for health for the treatment of psoriasis, and upon the grant of regulatory approval in the United States and Canada, for us to promote sales of Cimzia to dermatologists and conduct related medical affairs activities in the United States and Canada. For more information regarding this agreement, see "Business Collaborations and License Agreements Collaboration with UCB" appearing in our 2014 Annual Report, which is incorporated by reference in this prospectus.

In April 2014, UCB S.A., an affiliate of UCB Pharma S.A., purchased 593,507 shares of our Series B convertible preferred stock for an aggregate purchase price of approximately \$5.0 million. In August 2014, UCB S.A. purchased 778,977 shares of our Series C convertible preferred stock for an aggregate purchase price of approximately \$7.5 million.

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In September 2014, we entered into a purchase agreement pursuant to which UCB S.A. purchased from us in a private placement 468,750 shares of our common stock with an aggregate purchase price of \$7.5 million, at a price per share of \$16.00, which is equal to the price per share at which we sold shares of common stock in our initial public offering. The sale of these shares to UCB S.A. was not registered in our initial public offering. UCB S.A. agreed to enter into the purchase agreement providing for the concurrent private placement pursuant to the terms of the UCB Agreement.

Mark D. McDade, a member of our board of directors, is Executive Vice President, Chief Operating Officer of UCB. Pursuant to the UCB Agreement, UCB is entitled to designate one member of our board of directors, currently Mr. McDade, and we have agreed not to remove the UCB designee from our board of directors prior to, and to re-nominate the UCB designee for election to our board of directors at, each annual meeting of stockholders taking place prior to the earliest of the date that (1) Dermira has terminated the UCB Agreement for certain breaches of UCB, (2) UCB has terminated the UCB Agreement for certain breaches of Dermira, (3) UCB ceases to own 50% of the shares of Dermira that it has purchased directly from Dermira, (4) Dermira consummates a change of control, (5) specified time periods after the termination of the UCB Agreement, other than termination for a breach, have lapsed and (6) the later of the date on which (a) all valid claims under a patent relevant to the UCB Agreement have expired or the last unexpired valid claim of this patent is declared invalid and (b) the net sales of Cimzia to dermatologists in a calendar year during the term of the UCB Agreement are less than a specified percentage of the net sales of Cimzia to dermatologists in any prior calendar year during the term of the UCB Agreement.

**Amended and Restated Investors' Rights Agreement**

In connection with our sale of Series C convertible preferred stock in August 2014, we entered into an amended and restated investors' rights agreement with certain holders of our common stock and holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. These stockholders are entitled to rights with respect to the registration of their shares under the Securities Act. For a description of these registration rights, see "Description of Capital Stock Registration Rights."

**Indemnity Agreements**

We have entered into indemnity agreements with each of our directors and executive officers. The indemnity agreements, our restated certificate of incorporation and our restated bylaws require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and officers. For more information regarding these agreements, see "Executive Compensation Limitations on Liability and Indemnification Matters" appearing in our 2015 Proxy, which is incorporated by reference in this prospectus.

**Review, Approval or Ratification of Transactions with Related Parties**

Our board of directors has adopted a written related-party transactions policy. Under this policy, the audit committee reviews transactions that may be "related-person transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of the policy, a related person is a person who is, or at any time since the beginning of the our last fiscal year was, a director, executive officer or nominee for director; a beneficial owner of greater than 5% of our common stock; or a member of the immediate family of any of the foregoing. Our related-party transactions policy sets forth the procedures for the identification, review, consideration and approval of related-party transactions.

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**PRINCIPAL STOCKHOLDERS**

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of June 30, 2015, by:

each stockholder, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our common stock;

each of our directors;

each of our named executive officers; and

all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Applicable percentage ownership is based on 24,730,462 shares of common stock issued and outstanding as of June 30, 2015. For purposes of computing the applicable percentage of shares beneficially owned by a person after this offering in the table below, we have given effect to the 3,750,000 shares of common stock to be issued by us in the offering. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of June 30, 2015. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each of the individuals and

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entities that beneficially owns 5% or more of our common stock listed in the table below is c/o Dermira, Inc., 275 Middlefield Road, Suite 150, Menlo Park, CA 94025.

Name of Beneficial Owner	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned After this Offering	
	Number	Percentage	Number	Percentage
<b>5% Stockholders</b>				
Entities affiliated with New Enterprise Associates(1)	3,506,649	14.2%	3,506,649	12.3%
Entities affiliated with Bay City Capital(2)	3,506,647	14.2	3,506,647	12.3
Entities affiliated with Fidelity(3)	3,236,136	13.1	3,236,136	11.4
Canaan VIII L.P.(4)	2,500,149	10.1	2,500,149	8.8
UCB S.A.(5)	1,841,234	7.4	1,841,234	6.5
<b>Directors and Named Executive Officers</b>				
<b>Executive Officers</b>				
Thomas G. Wiggans(6)	695,075	2.8	695,075	2.4
Eugene A. Bauer(7)	334,259	1.3	334,259	1.2
Andrew Guggenlime(8)	57,960	*	57,960	*
Luis C. Peña(9)	165,393	*	165,393	*
<b>Directors</b>				
David E. Cohen(10)	60,774	*	60,774	*
Fred B. Craves(2)	3,506,647	14.2	3,506,647	12.3
Matthew K. Fust(11)	16,344	*	16,344	*
Wende S. Hutton(12)		*		*
Mark D. McDade(13)	7,758	*	7,758	*
Jake R. Nunn(14)		*		*
William R. Ringo(15)	8,404	*	8,404	*
All executive officers and directors as a group (12 persons)(16)	5,020,809	19.5	5,020,809	17.0

\* Represents beneficial ownership of less than one percent.

(1) Consists of (a) 3,502,922 shares held by New Enterprise Associates 13, L.P. (NEA 13) and (b) 3,727 shares held by NEA Ventures 2011, L.P. (NEA Ventures 2011). The shares held by NEA 13 are indirectly held by NEA Partners 13, L.P. (NEA Partners 13), its sole general partner, NEA 13 GP, LTD (NEA 13 LTD), the sole general partner of NEA Partners 13, and each of the individual directors of NEA 13 LTD. The individual directors of NEA 13 LTD are M. James Barrett, Peter J. Barris, Forest Baskett, Patrick J. Kerins, Krishna "Kittu" Kolluri, David M. Mott, Scott D. Sandell, Ravi Viswanathan and Harry R. Weller, which we refer to collectively as the NEA 13 Directors. The shares held by NEA Ventures 2011 are indirectly held by Karen P. Welsh, the general partner of NEA Ventures 2011. NEA Partners 13, NEA 13 LTD and the NEA 13 Directors share voting and investment power over the shares held by NEA 13. Karen P. Welsh has sole voting and investment power over the shares held by NEA Ventures 2011. The address of NEA 13 is 1954 Greenspring Drive, Suite 600, Timonium, MD 21093.

(2) Consists of (a) 3,441,075 shares held by Bay City Capital Fund V, L.P. (BCC Fund V) and (b) 65,572 shares held by Bay City Capital Fund V Co-Investment Fund, L.P. (BCCCI). Bay City Capital Management V LLC (BCCMV) is the general partner of BCC Fund V and BCCCI and has sole voting and investment power over the shares held by BCC Fund V and BCCCI. Bay City Capital LLC (BCC LLC) is the manager of BCCMV, and thus has sole voting and investment power over the shares held by BCC Fund V and BCCCI. Fred B. Craves and Carl Goldfischer are the Managing Directors of BCC LLC and share such powers. Fred B. Craves, a member of our

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board of directors, is a Managing Director of Bay City Capital and therefore may be deemed to share voting and investment power over these entities. The address for the entities affiliated with Bay City Capital is 750 Battery Street Suite 400, San Francisco, CA 94111.

- (3) Based on information contained in a Schedule 13G/A filed with the SEC by FMR LLC on February 13, 2015. Consists of (a) 3,236,136 shares beneficially owned by FMR LLC, of which 2,041,105 shares are beneficially owned by Select Biotechnology Portfolio. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Edward C. Johnson 3d is a Director and the Chairman of FMR LLC and Abigail P. Johnson is a Director, the Vice Chairman and the President of FMR LLC. Members of the family of Edward C. Johnson 3d, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company, a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, MA 02210.
- (4) Canaan Partners VIII LLC is the general partner of Canaan VIII L.P. and may be deemed to have sole investment and voting power over the shares held by Canaan VIII L.P. through its control of such entity. Brenton K. Ahrens, John V. Balen, Stephen M. Bloch, Wende S. Hutton, Maha Ibrahim, Deepak Kamra, Guy M. Russo and Eric A. Young are the managing members of Canaan Partners VIII LLC. Investment and voting decisions with respect to the shares held by Canaan VIII L.P. are made by the managers of Canaan Partners VIII LLC, collectively. No manager of Canaan Partners VIII LLC has beneficial ownership of any shares held by Canaan VIII L.P. The address for Canaan VIII L.P. is 285 Riverside Avenue, Suite 250, Westport, CT 06880.
- (5) The address for UCB S.A. is Allée de la Recherche 60, B-1070, Brussels, Belgium.
- (6) Consists of (a) 1,259 shares of common stock held directly by Mr. Wiggans, (b) 263,180 shares of stock held by the Wiggans Living Trust dated 5/14/02, of which Mr. Wiggans is a co-trustee, (c) 8,620 shares of common stock held by the Amanda Wiggans Irrevocable Gifting Trust dated 2/24/11, with respect to which Mr. Wiggans has no voting or dispositive power, (d) 8,620 shares of common stock held by the Elizabeth Wiggans Irrevocable Gifting Trust dated 2/24/11, with respect to which Mr. Wiggans has no voting or dispositive power, and (e) 413,396 shares of common stock issuable to Mr. Wiggans pursuant to options exercisable within 60 days of June 30, 2015.
- (7) Consists of (a) 844 shares of common stock held directly by Dr. Bauer, (b) 104,478 shares of common stock held in the Bauer Family 1995 Trust dated June 15, 1995, of which Dr. Bauer is a co-trustee, and (c) 228,937 shares of common stock issuable to Dr. Bauer pursuant to options exercisable within 60 days of June 30, 2015.
- (8) Consists of (a) 1,551 shares of common stock held directly by Mr. Guggenhime, and (b) 56,409 shares of common stock issuable to Mr. Guggenhime pursuant to options exercisable within 60 days of June 30, 2015.

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- (9) Consists of (a) 1,551 shares of common stock held directly by Mr. Peña, and (b) 163,842 shares of common stock issuable to Mr. Peña pursuant to options exercisable within 60 days of June 30, 2015.
- (10) Consists of (a) 34,482 shares of common stock held directly by Dr. Cohen and (b) 26,292 shares of common stock issuable to Dr. Cohen pursuant to options exercisable within 60 days of June 30, 2015.
- (11) Consists of (a) 6,000 shares of common stock held directly by Mr. Fust and (b) 10,344 shares of common stock issuable to Mr. Fust pursuant to an option exercisable within 60 days of June 30, 2015.
- (12) Ms. Hutton is a member and manager of Canaan Partners VIII LLC, the general partner of Canaan VIII L.P. Ms. Hutton does not have voting or investment power over any of the shares directly held by Canaan VIII L.P. referenced in footnote (4) above. Ms. Hutton's business address is 2765 Sand Hill Road, Menlo Park, CA 94025.
- (13) Consists of shares of common stock issuable to Mr. McDade pursuant to an option exercisable within 60 days of June 30, 2015. Mr. McDade is an employee of UCB S.A. but does not have voting or investment power over any of the shares held by UCB S.A. referenced in footnote (5) above. Mr. McDade's business address is Allée de la Recherche 60, B-1070, Brussels, Belgium.
- (14) Mr. Nunn is a partner of New Enterprise Associates. Mr. Nunn does not have voting or investment power over any of the shares directly held by NEA 13 or NEA Ventures 2011 referenced in footnote (2) above. Mr. Nunn's business address is 2855 Sand Hill Road, Menlo Park, CA 94025.
- (15) Consists of shares of common stock issuable to Mr. Ringo pursuant to an option exercisable within 60 days of June 30, 2015.
- (16) Consists of (a) 3,990,937 shares of issued and outstanding stock held by our directors and named executive officers or their affiliates and (b) 1,029,872 shares of common stock issuable to our directors and executive officers as a group pursuant to options exercisable within 60 days of June 30, 2015

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**DESCRIPTION OF CAPITAL STOCK**

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 forms a part, and to the applicable provisions of Delaware law.

**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 2014 Annual Report, 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 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



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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 have no current plan to issue any shares of preferred stock.

**Stock Options**

As of March 31, 2015, we had outstanding options to purchase an aggregate of 3,446,904 shares of our common stock issuable upon the exercise of outstanding options under our 2010 Equity Incentive Plan and 2014 Equity Incentive Plan, with a weighted-average exercise price of \$7.23 per share.

**Registration Rights**

As of March 31, 2015, holders of an aggregate of no more than 15,689,324 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. Immediately following this offering, there will be no change to the number of registrable securities outstanding. 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

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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***

In connection with this offering, holders of our registrable securities were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their registrable securities in this offering. If we register any of our securities for public sale in another offering, 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.

**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

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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<sup>2</sup>/<sub>3</sub>% 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 2015 Proxy, which is incorporated by reference in this prospectus.

***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

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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 15<sup>th</sup> Avenue, Brooklyn, New York 11219, and its telephone number is (800) 937-5449.

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**SHARES ELIGIBLE FOR FUTURE SALE**

We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of our common stock, including shares issued upon exercise of outstanding options, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

Upon the closing of this offering, based on the number of shares outstanding as of June 30, 2015, we will have a total of 28,480,462 shares of our common stock outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercises of outstanding stock options after June 30, 2015. Of these outstanding shares, all of the 3,750,000 shares of common stock sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, except that any shares purchased in this offering by our affiliates, as that term is defined in Rule 144 promulgated under the Securities Act, could only be sold in compliance with the Rule 144 limitations described below.

The remaining outstanding shares of our common stock will be deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, all of our directors and officers, together with their affiliates, have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 90 days following the date of this prospectus, as described below. As a result of these agreements and the provisions of our amended and restated investors' rights agreement described above under "Description of Capital Stock Registration Rights," subject to the provisions of Rule 144 or Rule 701, shares will be available for sale in the public market as follows:

beginning on the date of this prospectus, all of the shares sold in this offering will be immediately available for sale in the public market without restriction;

11,829,918 shares will become eligible for sale in the public market beginning on the 91<sup>st</sup> day following the date of this prospectus pursuant to the lock-up agreements entered into in connection with this offering; provided, however, that Leerink Partners LLC may permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the end of the lock-up period; and

12,900,544 shares that are already issued and outstanding are immediately available for sale in the public market subject to securities laws and our insider trading policy.

**Lock-Up Agreements**

All of our directors and officers, together with their affiliates, are subject to lock-up agreements that, subject to exceptions described in the section entitled "Underwriting" below, prohibit them from offering for sale, selling, contracting to sell, granting any option for the sale of, transferring or otherwise disposing of any shares of our common stock, options to acquire shares of our common stock or any security or instrument related to our common stock, or entering into any swap, hedge or other arrangement that transfers any of the economic consequences of ownership of our common stock, for a period of 90 days following the date of this prospectus, without the prior written consent of Leerink Partners LLC. These agreements are subject to certain exceptions. See "Underwriting."

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**Rule 144**

In general, under Rule 144 as currently in effect, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up and market standoff agreements described above, within any three-month period, a number of shares that does not exceed the greater of:

1% of the number of shares of our common stock then outstanding, which will equal approximately 284,805 shares immediately after this offering; or

the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

**Rule 701**

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701.

**Equity Incentive Plans and Employee Stock Purchase Plan**

We have filed with the SEC registration statements on Form S-8 under the Securities Act covering the shares of common stock that we may issue (1) upon exercise of outstanding options under the 2010 Equity Incentive Plan and upon exercise of outstanding options under the 2014 Equity Incentive Plan, or 2014 Plan, (2) pursuant to any future awards issued under the 2014 Plan, and (3) pursuant to issuances under the 2014 Employee Stock Purchase Plan. Such registration statements were filed and became effective on October 2, 2014 and March 25, 2015. Accordingly, 5,634,000 shares of common stock were registered under such registration statements are available for sale in the open market, subject to Rule 144 volume limitations for affiliates and the lock-up agreements described above, if applicable.

**Registration Rights**

As of March 31, 2015, the holders of an aggregate of no more than 15,689,324 shares of our common stock will be entitled to demand, piggyback and Form S-3 registration rights. Immediately following this offering, there will be no change to the number of registrable securities outstanding. Registration of the sale of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. For further description of these rights, see "Description of Capital Stock Registration Rights."

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**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK**

This section summarizes the material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of our common stock by "non-U.S. holders" (as defined below) pursuant to this offering. This summary does not provide a complete analysis of all potential U.S. federal income tax considerations relating thereto. The information provided below is based upon provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions currently in effect. These authorities may change at any time, possibly retroactively, or the Internal Revenue Service, or IRS, might interpret the existing authorities differently. In either case, the tax considerations of the acquisition, ownership and disposition of our common stock could differ from those described below. As a result, we cannot assure you that the tax consequences described in this discussion will not be challenged by the IRS or will be sustained by a court if challenged by the IRS.

This summary does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal generation-skipping, gift and estate tax laws, except to the limited extent provided below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including:

banks, insurance companies or other financial institutions;

partnerships or entities or arrangements treated as partnerships or other pass-through entities for U.S. federal tax purposes (or investors in such entities);

corporations that accumulate earnings to avoid U.S. federal income tax;

persons subject to the alternative minimum tax or medicare contribution tax;

tax-exempt organizations or tax-qualified retirement plans;

real estate investment trusts or regulated investment companies;

controlled foreign corporations or passive foreign investment companies;

persons who acquired our common stock as compensation for services;

dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);

certain former citizens or long-term residents of the United States;

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persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction;

persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes); or

persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes is a beneficial owner of our common stock, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. Accordingly, this summary does not address tax consideration



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applicable to partnerships that hold our common stock. Partnerships and partners in such partnerships should consult their tax advisors.

**INVESTORS CONSIDERING THE PURCHASE OF OUR COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF FOREIGN, GENERATION-SKIPPING, GIFT, ESTATE, STATE OR LOCAL TAX LAWS, AND TAX TREATIES.**

**Non-U.S. Holder Defined**

For purposes of this summary, a "non-U.S. holder" is any holder of our common stock, other than a partnership, that is not:

an individual who is a citizen or resident of the United States;

a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state therein or the District of Columbia;

a trust if it (1) is subject to the primary supervision of a U.S. court and one of more U.S. persons have authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person; or

an estate whose income is subject to U.S. income tax regardless of source.

If you are a non-U.S. citizen individual, you may, in many cases, be deemed to be a resident alien, as opposed to a nonresident alien, by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For these purposes, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year are counted. Resident aliens are subject to U.S. federal income tax as if they were U.S. citizens. Such an individual is urged to consult his or her own tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock.

**Dividends**

We do not expect to declare or make any distributions on our common stock in the foreseeable future and the terms of our credit facility currently restrict our ability to pay dividends. If we do pay dividends on shares of our common stock, however, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder's adjusted tax basis in shares of our common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of our common stock. See " Sale of Common Stock."

Any dividend paid to a non-U.S. holder on our common stock that is not effectively connected with a non-U.S. holder's conduct of a trade or business in the United States will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might not apply, however, or might apply at a reduced rate, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence. You should consult your tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for us or our paying agent to withhold tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing a Form W-8BEN or

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Form W-8BEN-E (or any successor form) or any other appropriate Form W-8 or appropriate substitute form to us or our paying agent. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. For payments made to a partnership or other pass-through entity, the certification requirements generally apply to the partners or other owners rather than to the partnership or other entity, and the partnership or other entity must provide the partners' or other owners' documentation to us or our paying agent. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, and if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, are attributable to a permanent establishment maintained by the non-U.S. holder in the United States, are not subject to U.S. withholding tax. To obtain this exemption, a non-U.S. holder must provide us or our paying agent with a Form W-8ECI properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition to being taxed at graduated tax rates, dividends received by corporate non-U.S. holders that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable tax treaty.

For additional withholding rules that may apply to dividends paid to certain foreign entities, see the discussion below under the heading "Foreign Account Tax Compliance Act."

**Sale of Common Stock**

Subject to the discussion below regarding the Foreign Account Tax Compliance Act, non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other disposition of our common stock unless:

the gain (1) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (2) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment (or, in certain cases involving individual holders, a fixed base) maintained by the non-U.S. holder in the United States (in which case the special rules described below apply);

the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States); or

the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA, treat the gain as effectively connected with a U.S. trade or business.

The FIRPTA rules may apply to a sale, exchange or other disposition of our common stock if we are, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a "U.S. real property holding corporation," or USRPHC. In general, we would be a USRPHC if interests in U.S. real estate comprised at least half of the value of our business assets. We do not believe that we are a USRPHC and we do not anticipate becoming one in the future. Even

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if we become a USRPHC, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if beneficially owned by a non-U.S. holder that actually or constructively owned more than 5% of our outstanding common stock at some time within the five-year period preceding the disposition.

If any gain from the sale, exchange or other disposition of our common stock, (1) is effectively connected with a U.S. trade or business conducted by a non-U.S. holder and (2) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment (or, in certain cases involving individuals, a fixed base) maintained by such non-U.S. holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject also to a "branch profits tax." The branch profits tax rate is 30%, although an applicable income tax treaty between the United States and the non-U.S. holder's country of residence might provide for a lower rate.

**Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder the entire amount of a distribution on our common stock (whether or not the distribution represents a dividend or is subject to U.S. federal withholding tax) and the tax withheld, if any. Copies of these reports may be made available to tax authorities in the country where the non-U.S. holder resides.

The information reporting and backup withholding rules that apply to payments of dividends to certain U.S. shareholders of our common stock generally will not apply to dividends paid to a non-U.S. holder so long as the non-U.S. holder certifies its foreign status or otherwise establishes an exemption (and we or our paying agent do not have actual knowledge or reason to know the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied).

Under the Treasury regulations, the payment of proceeds from the disposition of shares of our common stock by a non-U.S. holder made to or through a U.S. office of a broker generally will be subject to information reporting and backup withholding unless the beneficial owner certifies, under penalties of perjury, among other things, its status as a non-U.S. holder (and the broker does not have actual knowledge or reason to know the holder is a U.S. person) or otherwise establishes an exemption. The payment of proceeds from the disposition of shares of our common stock by a non-U.S. holder made to or through a non-U.S. office of a broker generally will not be subject to backup withholding and information reporting, except as noted below. Information reporting, but not backup withholding, will apply to a payment of proceeds, even if that payment is made outside of the United States, if you sell our common stock through a non-U.S. office of a broker that is:

a U.S. person (including a foreign branch or office of such person);

a "controlled foreign corporation" for U.S. federal income tax purposes;

a foreign person 50% or more of whose gross income from certain periods is effectively connected with a U.S. trade or business; or

a foreign partnership if at any time during its tax year (a) one or more of its partners are U.S. persons who, in the aggregate, hold more than 50% of the income or capital interests of the partnership or (b) the foreign partnership is engaged in a U.S. trade or business;

unless the broker has documentary evidence that the beneficial owner is a non-U.S. holder and certain other conditions are satisfied, or the beneficial owner otherwise establishes an exemption (and the broker has no actual knowledge or reason to know to the contrary).

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Backup withholding is not an additional tax. Any amounts withheld from a payment to a holder of common stock under the backup withholding rules can be credited against any U.S. federal income tax liability of the holder and may entitle the holder to a refund, provided that the required information is furnished to the IRS in a timely manner.

**Foreign Account Tax Compliance Act**

The Foreign Account Tax Compliance Act, or FATCA, imposes a U.S. federal withholding tax of 30% on certain "withholdable payments" (including U.S. source dividends and the gross proceeds from the sale or other disposition of U.S. stock) to foreign financial institutions (as specifically defined for this purpose) and other non-U.S. entities that fail to comply with certain certification and information reporting requirements. The obligation to withhold under FATCA currently applies to, among other items, dividends on our common stock and will apply to gross proceeds from the disposition of our common stock paid after December 31, 2016. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing these withholding and reporting requirements may be subject to different rules. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules.

**U.S. Federal Estate Tax**

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent, unless an applicable estate tax treaty between the United States and the decedent's country of residence provides otherwise.

**THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.**

Table of Contents**UNDERWRITING**

Leerink Partners LLC, Cowen and Company, LLC and Guggenheim Securities, LLC are acting as representatives of each of the underwriters named below and as joint bookrunning managers for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<b>Underwriter</b>	<b>Number of Shares</b>
Leerink Partners LLC	
Cowen and Company, LLC	
Guggenheim Securities, LLC	
Needham & Company, LLC	
<b>Total</b>	<b>3,750,000</b>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of the shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Commissions and Discounts**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. After the initial offering of the shares, the public offering price, concession or any other term of the offering may be changed by the representatives.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares of our common stock.

	<b>Per Share</b>	<b>Total</b>	
		<b>Without Option</b>	<b>With Option</b>
Public offering price	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$550,000. We also have agreed to

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reimburse the underwriters for up to \$30,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

**Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 562,500 additional shares at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

**No Sales of Similar Securities**

We and our executive officers and directors, together with their affiliates, have agreed not to sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock, for 90 days after the date of this prospectus without first obtaining the written consent of Leerink Partners LLC and Cowen and Company, LLC in the case of us, and Leerink Partners LLC in the case of our executive officers and directors, together with their affiliates, on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to offer, sell, contract to sell, pledge or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise)), directly or indirectly, including the filing (or participation in the filing) of a registration statement with the SEC in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder with respect to any shares of our common stock or any securities convertible into, or exercisable or exchangeable for our common stock.

**NASDAQ Global Select Market Listing**

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

**Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option described above. The underwriters may close out any covered short position by either exercising their option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors

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who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the closing of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on The NASDAQ Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

The underwriters may also engage in passive market making transactions in our common stock on The NASDAQ Global Select Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

**Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

**Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

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**Selling Restrictions**

***Notice to Prospective Investors in the European Economic Area***

In relation to each Member State of the European Economic Area (each, a Relevant Member State), no offer of shares may be made to the public in that Relevant Member State other than:

to any legal entity which is a qualified investor as defined in the Prospectus Directive;

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or

in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and each of our and the representatives' and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly, any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the company nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression "an offer to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.



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***Notice to Prospective Investors in the United Kingdom***

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (1) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (2) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a "relevant person"). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

***Notice to Prospective Investors in France***

Neither this prospectus nor any other offering material relating to the shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares has been or will be:

released, issued, distributed or caused to be released, issued or distributed to the public in France; or

used in connection with any offer for subscription or sale of the shares to the public in France.

Such offers, sales and distributions will be made in France only:

to qualified investors (*investisseurs qualifiés*) or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;

to investment services providers authorized to engage in portfolio management on behalf of third parties; or

in a transaction that, in accordance with article L.411-2-II-1<sup>o</sup>-or-2<sup>o</sup>-or 3<sup>o</sup> of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).

The shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

***Notice to Prospective Investors in Hong Kong***

The shares may not be offered or sold in Hong Kong by means of any document other than (1) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), (2) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (3) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning

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of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

***Notice to Prospective Investors in Japan***

The shares offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (1) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (2) in compliance with any other applicable requirements of Japanese law.

***Notice to Prospective Investors in Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (2) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA, or (3) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;

where no consideration is or will be given for the transfer; or

where the transfer is by operation of law.

***Notice to Prospective Investors in Australia***

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or the Corporations Act) in relation to the common stock has been or will be lodged with

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the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

you confirm and warrant that you are either:

a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;

a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;

a person associated with the company under section 708(12) of the Corporations Act; or

a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and

you warrant and agree that you will not offer any of the common stock for resale in Australia within 12 months of that common stock being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

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**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 0.17% of our outstanding shares of capital stock as of March 31, 2015. Certain legal matters relating to this offering will be passed upon for the underwriters by Cooley LLP, San Francisco, California.

**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 have filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, 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 registration statement and the exhibits filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement 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. A copy of the registration statement and the exhibits filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, NE, Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from that office. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is [www.sec.gov](http://www.sec.gov).

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**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).

our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 25, 2015;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 12, 2015;

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; and

our Current Report on Form 8-K, filed with the SEC on June 16, 2015.

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 web site 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).

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.

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**3,750,000 SHARES OF COMMON STOCK**

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**Leerink Partners**

**Cowen and Company**

**Guggenheim Securities**

**Needham & Company**

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee:

	Amount Paid or to be Paid
SEC registration fee	\$ 11,359
FINRA filing fee	15,163
Printing and engraving expenses	70,000
Legal fees and expenses	266,000
Accounting fees and expenses	100,000
Transfer agent and registrar fees and expenses	5,000
Miscellaneous expenses	82,478
Total	\$ 550,000

**Item 14. Indemnification of Directors and Officers.**

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.

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;

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;

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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.

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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. Reference is also made to Section 8 of the underwriting agreement to be filed as Exhibit 1.1 to this registration statement, which provides for the indemnification of executive officers, directors and controlling persons of the Registrant against certain liabilities. 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.

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:

Exhibit Document	Number
Form of Underwriting Agreement	1.1
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
Form of Indemnity Agreement	10.1

**Item 15. Recent Sales of Unregistered Securities.**

Since July 25, 2012 and through August 3, 2015, the Registrant has issued and sold the following securities:

1. Since July 25, 2012 and through October 2, 2014, the Registrant has granted to its directors, officers, employees and consultants options to purchase 836,460 shares of common stock under its 2010 Equity Incentive Plan with per share exercise prices ranging from \$1.218 to \$5.51, and has issued 9,051 shares of common stock upon exercise of such options. These transactions were exempt from the registration requirements of the Securities Act in reliance upon Section 4(2) of the Securities Act or Rule 701 promulgated under the Securities Act.
2. In August 2012, the Registrant sold an aggregate of 2,255,357 shares of its Series A convertible preferred stock at a purchase price of \$5.365 per share for an aggregate purchase price of approximately \$12.1 million to six purchasers, each of whom represented to the Registrant that it was a sophisticated accredited investor or a qualified institutional buyer. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(2) of the Securities Act or Regulation D promulgated under the Securities Act.
3. In March 2013 and April 2014, the Registrant sold an aggregate of 3,561,040 shares of its Series B convertible preferred stock at a purchase price of \$8.4245 per share for an aggregate purchase price of approximately \$30.0 million to six purchasers, each of whom represented to the Registrant that it was a sophisticated accredited investor or a qualified institutional buyer. This transaction was exempt from the registration requirements of the Securities Act in

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reliance upon Section 4(2) of the Securities Act or Regulation D promulgated under the Securities Act.

4. In December 2013, the Registrant issued a warrant to purchase up to an aggregate of 17,805 shares of its Series B convertible preferred stock to a lender of the Registrant with an exercise price of \$8.4245 per share. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(2) of the Securities Act.
5. In August 2014, the Registrant sold an aggregate of 5,297,041 shares of its Series C convertible preferred stock at a purchase price of \$9.628 per share for an aggregate purchase price of approximately \$51.0 million to 15 purchasers, each of whom represented to the Registrant that it was a sophisticated accredited investor or a qualified institutional buyer. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(2) of the Securities Act or Regulation D promulgated under the Securities Act.
6. In October 2014, concurrently with the Registrant's initial public offering, the Registrant sold an aggregate of 468,750 shares of its common stock at a purchase price of \$16.00 per share for an aggregate purchase price of \$7.5 million to one purchaser, who represented to the Registrant that it was not a U.S. person as defined in Rule 902(k) of Regulation S promulgated under the Securities Act. This transaction was exempt from the registration requirements of the Securities Act in reliance upon Regulation S promulgated under the Securities Act.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering, and the Registrant believes each transaction was exempt from the registration requirements of the Securities Act as stated above. All recipients of the foregoing transactions either received adequate information about the Registrant or had access, through their relationships with the Registrant, to such information. Furthermore, the Registrant affixed appropriate legends to the share certificates and instruments issued in each foregoing transaction setting forth that the securities had not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits and Financial Statement Schedules.**

**(a) Exhibits.**

Exhibit Number	Description of Document	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
1.1	Form of Underwriting Agreement.					X
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	
5.1	Opinion of Fenwick & West LLP.					X
10.1	Form of Indemnity Agreement.	S-1	333-198410	10.1	9/19/2014	

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Exhibit Number	Description of Document	Incorporated by Reference			Filed Herewith
		Form	File No.	Filing Date	
10.2	2010 Equity Incentive Plan and forms of award agreements.	S-1	333-198410	10.2	8/27/2014
10.3	2014 Equity Incentive Plan and forms of stock option award agreement, stock option exercise agreement, restricted stock agreement, stock appreciation right award agreement, restricted stock unit award agreement, performance shares award agreement and stock bonus agreement.	10-Q	001-36668	10.3	11/12/2014
10.4	2014 Employee Stock Purchase Plan and form of subscription agreement.	10-Q	001-36668	10.4	11/12/2014
10.5	Amended and Restated Employment Agreement, dated August 4, 2011, by and between the Registrant and Thomas G. Wiggans.	S-1	333-198410	10.5	8/27/2014
10.6	Offer Letter, accepted and agreed to April 24, 2014, by and between the Registrant and Andrew L. Guggenhime.	10-K	001-36668	10.6	3/25/2015
10.7	Offer Letter, accepted and agreed to July 17, 2012, by and between the Registrant and Luis C. Peña.	S-1	333-198410	10.7	8/27/2014
10.8	Development and Commercialisation Agreement, dated March 21, 2014, by and between the Registrant and UCB Pharma S.A.	S-1	333-198410	10.9	9/29/2014
10.9	Exclusive License Agreement, dated April 26, 2013, by and between the Registrant and Rose U LLC.	S-1	333-198410	10.10	9/29/2014
10.10	Loan and Security Agreement, dated December 11, 2013, as amended, by and between the Registrant and Square 1 Bank.	10-K	001-36668	10.10	3/25/2015
10.11	Right of First Negotiation Agreement, dated March 28, 2013, by and between the Registrant and Maruho Co., Ltd.	S-1	333-198410	10.12	9/29/2014
10.12	Lease Agreement, dated July 24, 2014, as amended, by and between the Registrant and Middlefield Park.	S-1	333-198410	10.13	9/12/2014
10.13	Form of Severance and Change in Control Agreement.	S-1	333-198410	10.14	9/12/2014
21.1	Subsidiaries of the Registrant.	10-K	001-36668	21.1	3/25/2015

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Exhibit Number	Description of Document	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
23.1	Consent of independent registered public accounting firm.					X
23.2	Consent of Fenwick & West LLP (included in Exhibit 5.1).					X
24.1	Power of Attorney.	S-1	333-205907	24.1	7/28/2015	

Portions of this exhibit, which have been granted confidential treatment by the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 406 promulgated under the Securities Act, have been omitted.

#### **(b) Financial Statement Schedule.**

No financial statement schedules are provided because the information called for is not required or is shown either in the consolidated financial statements or notes.

#### **Item 17. Undertakings.**

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act 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 SEC 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.

The undersigned Registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus 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.



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<b>Signature</b>	<b>Title</b>	<b>Date</b>
* _____ Mark D. McDade	Director	August 4, 2015
* _____ Jake R. Nunn	Director	August 4, 2015
* _____ William R. Ringo	Director	August 4, 2015
*By: /s/ ANDREW L. GUGGENHIME _____ Andrew L. Guggenhime	Attorney-in-fact	August 4, 2015

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