Dermira, Inc.
Form 10-K
March 04, 2016

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2015

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-36668

DERMIRA, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**27-3267680**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

275 Middlefield Road, Suite 150
Menlo Park, CA 94025
(Address of principal executive offices) (Zip Code)

(650) 421-7200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on which Registered**

Common Stock, par value $0.001 per share	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ý

As of June 30, 2015, the last business day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the Registrant was approximately $201,830,581 (based on a closing price of $17.55 per share as reported by The NASDAQ Global Select Market on June 30, 2015). For purposes of this calculation, shares of common stock beneficially owned by the registrant's officers and directors as of June 30, 2015 and shares of common stock held by persons who held more than 10% of the outstanding common stock of the registrant as of June 30, 2015 (based solely upon Schedule 13G filings made with the SEC) have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The Registrant has no non-voting common equity.

As of February 29, 2016, the number of outstanding shares of the Registrant's common stock, par value $0.001 per share, was 29,972,845.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the Registrant's definitive Proxy Statement to be filed in connection with the Registrant's 2016 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K where indicated. The Proxy Statement will be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2015. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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

We have registered the trademark "Dermira" in Australia, Canada, the European Union, Japan, Switzerland and the United States, and have trademark applications for the trademark "Dermira" pending in Canada, the European Union, Japan, Mexico, South Korea and the United States. The Dermira logo and all product names are our common law trademarks. All other service marks, trademarks and tradenames appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and tradenames referred to in this Annual Report on Form 10-K 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections titled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements. All statements contained in this Annual Report on Form 10-K 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 within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases you can identify these statements by forward-looking words, such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "potential," "seek," "expect," "goal" or the negative or plural of these words or similar expressions.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. 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 forward-looking events and circumstances discussed in this report 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. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Such forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Except as may be required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

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PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or 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.

Since our founding in 2010, we have executed three transactions resulting in our portfolio of product candidates. In August 2011, we acquired Valocor Therapeutics, Inc., which gave us rights to a portfolio of intellectual property and product candidates to treat acne and inflammatory skin diseases. In April 2013, we entered into agreements with Rose U LLC and Stiefel Laboratories, Inc., a GSK company, to obtain rights to intellectual property related to DRM04 for the treatment of hyperhidrosis. In March 2014, we entered into an agreement to collaborate with UCB to develop and commercialize Cimzia in dermatology.

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 chronic 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 chronic plaque psoriasis in December 2014. We completed enrollment in the three clinical trials comprising the Phase 3 program in September 2015, November 2015 and December 2015 and expect to announce topline results from these trials by the end of the first quarter of 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

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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 hyperhidrosis in July 2015. We completed enrollment in the two pivotal clinical trials comprising the Phase 3 program in February 2016 and expect to announce topline results from these trials in the second quarter 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 completed enrollment in the clinical trial comprising this Phase 2b program in January 2016 and expect to announce topline results from this trial in the second quarter of 2016.

Our Strategy

Our strategy is to in-license, acquire, develop and commercialize innovative and differentiated therapies that we believe can advance the standard of care for patients with dermatologic diseases. 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.

In-license and acquire new product candidates and, potentially, commercial-stage products. Since our founding in 2010, we have executed three transactions resulting in our portfolio of 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.

Efficiently establish proof-of-concept for early-stage product candidates and advance promising candidates into late-stage development. In developing 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 such 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

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and enhances our likelihood of successfully developing and commercializing our product candidates.

Build specialized medical affairs and sales and marketing organizations of highly experienced professionals who can effectively communicate the science behind our programs and 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 specialized medical affairs and sales and marketing organizations focused solely on dermatologists and their patients. To effectively communicate the science behind our programs and commercialize any approved products we may successfully develop or acquire, we intend to build specialized, separate medical affairs and sales and marketing organizations 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.

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.

Our Product Candidates

Our portfolio of product candidates is summarized in the following figure:

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Cimzia

Overview

Cimzia is our late-stage product candidate for the treatment of moderate-to-severe chronic plaque psoriasis. Cimzia is an injectable biologic TNF inhibitor that was launched by UCB in 2008 and has been used in tens of thousands of patients. It is approved for numerous indications spanning multiple medical specialties in multiple countries, including the United States. In 2015, Cimzia generated worldwide sales of €1.1 billion, an increase of 36% compared to 2014. In March 2014, we entered into an agreement to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval for marketing of the psoriasis indication, to market Cimzia to dermatologists in the United States and Canada.

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. Approximately 80% of psoriasis patients have plaque psoriasis, and approximately 20% of plaque psoriasis patients have moderate-to-severe disease. The symptoms of psoriasis are not limited to the skin, and there is increasing evidence to suggest that skin symptoms of psoriasis are a dermal manifestation of a systemic autoimmune disorder. As a result, there is growing interest in treating psoriasis patients with products that can address both the skin and other potential systemic manifestations of the autoimmune disorder.

The treatment of moderate-to-severe plaque psoriasis has been transformed by the introduction of biologic TNF inhibitors. TNF is a naturally occurring molecule that promotes inflammation in the body. In psoriasis and many other inflammatory diseases, such as rheumatoid arthritis and psoriatic arthritis, TNF promotes inflammation in certain areas of the body that leads to clinical manifestations of the disease, such as excessive growth of skin cells in psoriasis, damage to joint tissue in rheumatoid arthritis and both of these manifestations in psoriatic arthritis. Consistent with its role in a number of inflammatory conditions that involve organs other than the skin, it is thought that TNF may play a role in comorbidities of psoriasis that are associated with inflammatory etiology, such as joint disease and cardiovascular disease. TNF inhibitors treat psoriasis and other inflammatory conditions by binding to and suppressing the biological activity of TNF. In psoriasis and many other inflammatory diseases, TNF inhibitors offer improved efficacy over traditional systemic therapies that have more frequent side effects and require more intensive monitoring. 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 2015 data provided by IMS Health National Prescription Audit, or IMS NPA, among U.S. dermatologists, prescriptions for TNF inhibitors accounted for approximately 80% of total biologic prescriptions.

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 2013, according to Decision Resources, only 10.3% of treated moderate-to-severe psoriasis patients received biologics, and 22.4% 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 with the established safety record of TNF inhibitors, and as new biologic products reach the market. Decision Resources

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projects that U.S. sales of branded, systemic psoriasis therapies will increase from approximately $3.9 billion in 2013 to $5.8 billion by 2023.

Based on the results of two Phase 2 clinical trials conducted by UCB and our end-of-Phase 2 meeting with the FDA, we and UCB commenced a Phase 3 clinical program for Cimzia in moderate-to-severe chronic plaque psoriasis in December 2014. We completed enrollment in the three clinical trials comprising the Phase 3 program in September 2015, November 2015 and December 2015 and expect to announce topline results from these trials by the end of the first quarter of 2017. If the results of the Phase 3 clinical trials are positive, we plan to work with UCB to secure approval of Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis and market the product to dermatologists in the United States and Canada.

Clinical Development

Phase 2 Clinical Trials. In addition to a number of studies in other indications, UCB conducted two Phase 2 clinical trials evaluating Cimzia in adults with moderate-to-severe chronic plaque psoriasis. The first Phase 2 clinical trial demonstrated that Cimzia improved the signs and symptoms of psoriasis, with up to 82.8% of patients achieving an improvement of at least 75% in the clinical grading scale called the Psoriasis Area and Severity Index, or PASI 75 response, the endpoint most widely used to measure treatment success in clinical psoriasis trials. The second Phase 2 clinical trial demonstrated that patients who relapsed after withdrawal of Cimzia therapy achieved a similar response after subsequent treatment with Cimzia.

The first Phase 2 clinical trial was a multi-center, double-blind, placebo-controlled study in which 176 patients were randomized to receive 12 weeks of therapy in accordance with one of three regimens: (1) an initial loading dose of 400 milligrams, or mg, of Cimzia, followed by Cimzia at a dose of 200 mg once every two weeks, or q2w, or Cimzia 200 mg; (2) Cimzia at a dose of 400 mg q2w, or Cimzia 400 mg; or (3) placebo. At the end of the 12-week treatment period, patients entered a follow-up period of 12 to 24 weeks. The co-primary efficacy endpoints were the proportion of patients achieving a PASI 75 response and the proportion of patients achieving a score representing "clear" or "almost clear" skin, as assessed by the investigator on a six-point scale called the Physician's Global Assessment, or PGA, 12 weeks after the start of therapy.

As shown in the charts below, both Cimzia dosing regimens demonstrated meaningful and statistically significant improvements relative to placebo for both co-primary efficacy endpoints.

Primary Endpoint: PASI 75 at Week 12

Primary Endpoint: PGA at Week 12

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* $P < 0.001$ vs. placebo. P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is

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determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

Adapted from Reich K et al. Br J Dermatol. 2012; 167(1): 180-90. Intention to treat (ITT) population shown = all randomized patients (n=176).

The second Phase 2 clinical trial was a re-treatment extension study, in which patients who achieved a PASI 75 response 12 weeks after the start of therapy in the first Phase 2 clinical trial and subsequently relapsed during the follow-up period began receiving the same treatment as they did in the first Phase 2 clinical trial. Relapse was defined as a loss of more than 50% of the maximum PASI improvement achieved in the first Phase 2 clinical trial. The primary efficacy endpoint was a comparison between the median PASI score achieved 12 weeks after the start of therapy in the first Phase 2 clinical trial and the median PASI score achieved 12 weeks after the start of re-treatment in the second Phase 2 clinical trial. At the end of the 12-week re-treatment period, improvements in PASI score were once again observed for both Cimzia treatment regimens. No significant difference was observed between the median PASI score achieved 12 weeks after the start of therapy in the first Phase 2 clinical trial and the median PASI score achieved 12 weeks after the start of re-treatment in the second Phase 2 clinical trial. The authors of the study publication reported that efficacy observed in the second Phase 2 clinical trial was similar to that observed during the first Phase 2 clinical trial. Efficacy results are presented below.

Adapted from Reich K et al. Br J Dermatol. 2012; 167(1): 180-90. Actual values taken from UCB (Study C87040 CSR 2008. Table 14.2.2:7).

Further, the authors who published the clinical trial results in the British Journal of Dermatology reported that the safety profile of Cimzia in these Phase 2 clinical trials in psoriasis was consistent with that observed in previous Cimzia clinical trials in other indications, as well as in clinical trials of other TNF inhibitors. Most adverse events were mild or moderate. In the first Phase 2 clinical trial, which was placebo-controlled, no meaningful differences in the incidence of treatment-emergent adverse events, or TEAEs, were observed among treatment groups. The most frequently reported TEAEs were nasal congestion, headache and itching. Excluding pregnancies reported as serious adverse events

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leading to permanent discontinuation of treatment in two patients receiving Cimzia 400 mg, serious adverse events were reported in six patients, including (1) one patient who received placebo and experienced hemorrhagic diarrhea, (2) two patients who received Cimzia 200 mg, comprising one who experienced a contusion related to a motor vehicle accident and one who experienced a urinary tract infection and gastroenteritis, and (3) three patients who received Cimzia 400 mg, comprising one who experienced disseminated tuberculosis, one with anxiety and gastroenteritis and one with psoriasis. The patient who developed tuberculosis had previously received an attenuated, live tuberculosis vaccine and had good resolution of tuberculosis following treatment with anti-tuberculosis medication. In the second Phase 2 clinical trial, a lower proportion of patients reported TEAEs in comparison to the first Phase 2 clinical trial, and there were no serious adverse events or permanent discontinuations from treatment due to adverse events.

Phase 3 Clinical Program. Based on the results of these two Phase 2 clinical trials, we and UCB conducted an end-of-Phase 2 meeting with the FDA and a scientific advice procedure with the European Medicines Agency, or the EMA, in June 2014 during which we requested and received feedback from the FDA and EMA regarding certain elements of our proposed clinical development plan for Cimzia in psoriasis, including the design and size of Phase 3 clinical trials. As the Phase 2 psoriasis clinical trials were conducted in France and Germany, they were not covered by a U.S. investigational new drug application, or IND. UCB filed an IND for the treatment of moderate-to-severe chronic plaque psoriasis with the FDA in September 2014, and we and UCB initiated our Phase 3 clinical program in December 2014.

Our Phase 3 clinical program consists of three randomized, multi-center, blinded Phase 3 clinical trials that are being conducted in multiple countries. In these trials, we have completed enrollment of 1,020 moderate-to-severe chronic plaque psoriasis patients, including patients who had and patients who had not previously been treated with biologic products, such as TNF inhibitors. The program comprises two clinical trials named CIMPASI-1 and CIMPASI-2 that are designed to demonstrate the superiority of treatment with Cimzia relative to placebo and one clinical trial named CIMPACT that is designed to demonstrate the superiority of treatment with Cimzia relative to placebo and relative to treatment with Enbrel, a biologic TNF inhibitor that is widely used to treat moderate-to-severe plaque psoriasis.

CIMPASI-1 and CIMPASI-2 Trials. CIMPASI-1 completed enrollment of 234 patients in November 215 and CIMPASI-2 completed enrollment of 227 patients in September 2015. In each trial, patients were randomized to receive one of three regimens for at least 16 weeks: (1) Cimzia at a dose of 400 mg at the beginning of treatment, two weeks later and four weeks later, which we call a loading dose of Cimzia, followed by Cimzia at a dose of 200 mg q2w for 12 weeks; (2) Cimzia at a dose of 400 mg q2w for 16 weeks; or (3) placebo. In each trial, the co-primary efficacy endpoints are the proportion of patients achieving a PASI 75 response 16 weeks after the start of treatment and the proportion of patients achieving an improvement on a five-point PGA scale from an initial score of three, representing moderate disease, or four, representing severe disease, to a final score of zero, representing "clear," or one, representing "almost clear," 16 weeks after the start of treatment. Following the initial 16-week period, patients are assigned to receive the same or different regimens for up to an additional 32 weeks in order to assess secondary endpoints and other measures pertaining to the safety and efficacy of longer-term treatment, including maintenance therapy. Thereafter, some patients will receive Cimzia on an open-label basis for up to an additional 96 weeks in order to gather additional data on the long-term use of Cimzia in moderate-to-severe chronic plaque psoriasis.

CIMPACT Trial. CIMPACT completed enrollment of 559 patients in December 2015. In the trial, patients were randomized to receive one of four regimens for at least 12 weeks: (1) a loading dose of Cimzia, followed by Cimzia at a dose of 200 mg q2w for 8 weeks; (2) Cimzia at a dose of 400 mg q2w for 12 weeks; (3) placebo; or (4) Enbrel at a dose of 50 mg twice weekly for 12 weeks, which is the recommended initial dose in the U.S. prescribing information. In this

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trial, the primary efficacy endpoint is the proportion of patients achieving a PASI 75 response 12 weeks after the start of treatment. Following the initial 12-week period, patients are assigned to receive the same or different regimens for up to an additional 36 weeks in order to assess secondary endpoints and other measures pertaining to the safety and efficacy of longer-term treatment, including evaluation of the optimal regimen for maintenance therapy, as well as the effect of Cimzia treatment in patients who were initially treated with Enbrel. Thereafter, some patients will receive Cimzia on an open-label basis for up to an additional 96 weeks in order to gather additional data on the long-term use of Cimzia in moderate-to-severe chronic plaque psoriasis.

We and UCB anticipate that marketing applications for Cimzia in adults with moderate-to-severe chronic plaque psoriasis in the United States and European Union will be based on the results of the primary endpoints at either 12 or 16 weeks, as applicable, with additional data collected through week 48 to provide further support for dosing recommendations. While any marketing approval will be based on the overall results of the trials, we expect that marketing approval for Cimzia in moderate-to-severe chronic plaque psoriasis in the United States and European Union will require that each of the CIMPASI trials (CIMPASI-1 and CIMPASI-2) demonstrates that Cimzia produces a statistically significant improvement relative to placebo in each of its co-primary endpoints. In addition, we expect that European Union approval for Cimzia in moderate-to-severe chronic plaque psoriasis will require that the CIMPACT trial demonstrates that Cimzia produces a statistically significant improvement relative to placebo and to Enbrel in the proportion of patients achieving a PASI 75 response 12 weeks after the start of treatment. We believe that if these results are positive, data on 48 weeks of treatment would be sufficient to support an initial marketing application for the treatment of a chronic disease such as moderate-to-severe chronic plaque psoriasis.

We expect to announce topline results from these Phase 3 clinical trials by the end of the first quarter of 2017. If the results of the Phase 3 clinical trials are positive, we plan to work with UCB to secure approval of Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis and market the product to dermatologists in the United States and Canada.

DRM04

Overview

DRM04 is our late-stage product candidate for the treatment of hyperhidrosis, or excessive sweating. DRM04, a topical formulation of a novel form of a small-molecule anticholinergic agent that has been approved for systemic administration in other indications, is designed to inhibit sweat production by blocking the interaction between acetylcholine and the cholinergic receptors responsible for sweat gland activation.

Hyperhidrosis is a condition of sweating beyond what is physiologically required to maintain normal thermal regulation. Sweat is produced by glands in the skin and released to the skin surface through ducts. Sweat gland activity is controlled by the nervous system. The nervous system transmits signals to the sweat glands through acetylcholine, which is known as a neurotransmitter. 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, and approximately one-third of axillary hyperhidrosis sufferers, or 1.3 million Americans, have severe disease that is barely tolerable and frequently interferes or is intolerable and always interferes with daily activities.

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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. In addition, patients may suffer from excessive sweating for years before seeking treatment. One study analyzing data from 1993-2005 indicated that patients experienced an average duration of untreated symptoms of 8.9 years. We believe that this is largely a 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 430,000 prescriptions in the United States in 2015. 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. Therapeutic options for patients who are unsatisfied with topical antiperspirants are largely limited to more cumbersome or invasive strategies directed to blocking the activation of, destroying or removing the sweat glands by injectable, systemic, surgical or other means. These treatment options, which include injectable botulinum toxin, or Botox, and off-label use of oral anticholinergic agents, are used much less frequently than topical therapies.

Based on the results of our Phase 2 program described below and an 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 hyperhidrosis in July 2015. We completed enrollment in the two pivotal clinical trials comprising the Phase 3 program in February 2016 and expect to announce topline results from these trials in the second quarter of 2016. Subject to the successful completion of all three trials comprising the DRM04 Phase 3 program and other registration-enabling activities, we expect to submit a new drug application, or NDA, to the FDA in the second half of 2017.

Clinical Development

Our initial target indication for DRM04 is primary axillary hyperhidrosis. Our Phase 2 program comprised three randomized, double-blind, vehicle-controlled clinical trials conducted in 341 patients with primary axillary hyperhidrosis and was designed to accomplish three primary objectives in a stepwise fashion. First, a 38-patient Phase 2a clinical trial was conducted to establish proof of concept for the treatment of hyperhidrosis with a topical formulation of the anticholinergic agent that has been approved for systemic administration in other indications, which we call the topical formulation of the reference agent. Second, we conducted a 198-patient, multi-center, dose-ranging Phase 2b clinical trial to establish the profile of the topical formulation of the reference agent across a range of doses. Finally, we conducted a 105-patient, multi-center Phase 2b clinical trial to gain clinical experience with DRM04, the proprietary product containing a novel form of the reference agent that we intend to advance into Phase 3 development, and validate the psychometric properties of the Axillary Sweating Daily Diary, or ASDD, a new proprietary patient-reported outcome, or PRO, instrument, as a potential additional measure of disease severity. We conducted both Phase 2b clinical trials under an IND that was originally filed by Stiefel and that we reactivated in November 2013.

All three Phase 2 clinical trials demonstrated significant reductions in the signs and symptoms of primary axillary hyperhidrosis in patients treated with the topical formulation of the reference agent. The second Phase 2b study, completed in January 2015, also demonstrated significant reductions in the signs and symptoms of primary axillary hyperhidrosis in patients treated with DRM04.

We intend to develop DRM04 under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the 505(b)(2) pathway. Under the 505(b)(2) pathway, the FDA may allow us to leverage findings made by the FDA with regard to safety in approving the systemic administration of the

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reference agent in other indications and thereby reduce the amount of additional data we need to generate to support marketing approval of DRM04. The degree to which we can leverage such findings will be dependent upon the similarity between DRM04 in hyperhidrosis and the reference agent in its approved dosage forms and indications. Key differences, such as chemical form, route of administration, dosage form and indication, may affect the amount of additional data we will be required to generate.

Phase 2a Clinical Trial. The completed Phase 2a clinical trial was a randomized, double-blind study in 38 patients with severe, primary axillary hyperhidrosis. In six cohorts of six or seven patients each, two concentrations of the reference agent (2% and 4%) in each of two topical formulations were compared with their respective vehicles, which contain no active ingredient. Based on the positive results of this trial, we selected the formulation for further development and commenced our Phase 2b clinical program.

Phase 2b Clinical Program. Our Phase 2b clinical program comprised two randomized, multi-center, double-blind, vehicle-controlled clinical trials in 303 patients with primary axillary hyperhidrosis:

Study DRM04-HH01, a dose-ranging study assessing the safety, efficacy and pharmacokinetics of the topical formulation of the reference agent in comparison with vehicle only in 198 patients; and

Study DRM04-HH02, a study assessing the safety, efficacy and pharmacokinetics of DRM04, the topical formulation of the reference agent and vehicle only in 105 patients.

All study product administered in these two Phase 2b clinical trials contained the same vehicle, regardless of whether patients received the topical formulation of the reference agent, DRM04, or vehicle only.

Study DRM04-HH01. In Study DRM04-HH01, 198 patients with severe, primary axillary hyperhidrosis were randomized to receive a topical formulation containing one of four concentrations of the reference agent (1%, 2%, 3% or 4%) or vehicle only. Patients were instructed to apply the study product to each axilla once daily for four weeks using wipes containing either drug product or vehicle only, and efficacy was evaluated based on axillary sweat production and disease severity. Disease severity was measured using a widely-used patient outcome assessment tool called the Hyperhidrosis Disease Severity Scale, or HDSS, wherein patients rate the severity of their disease on a four-point scale. Patients who rate the severity of their disease as a three or a four on the HDSS are considered to have severe disease, while those who rate it as a one or a two are considered to have mild or moderate disease. Assessments were conducted approximately weekly during the four-week treatment period and the two-week period after the end of this treatment period. All 198 patients enrolled in the clinical trial rated the severity of their disease as a three or a four on the four-point HDSS prior to the start of treatment. Trial inclusion criteria required that prior to the start of treatment, all patients produce at least 50 mg of sweat in each axilla over a five-minute period.

The two primary efficacy endpoints evaluated in this trial were (1) the proportion of patients achieving an improvement of at least two points from baseline in HDSS score and (2) the average absolute change from baseline in sweat production, each as measured at the end of the four-week treatment period. In addition, we conducted several non-primary efficacy analyses, including an evaluation of the average percent change from baseline in sweat production at the end of the four-week treatment period. For the purpose of the primary endpoint pertaining to sweat production, sweat production was assessed in each patient as the average of the amounts of sweat produced in each axilla during a five-minute period.

As outlined below, the topical formulation of the reference agent demonstrated dose-dependent and, at certain doses, statistically significant improvements relative to vehicle in both primary efficacy

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endpoints. The following chart summarizes the impact of the reference agent on disease severity, assessed as the proportion of patients achieving an improvement of at least two points in HDSS score from baseline to the end of the four-week treatment period. Based on these results, patients treated with the reference agent were between 63% and 133% more likely, depending on the concentration of the reference agent they received, to achieve an improvement of at least two points in HDSS score than patients who received the vehicle only.

Primary Endpoint: HDSS Response Rate at Week Four

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P < 0.05 vs. placebo. P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

ITT population shown = all randomized patients dispensed study product (n = 198). Patients with missing data points were considered non-responders.

The following charts summarize the impact of the reference agent on sweat production, assessed as (1) the average absolute change in sweat production from baseline to the end of the four-week

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treatment period and (2) the average percent change in sweat production from baseline to the end of the four-week treatment period.

Primary Endpoint: Absolute Change in Sweat Production at Week Four	Non-Primary Analysis: Percent Change in Sweat Production at Week Four

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P < 0.01 vs. placebo. P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

ITT population shown = all randomized patients dispensed study product (n = 198). The last available on-treatment observation was used to estimate missing data points.

In this trial, the most common adverse events were dry mouth, upper respiratory tract infection, dry skin and blurred vision. Dry mouth, dry skin and blurred vision are well-known, reversible side effects of anticholinergic agents and were generally observed more frequently in patients who received higher concentrations of the reference agent. Upper respiratory tract infections were observed at similar frequencies in patients receiving the reference agent and patients receiving the vehicle only. Patients treated with the reference agent withdrew from the study due to adverse events at rates of 2.6% (1/38) in the 1% cohort, 5.0% (2/40) in the 2% cohort, 2.5% (1/40) in the 3% cohort and 20.0% (8/40) in the 4% cohort. None of the patients who received the vehicle only withdrew due to an adverse event. No treatment-related serious adverse events were reported.

Study DRM04-HH02. Given the clinical experience gained with the topical formulation of the reference agent in Study DRM04-HH01, Study DRM04-HH02 was designed to gain clinical experience with DRM04 and validate the psychometric properties of the ASDD prior to the initiation of Phase 3 development. Accordingly, Study DRM04-HH02 was not powered to demonstrate statistical significance. In Study DRM04-HH02, 105 patients with severe, primary axillary hyperhidrosis were randomized into five cohorts to receive a topical formulation containing one of two concentrations of the reference agent, one of two concentrations of DRM04, or vehicle only.

As in the Phase 2a clinical trial and Study DRM04-HH01, patients enrolled in study DRM04-HH02 were instructed to apply the study product to each axilla once daily for four weeks using wipes containing either drug product or vehicle only, and efficacy was evaluated based on axillary sweat production and the HDSS. Assessments were conducted approximately weekly during the four-week treatment period and the two-week period after the end of this treatment period. All 105 patients enrolled in the clinical trial rated the severity of their disease as a three or a four on the four-point HDSS prior to the start of treatment. Trial inclusion criteria required that prior to the start of treatment, all patients produce at least 50 mg of sweat in each axilla over a five-minute period.

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Two of the primary efficacy endpoints evaluated in this trial were (1) the proportion of patients achieving an improvement of at least two points from baseline in HDSS score and (2) the average absolute change from baseline in sweat production, each as measured at the end of the four-week treatment period. Consistent with Study DRM04-HH01, we conducted several non-primary efficacy analyses, including an evaluation of the average percent change from baseline in sweat production at the end of the four-week treatment period. For the purpose of the primary endpoint pertaining to sweat production, sweat production was assessed in each patient as the average of the amounts of sweat produced in each axilla during a five-minute period. The study also explored the new, proprietary ASDD PRO instrument as a potential additional measure of disease severity.

As outlined below, the results of Study DRM04-HH02 were consistent with those observed in Study DRM04-HH01. The following chart summarizes the impact of DRM04 on disease severity, assessed as the proportion of patients achieving an improvement of at least two points in HDSS score from baseline to the end of the four-week treatment period.

P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

ITT population shown = all randomized patients dispensed study product (n = 105). Patients with missing data points were considered non-responders.

For patients in the two cohorts treated with the topical formulation of the reference agent, the results were consistent with those observed in Study DRM04-HH01.

The following charts summarize the impact of DRM04 on sweat production, assessed as (1) the average absolute change in sweat production from baseline to the end of the four-week treatment

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period and (2) the average percent change in sweat production from baseline to the end of the four-week treatment period.

Primary Endpoint: Absolute Change in Sweat Production at Week Four	Non-Primary Analysis: Percent Change in Sweat Production at Week Four

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* P < 0.05 vs. placebo. P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

ITT population shown = all randomized patients dispensed study product (n = 105). The last available on-treatment observation was used to estimate missing data points.

For patients in the two cohorts treated with the topical formulation of the reference agent, the results were consistent with those observed in Study DRM04-HH01.

ASDD data demonstrated greater improvements in disease severity in all treatment cohorts than in the vehicle cohort, and the psychometric properties of the ASDD were validated according to the FDA guidance document for PRO measures.

In this trial, the most common adverse events were dry mouth, application site pain and headache. Dry mouth is a well-known, reversible side effect of anticholinergic agents. One patient, who received DRM04 Dose 1, withdrew from the study due to an adverse event. No treatment-related serious adverse events were reported.

Phase 3 Clinical Program. Based on the results of these three Phase 2 clinical trials, we conducted an end-of-Phase 2 meeting with the FDA in April 2015 during which we requested and received feedback from the FDA regarding certain elements of our proposed development plan for DRM04 in axillary hyperhidrosis, including the design and size of Phase 3 clinical trials. We initiated our Phase 3 clinical program in July 2015.

The DRM04 Phase 3 program is designed to assess the safety and efficacy of DRM04 to support a potential NDA submission to the FDA. The program consists of two pivotal studies, ATMOS-1 and ATMOS-2, to assess the safety and efficacy of DRM04 compared to vehicle and an open-label study, ARIDO, to assess the long-term safety of DRM04. The program is being conducted at approximately 50 trial sites in the United States and Germany.

The ATMOS-1 and ATMOS-2 studies are identical, randomized, double-blind, vehicle-controlled trials that completed enrollment in February 2016 of 697 adult and adolescent (ages nine and older) patients with primary axillary hyperhidrosis. In each of these trials, approximately two-thirds of the patients were randomized to receive DRM04 and approximately one-third of the patients were

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randomized to 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 are 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 our proprietary ASDD instrument. 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 include (1) the proportion of subjects who have at least a two-grade improvement from baseline in their HDSS score and (2) the proportion of subjects with at least a 50% reduction from baseline in gravimetrically-measured sweat production. Both the primary and secondary endpoints will be assessed at the end of the four-week treatment period. In the open-label ARIDO study assessing the long-term safety of DRM04, patients from either of the ATMOS-1 and ATMOS-2 Phase 3 studies are permitted to continue to receive active treatment for up to an additional 44 weeks from the end of the 4-week treatment periods in the ATMOS studies.

We expect to announce topline results from the ATMOS-1 and ATMOS-2 Phase 3 clinical trials in the second quarter of 2016. The ARIDO trial continues to enroll patients. Pending the successful completion of these studies and other registration-enabling activities, we expect to submit an NDA to the FDA in the second half of 2017.

DRM01

Opportunity

DRM01 is our late-stage product candidate for the treatment of acne. It is a novel, topical, small-molecule lipid synthesis inhibitor designed to reduce the production of sebum. 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.

Acne is one of the most common skin diseases. It is characterized by clogging of the pores and associated local skin lesions that usually appear on the face, chest or back. Acne lesions are believed to result from an interaction of four primary pathogenic, or contributing, factors: (1) excessive production of sebum; (2) alterations in skin cells that, in concert with excess sebum production, contribute to clogging of pores through which sebum is normally released to the skin surface; (3) colonization of the area in and around the sebaceous glands by bacteria that are nourished by sebum; and (4) inflammation often associated with colonization by bacteria and their breakdown of sebum into irritating breakdown products. Clogged pores can become enlarged and inflamed as sebum and its breakdown products accumulate, resulting in visible lesions that can be unsightly and cause permanent scarring.

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.

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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.

In June 2014, we completed a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial that demonstrated significant reductions in the signs and symptoms of acne. As this Phase 2 clinical trial was conducted in Canada, it was not covered by an IND. Based on the results of this trial, we filed an IND with the FDA in January 2015 and commenced a Phase 2b clinical trial in April 2015. We completed enrollment in the Phase 2b clinical trial in January 2016 and expect to announce topline results in the second quarter of 2016.

Clinical Development

We are developing DRM01 in accordance with published FDA draft guidance regarding the development of acne drugs. Established in 2005, this draft guidance has been widely used in the design, conduct and analysis of clinical trials intended to support marketing approval for new acne products.

We have completed a Phase 1 clinical trial and a Phase 2a clinical trial to assess the efficacy, safety and tolerability of DRM01. Both clinical trials were conducted in Canada.

Phase 1 Clinical Trial. In the Phase 1 clinical trial, six healthy volunteers applied topical DRM01 gel to the face for seven days. All subjects completed dosing, and no adverse events were reported.

Phase 2a Clinical Trial. The FDA recommends that the principal clinical trials used to demonstrate safety and efficacy in support of marketing approval be randomized, multi-center, blinded trials designed to demonstrate superiority of the investigational product relative to a vehicle or placebo control following a treatment duration of at least 12 weeks. Our Phase 2a clinical trial was a randomized, multi-center, double-blind, vehicle-controlled study designed in accordance with the published FDA draft guidance. In this trial, 108 patients with moderate or severe acne were instructed to apply either DRM01 gel or vehicle gel to the face twice daily for 12 weeks. DRM01 gel was formulated at a concentration of 7.5%. Of the 108 patients enrolled in the trial, 53 were randomized to receive DRM01, and the other 55 were randomized to receive vehicle only.

Three primary efficacy endpoints recommended in the published FDA draft guidance were used as primary efficacy endpoints in this trial:

Inflammatory lesion count, assessed as the absolute change from baseline in the number of inflammatory acne lesions;

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Non-inflammatory lesion count, assessed as the absolute change from baseline in the number of non-inflammatory acne lesions; and

Investigator's Global Assessment, or IGA, assessed as the proportion of patients who achieve a successful improvement in the investigator's assessment of disease severity, as assessed on a five-point scale that ranges from a score of zero, representing clear skin, to a score of four, representing severe disease. The FDA recommends that a successful improvement be defined a priori as achievement of either (1) a reduction from baseline of at least two points on the IGA scale or (2) a reduction from baseline to a final score of zero, representing clear skin, or a score of one, representing almost clear skin, on the IGA scale.

In our trial, lesions were counted by the investigators, and a successful improvement in IGA score was defined as a reduction from baseline of at least two points on the IGA scale. As is standard practice in acne clinical trials, the primary efficacy endpoints were assessed at the end of the 12-week treatment period. In addition to evaluating the primary efficacy endpoints, we conducted several non-primary efficacy analyses, including an evaluation of the percent change from baseline in the number of inflammatory lesions and an evaluation of the percent change from baseline in the number of non-inflammatory lesions, each as assessed at the end of the 12-week treatment period.

As outlined below, DRM01 demonstrated statistically significant improvements relative to vehicle in all three primary efficacy endpoints. The following chart summarizes the impact of DRM01 on acne lesion counts. Based on these results, patients treated with DRM01 achieved a 45% greater average absolute reduction in inflammatory lesion count and a 78% greater average absolute reduction in non-inflammatory lesion count than patients who received vehicle only.

Primary Endpoints:
Absolute Changes in Lesion Counts at Week 12

Non-Primary Analyses:
Percent Changes in Lesion Counts at Week 12

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P < 0.01 vs. placebo. P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

As recommended in the published FDA draft guidance regarding the development of acne drugs, data are presented from the ITT population, defined as all randomized patients who were dispensed study product, and the last available on-treatment observation is used to estimate missing data points. The average lesion count at baseline includes all 108 patients in the ITT population. Missing data for one patient in the vehicle cohort for whom no on-treatment efficacy

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assessment was available are excluded from the patient population observed the end of the 12-week treatment period.

The following chart summarizes the impact of DRM01 on the third primary efficacy endpoint: the proportion of patients who achieved a successful improvement in the severity of their disease, as assessed using the IGA. Based on these results, patients treated with DRM01 were more than three times more likely than patients who received vehicle only to achieve a successful improvement in IGA score.

Primary Endpoint: IGA Response Rate at Week 12

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P < 0.01 vs. placebo. P-values are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less typically represents a statistically significant result.

As recommended in the published FDA draft guidance regarding the development of acne drugs, data are presented from the ITT population, defined as all randomized patients who were dispensed study product. In this analysis, patients with missing data points were considered non-responders.

When analyzing the Phase 2a study data looking at per-protocol patients, a population that is smaller in size and thus has lower statistical power, although the IGA and inflammatory lesion count results are statistically significant (p = 0.0314 and p = 0.0048, respectively), the non-inflammatory lesion count results do not reach statistical significance (p = 0.0566).

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The most common adverse events observed in this clinical trial were upper respiratory tract infections, which were considered unrelated to treatment, and application-site conditions, which are frequently observed in most clinical trials of topical products. No treatment-related serious adverse events were reported.

Phase 2b Clinical Trial. Based on the efficacy, safety and tolerability profile observed in the Phase 2a clinical trial, we filed an IND with the FDA in January 2015 and commenced a Phase 2b clinical trial in April 2015 in patients with facial acne. The Phase 2b clinical trial is a randomized, multi-center, double-blind, parallel-group, vehicle-controlled study designed to assess the safety and efficacy of DRM01 compared to vehicle. The goal of the study, which completed enrollment in January 2016, is to establish the optimal dose for a potential Phase 3 program. In the Phase 2b trial, 420 adult patients with moderate-to-severe facial acne were randomized into five separate arms evaluating different DRM01 dosing regimens compared to vehicle. Approximately 100 patients were enrolled in each of three active treatment 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 patients received vehicle, with approximately 50 patients receiving vehicle once a day and approximately 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 IGA score. Each endpoint will be measured at the end of the 12-week treatment period. The trial is being conducted at approximately 30 sites in the United States 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.

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our development and commercialization experience, scientific knowledge and industry relationships provide us with competitive advantages, we face competition from pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, and generic drug companies, academic institutions, government agencies and research institutions.

Many of our competitors have significantly greater financial, technical and human resources than we have. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future product candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our product candidates. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products.

Moderate-to-Severe Plaque Psoriasis

If approved for the treatment of moderate-to-severe chronic plaque psoriasis, we anticipate that Cimzia would compete with other approved psoriasis therapeutics, including:

Injected Biologic Products. Several injected biologic products are prescribed for the treatment of moderate-to-severe plaque psoriasis, including the following TNF inhibitors: Humira, marketed by AbbVie Inc. and Eisai Co., Ltd.; Enbrel, marketed by Amgen Inc., Pfizer Inc. and Takeda Pharmaceutical Company Limited; and Remicade, marketed by Janssen Biotech, Inc., a division of Johnson & Johnson, Merck & Co., Inc. and Mitsubishi Tanabe Pharma Corporation. Other injected biologic products prescribed for the treatment of moderate-to-severe plaque psoriasis

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include: Stelara, marketed by Janssen; and Cosentyx, marketed by Novartis Pharmaceuticals Corporation and Maruho Co., Ltd.

Other Systemic Treatments. Other systemic treatments are prescribed for the treatment of moderate-to-severe plaque psoriasis, including: Otezla, an oral PDE4 inhibitor, marketed by Celgene Corporation; branded injectable and oral methotrexate products such as Otrexup, marketed by Antares Pharma, Inc., and Rasuvo, marketed by Medac Pharma, Inc.; generic injectable and oral methotrexate products marketed by Sandoz Inc., a division of Novartis, Mylan Inc., Teva Pharmaceutical Industries Ltd. and Hospira, Inc., a division of Pfizer; branded oral cyclosporine products such as Neoral, marketed by Novartis AG, and Gengraf, marketed by AbbVie; generic oral cyclosporine products marketed by Sandoz and IVAX Corporation; branded oral acitretin products such as Soriatane, marketed by Stiefel; and generic oral acitretin products marketed by Teva and Prasco, LLC.

Other Treatments. Various light-based treatments are used to treat moderate-to-severe plaque psoriasis, including various lasers and ultraviolet light-based therapies such as Oxsoralen-Ultra, marketed by Valeant Pharmaceuticals International. There are also several prescription, non-prescription and OTC topical treatments utilized to treat psoriasis, including tazarotene, salicylic acid and coal tar, as well as bath solutions and moisturizers.

In addition to approved moderate-to-severe plaque psoriasis treatments, there are several pharmaceutical product candidates under development that could potentially be used to treat psoriasis and compete with Cimzia, including innovative product candidates and generic and biosimilar versions of approved products. For example:

The FDA is currently reviewing applications for approval for marketing of: ixekizumab from Eli Lilly and Company; brodalumab from AstraZeneca plc and Valeant, by Valeant; a biosimilar version of adalimumab, the active ingredient in Humira, from Amgen; a biosimilar version of etanercept, the active ingredient in Enbrel, that is approved for marketing in the European Union from Samsung Bioepis Co., Ltd., a joint venture of Biogen Inc. and Samsung, by Merck; a biosimilar version of etanercept from Sandoz International GmbH and Hexal AG, divisions of Novartis; and a biosimilar version of infliximab, the active ingredient in Remicade, which is currently marketed outside the United States, from Celltrion Inc., by Pfizer.

Innovative product candidates in Phase 3 clinical development include: Xeljanz, which is currently marketed in rheumatoid arthritis, from Pfizer; tildrakizumab from Sun Pharmaceutical Industries Ltd.; guselkumab from Janssen Research & Development, LLC, a division of Johnson & Johnson; and LAS-41008 from Almirall, S.A.

Biosimilar product candidates in Phase 3 development include:

biosimilar versions of adalimumab from Coherus BioSciences Inc.; Samsung Bioepis; Pfizer; Biocon Ltd and Mylan Inc.; Fujifilm Kyowa Kirin Biologics Co. Ltd, a joint venture of Fujifilm and Kyowa Hakko Kirin; Baxalta Inc. and Momenta Pharmaceuticals Inc.; Boehringer Ingelheim Corp.; and Merck Serono S.A.;

a biosimilar version of etanercept from Baxalta, Coherus and Daiichi Sankyo Co. Ltd; and

biosimilar versions of infliximab from Samsung Bioepis and Pfizer.

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Hyperhidrosis

If approved for the treatment of primary axillary hyperhidrosis, we anticipate that DRM04 would compete with other therapies used for hyperhidrosis, including:

Self-Administered Treatments. Self-administered treatments include OTC and prescription topical antiperspirants. Oral and compounded topical anticholinergics may also be used off-label.

Non-Surgical Office-Based Procedures. Office-based procedures have been approved for the treatment of hyperhidrosis, including Botox intradermal injections marketed by Allergan plc, and MiraDry, a microwave-based treatment marketed by Miramar Labs, Inc.

Surgical Treatments. Surgical treatments include techniques for the removal of sweat glands, such as excision, curettage and liposuction. Surgical procedures, such as endoscopic thoracic sympathectomy, also are used to destroy nerves that transmit activating signals to sweat glands.

There are also several treatments under development that potentially could be used to treat hyperhidrosis and compete with DRM04, including: a laser-based procedure from Cynosure, Inc.; an ultrasound device from Ulthera, Inc., a subsidiary of Merz Pharma GmbH & Co. KGaA; topical forms of botulinum toxin A from Revance Therapeutics, Inc. and Allergan; topical anticholinergic product candidates from Brickell Biotech, Inc. and GlaxoSmithKline LLC, or GSK; and oral anticholinergic product candidates from Allergan and TheraVida, Inc.

Acne

If approved for the treatment of acne, we anticipate that DRM01 would compete with other approved prescription acne products, including:

Topical Retinoids. Single-agent topical retinoid products prescribed for the treatment of acne include: Differin, marketed by Galderma S.A.; Tazorac, marketed by Allergan; Fabior, marketed by GSK; and branded and generic tretinoin products, such as Retin-A Micro, marketed by Valeant. Topical retinoids are also used in combination products that include an antimicrobial, such as benzoyl peroxide, as in Epiduo, marketed by Galderma; or clindamycin phosphate, as in Ziana, marketed by Medicis Pharmaceutical Corporation, a division of Valeant, and Veltin, marketed by Aqua Pharmaceuticals, LLC, a division of Almirall.

Topical and Oral Antimicrobials. Several topical antimicrobial products are prescribed for the treatment of acne, including single-agent products such as: Aczone, marketed by Allergan; Clindagel, marketed by Onset Dermatologics LLC, a division of Valeant; and branded and generic benzoyl peroxide, clindamycin phosphate and erythromycin products. Topical antimicrobials are also used in combination products that include a retinoid, such as in Ziana and Veltin, or another antimicrobial, such as in Acanya and Onexton, marketed by Valeant. Oral antibiotics are also prescribed for the treatment of acne, including branded and generic doxycycline and minocycline products, such as: Doryx and Doxteric, marketed by Mayne Pharma Group Ltd.; Acticlate and Monodox, marketed by Aqua Pharmaceuticals; and Solodyn, marketed by Medicis.

Oral Isotretinoin. Several branded and generic oral isotretinoin products are prescribed for the treatment of acne, including: Absorica, marketed by Ranbaxy Laboratories Limited and Cipher Pharmaceuticals Inc.; Amnesteem, marketed by Mylan; Claravis, marketed by Teva; Myorisan, marketed by Versapharm Incorporated; and Zenatane, marketed by Promius Pharma, LLC, a division of Dr. Reddy's Laboratories Limited.

Oral Hormonal Therapies. Several branded and generic oral hormonal therapies are prescribed for the treatment of acne, including: branded and generic combinations of drospirenone and ethinyl estradiol, such as Yaz, marketed by Bayer HealthCare AG, and Ocella, marketed by

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Teva; and branded and generic combinations of norgestimate and ethinyl estradiol, such as Ortho Tri-Cyclen, marketed by Janssen, TriNessa, marketed by Allergan, and Tri-Sprintec, marketed by Teva.

In addition to approved prescription acne therapies, a number of prescription products are used off-label for the treatment of acne, including branded and generic products containing the oral hormonal therapy spironolactone, such as Aldactone, marketed by G.D. Searle LLC, a division of Pfizer. A wide range of OTC and device products are also used to treat acne, including: OTC benzoyl peroxide products and skin cleansers, such as Proactiv, marketed by Guthy-Renker LLC; and light-based therapies, such as Blu-U, marketed by Dusa Pharmaceuticals, Inc., a division of Sun Pharmaceutical Industries, Inc., and Acne Clearing Blue Light, marketed by Tria Beauty, Inc.

Furthermore, there are several product candidates in development that could potentially be used to treat acne and compete with DRM01. Product candidates in Phase 3 development include: a topical retinoid by Galderma; topical antimicrobials by each of Galderma, Valeant, Maruho and Allergan; a topical hormonal therapy by Cassiopea SpA, a subsidiary of Cosmo Pharmaceuticals SpA; an oral antibiotic by Allergan; a topical nitric oxide-based therapy by Novan Therapeutics; and light-based therapies by LEO Pharma A/S and KLOX Technologies, Inc.

Commercial Operations

We intend to build a commercial infrastructure in the United States and Canada to support the commercialization of our product candidates, if and when we believe that a regulatory approval of the first of such product candidates appears likely in the near term. We intend to build a targeted sales force to establish relationships with dermatologists. We expect that our sales force will be supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure, we will have to invest significant financial and management resources, some of which will be committed prior to any confirmation that our product candidates will be approved, and we could invest resources and then later learn that a particular product candidate is not being approved. To commercialize Cimzia, we intend to leverage the commercial infrastructure of our partner, UCB, in selected areas, such as manufacturing, distribution, managed care and patient access, which would provide us with additional resources and expertise in these areas. We may also partner with third parties to help us reach other geographic markets or therapeutic specialties.

Research and Development

Total research and development expenses were $66.8 million, $30.7 million and $17.9 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our products and technologies, and to operate without infringing the proprietary rights of others. With respect to the former, our policy is to protect our proprietary position by, among other methods, filing patent applications on inventions that are important to the development and conduct of our business with the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such developments, evaluate and take appropriate courses of action.

As of January 31, 2016, we own or have an exclusive license to 27 issued U.S. patents and 91 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 42 pending foreign patent applications. In addition, we have patents and patent applications not included in the figures noted

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above related to Cimzia licensed to us under the UCB agreement, including six issued U.S. patents and two issued Canadian patents. Yeda Research and Development Co. Ltd., or Yeda, has alleged that Cimzia infringes on U.S. Patent No. 6,090,923, a patent owned by Yeda, or the '923 Patent. In response, UCB filed a complaint in August 2014 seeking declaratory judgment that the '923 Patent is invalid, Cimzia does not infringe on the '923 Patent, the '923 Patent is unenforceable and any claim for infringement by UCB of the '923 Patent is barred. In July 2015, the court granted UCB's motion for summary judgment in part, finding that Cimzia does not infringe on the '923 Patent but dismissed UCB's claim for declaratory judgment of invalidity of the '923 Patent without prejudice in September 2015. The case is currently pending review by the United States Court of Appeals for the Federal Circuit pursuant to an appeal filed by Yeda in August 2015.

Issued U.S. and foreign patents and pending U.S. and foreign patent applications, if issued, for our lead product candidates, Cimzia, DRM04 and DRM01, will expire between 2020 and 2034.

We also use other forms of protection, such as trademark, copyright and trade secret protection, to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We aim to take advantage of all of the intellectual property rights that are available to us and believe that this comprehensive approach will provide us with proprietary positions for our product candidates, where available.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We also protect our proprietary information by requiring our employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. In addition, we also require confidentiality or service agreements from third parties that receive our confidential information or materials.

Collaborations and License Agreements

Collaboration with UCB

In March 2014, we entered into a development and commercialization agreement with UCB, or the UCB agreement, which provides that we will develop Cimzia for the treatment of psoriasis in order for UCB to seek regulatory approval from the FDA, the EMA and the Canadian federal department for health, or Health Canada, and upon the grant of regulatory approval in the United States and Canada, that we will promote sales of Cimzia to dermatologists and conduct related medical affairs activities in the United States and Canada. Unless earlier terminated, the term of the UCB agreement is 12.5 years following the first commercial launch following regulatory approval of Cimzia for the treatment of psoriasis in the United States and Canada. In connection with the UCB agreement, UCB purchased $5.0 million of shares of our Series B convertible preferred stock in April 2014, $7.5 million of shares of our Series C convertible preferred stock in August 2014 and $7.5 million of shares of our common stock from us in a private placement concurrent with our initial public offering, or IPO, at the IPO price.

We have agreed with UCB on a development plan to obtain regulatory approval from the FDA, EMA and Health Canada, which may be amended as necessary to meet the requirements of these regulatory authorities for approval. We are responsible for paying all development costs specified under the UCB agreement and incurred in connection with the development plan up to a specified amount greater than $75.0 million and less than $95.0 million, plus our internal development costs.

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Development costs include the costs of Cimzia and etanercept clinical trial materials used in the Phase 3 clinical program. UCB is responsible for providing these clinical trial materials and we reimburse UCB for such costs. Any development costs in excess of $95.0 million or for any required clinical trials in pediatric patients will be shared equally. Development costs for any EMA-specific post-approval studies will be borne solely by UCB. UCB is obligated to pay us up to an aggregate of $36.0 million if certain development milestones are met, and up to an additional aggregate of $13.5 million upon the grant of regulatory approval, including pricing and reimbursement approval, in certain European countries. The dosing of the first patient in the Phase 3 clinical program for Cimzia, which occurred in December 2014, triggered a $7.3 million development milestone payment from UCB, which we received in the first quarter of 2015. The completion of patient enrollment in a Phase 3 clinical trial for Cimzia, which occurred in September 2015, triggered another $7.3 million development milestone payment from UCB, which we received in the fourth quarter of 2015. As a result of achieving these milestones, there is $21.4 million in remaining development milestone payments that we are eligible to receive. Under the terms of the UCB agreement, we will have the exclusive rights upon regulatory approval of the psoriasis indication to promote Cimzia to dermatologists in the United States and Canada. Following such regulatory approval, UCB will book sales and is obligated to pay us royalties representing a percentage of the annual gross margin (after subtracting the costs of certain commercialization support services to be provided by UCB) from Cimzia sales attributed to dermatologists for all indications in the United States and Canada. In each year, the royalties will be payable quarterly and are tiered based upon increasing levels of annual net sales attributed to dermatologists in such year, with UCB retaining between 10% and, above $150.0 million of such annual net sales in such year, 50%, and Dermira receiving the balance, of such annual gross margin. In addition, UCB is obligated to pay us up to an aggregate of $40.0 million upon the achievement of tiered milestones based on annual net sales of Cimzia attributed to dermatologists in the United States and Canada.

We have decision-making authority for the level of commercial and medical affairs activities we conduct and are responsible for the costs and expenses that we incur in connection with such activities. We have agreed to make minimum annual numbers of promotional presentations to dermatologists in the United States or that a minimum portion of the incentive compensation paid to our sales force will be based on sales of Cimzia attributable to dermatologists in the United States.

The UCB agreement provides for the establishment of a joint steering committee, joint development committee and joint commercialization committee to oversee and coordinate the parties' activities under the UCB agreement. We and UCB have agreed to make committee decisions by consensus and although UCB has final decision-making authority for development, regulatory and commercialization strategy (including product pricing), except as required by regulatory authorities, UCB cannot amend the agreed development plan or increase the development budget without our approval.

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. UCB has agreed that during the term of the UCB agreement, except in limited circumstances, it and its affiliates will not clinically develop, seek regulatory approval for or commercialize a biologic TNF inhibitor other than Cimzia for the treatment of psoriasis or psoriatic arthritis in the United States or Canada, 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, UCB has the right to terminate the agreement if we do not either cease such clinical development or commercialization or divest such product. If we consummate a change of control with a third party that is clinically developing or

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commercializing a biologic TNF inhibitor, UCB has the right to terminate the UCB agreement. The sale, transfer, exclusive license or other disposition of our assets will be considered a change of control only if it constitutes all or substantially all of our assets and includes our rights to develop and/or commercialize Cimzia under the UCB agreement.

UCB does not have the right to terminate the UCB agreement if we consummate a change of control with a third party that is not clinically developing or commercializing a biologic TNF inhibitor, which we refer to as a non-competitor company, so long as (1) the non-competitor company either (a) is engaged in the development or commercialization of a pharmaceutical product or (b) will maintain us as an operating entity and will maintain at least 50% of our executive management team for at least 12 months, (2) the non-competitor 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 (3) 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 non-competitor company agrees in writing to complete such development obligations. If we consummate a change of control with a non-competitor company that does not meet all of these requirements, then UCB has the right to terminate the UCB agreement.

Without the prior written consent of UCB, we are not permitted to assign or transfer our rights or obligations under the UCB agreement other than to our affiliates or a non-competitor company that meets the requirements described in the prior paragraph or in the event UCB elects not to terminate the UCB agreement in connection with a change of control having had the right to do so.

If during the term of the UCB agreement UCB acquires or is acquired by, a third party that is clinically developing or commercializing a biologic TNF inhibitor for the treatment of psoriasis or targeting dermatologists for the treatment of psoriatic arthritis, in either case, in the United States or Canada, we have the right to terminate the agreement if UCB does not either cease such clinical development or commercialization or divest such product.

The UCB agreement is terminable by UCB if we commit an uncured material breach of the UCB agreement, in the event of our insolvency, or following our change of control with a competitor company or with a non-competitor company that does not meet the requirements described above. In these events, we are obligated to transition to UCB at our expense our activities under the UCB agreement and if such termination occurs prior to the grant of regulatory approval for Cimzia for the treatment of psoriasis, we are 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 when such milestones are achieved. UCB will remain responsible for its share of the development costs above the agreed amount and for pediatric clinical studies and its sole responsibility to fund any EMA-specific post-approval studies. If we comply with these development funding obligations, UCB is obligated to reimburse us for the development costs we incur less any applicable development milestone deductions, and if the termination occurs following regulatory approval, less any royalty payments and sales-based milestone payments made, by paying to us a low single-digit royalty on the net sales received by UCB from the sale of Cimzia in the United States and Canada in all indications until all such costs we have incurred have been reimbursed.

The UCB agreement is also 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 this event, UCB is obligated to reimburse us for the development, commercial and medical affairs costs we have incurred in accordance with the UCB agreement by paying to us a low single-digit royalty on the net sales received by UCB from the

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sale of Cimzia in the United States and Canada in all indications until all costs have been reimbursed. Upon such a termination, UCB is obligated to no longer develop or commercialize Cimzia for the treatment of psoriasis anywhere in the world.

The UCB agreement is terminable by us if UCB commits an uncured material breach of the UCB agreement or in the event of UCB's insolvency. In such events, UCB is obligated to pay us an amount equal to the fair market value of the UCB agreement to us subject, if termination occurs before we and UCB have received the complete data set used to assess the primary efficacy endpoint of the first Phase 3 clinical trial of Cimzia for the treatment of psoriasis, to a minimum amount equal to a multiple of more than one time but less than two times the sum of the development, commercial and medical affairs costs we have incurred, the costs we incur transitioning development and commercialization to UCB and the costs, which we refer to as disruption and transition costs, that we incur as a result of termination, including terminating employees, reducing or disposing of facilities and equipment and terminating or modifying agreements with third parties. The fair market value of the UCB agreement is the amount that a willing buyer would pay to a willing seller in an arm's length transaction for all of our rights under the UCB agreement, plus the disruption and transition costs. UCB is obligated to increase the payments to be made to us described in this paragraph by a tax gross-up equal to the income and other taxes incurred by us with respect to the receipt of such payments and the receipt of such gross-up amount, and if the payment to us is based on the minimum amount calculated above, instead of the determination of the fair market value of the UCB agreement, UCB may offset such payment by the aggregate amount of all development milestone payments that UCB previously paid to us. We and UCB have agreed to cooperate to minimize the amount of such taxes and if the resulting transaction structure results in taxation either to us, our affiliates or our stockholders, then the tax gross-up payment will also include an amount to be paid to such persons sufficient to cause their net tax costs to be no greater than the taxes they would have paid had the consideration received in such transaction been taxed net of basis at the long-term capital gains rate.

The UCB agreement is also terminable by us after we and UCB have received the complete data set used to assess the primary efficacy endpoint of the first Phase 3 clinical trial of Cimzia for the treatment of psoriasis. In this event, we are obligated to pay the costs of winding down all then-ongoing clinical studies or, if UCB elects to continue the development and commercialization of Cimzia for the treatment of psoriasis, continue to pay the costs for which we would have been responsible under the agreed development plan up to the completion, or the date of termination by UCB, of all then-ongoing clinical studies, reduced by the amount of development milestone payments that would have been payable upon achievement of applicable development milestones when such milestones are achieved. UCB will remain responsible for its share of development costs above the agreed amount and for pediatric clinical studies and its sole responsibility to fund any EMA-specific post-approval studies. If we comply with these development funding obligations and Cimzia is approved for the treatment of psoriasis, UCB is obligated to reimburse us for the net development costs we incur by paying to us a low single-digit royalty on the net sales received by UCB from the sale of Cimzia in the United States and Canada in all indications until all such costs we have incurred have been reimbursed.

The UCB agreement is also terminable by us following the commercial launch of Cimzia if UCB implements one or more business decision(s) specifically aimed and directed exclusively at Cimzia for the treatment of moderate-to-severe plaque psoriasis alone with the intention of materially benefiting the rest of UCB's Cimzia franchise and that UCB knew or reasonably should have known that such business decision(s) would, and such business decision(s) did, in fact, result in a material decrease in the amount of royalties payable to us under the UCB agreement. We shall have no right to terminate the UCB agreement if UCB (1) initiates corrective action immediately on receipt by it of a notice from us to reverse said material decrease in the amount of royalties payable to us under the UCB agreement and (2) until such corrective action has taken effect so as to reverse such material decrease, UCB has

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reimbursed us in an amount equivalent to the loss of royalties under the UCB agreement from the date of the implementation of such business decision(s) up to the date of such reversal.

Agreements with Rose U and Stiefel

In April 2013, we entered into an exclusive license agreement with Rose U pursuant to which we obtained a worldwide exclusive license within a field of use including hyperhidrosis to practice, enforce and otherwise exploit certain patent rights, know-how and data related to DRM04. The license agreement with Rose U included a sublicense of certain data and an assignment of certain regulatory filings which Rose U had obtained from Stiefel. In connection with the license agreement we entered into a letter agreement with Stiefel pursuant to which we assumed Rose U's obligation to pay Stiefel approximately $2.5 million in connection with the commercialization of products developed using the licensed data and to indemnify Stiefel for claims arising from the use, development or commercialization of products developed using the Stiefel data. The agreements require us to use commercially reasonable efforts to develop and commercialize products using the licensed patent rights, know-how and data.

Pursuant to these agreements with Rose U and the related agreement with Stiefel with respect to our DRM04 product candidate, we have paid license and other fees of $0.5 million to Rose U and are required to pay additional amounts totaling up to $4.4 million upon the achievement of specified development, commercialization and other milestones under these agreements to Rose U and Stiefel. In addition, we are obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments we are obligated to pay Rose U directly upon the events or sales triggering such payments.

We are permitted to grant sublicenses to the licensed rights and may assign the agreements upon an acquisition of us or our assets that relate to the license agreement, provided that in the event of an acquisition of our assets we must first pay to Stiefel the commercialization payment we are obligated to make on behalf of Rose U, if such amount has not already been paid. We may terminate the license agreement if Rose U experiences certain insolvency events or if Rose U commits a material breach of the license agreement, subject to applicable cure provisions. We may also terminate the license agreement if we determine that development results or market dynamics do not justify further development or commercialization of licensed products, in which case, all patent and technology rights shall revert to Rose U and we will (1) grant Rose U a perpetual nonexclusive license to any improvements owned by us that have been applied to or used with DRM04, at a royalty rate to be mutually agreed through good faith negotiation, and (2) for 120 days after such termination, assist and cooperate with Rose U (at Rose U's expense) in connection with the license of such improvements to Rose U. Rose U may terminate the license in certain circumstances if we experience certain insolvency events or if we commit a material breach of the license agreement or if we cause Rose U to be in material breach of its license agreement with Stiefel, subject in each case to applicable cure provisions. Subject to earlier termination, the license agreement remains in effect until 15 years following the first commercial sale of a licensed product have elapsed or, if later, the date that the last patent or patent application in the licensed patent rights has expired or been revoked, invalidated or abandoned. The last-to-expire issued patent relating to DRM04 that we license under the license agreement with Rose U expires in 2029.

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Government Regulation

FDA Drug Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. As a result of these regulations, pharmaceutical product development and approval are very expensive and time consuming.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. For dermatology products, Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials with statistically significant results to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of an effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States.

The FDA also may refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with the FDA's good clinical practice requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

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After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA. An alternative is a special type of NDA, commonly referred to as a Section 505(b)(2), or 505(b)(2), NDA, which enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Biologics

Cimzia is a biological product. Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a Biologics License Application, or BLA. However, the application process and requirements for approval of BLAs and BLA supplements, including review timelines, are very similar to those for NDAs and NDA supplements, and biologics are associated with similar approval risks and costs as drugs.

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Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity, patent or non-patent, for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing any clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory

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authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. Certain countries outside of the United States have a process similar to the FDA's that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and institutional review board, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and is optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Anti-Kickback, False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry. These laws include, among others, anti-kickback statutes, false claims statutes and other statutes pertaining to healthcare fraud and abuse. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The Patient Protection and Affordable Care Act, or PPACA, as amended, amended the intent element of the federal anti-kickback statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exceptions or safe harbor.

Other Federal and State Regulatory Requirements

The Centers for Medicare & Medicaid Services, or CMS, has issued a final rule pursuant to PPACA that requires certain manufacturers of prescription drugs to annually collect and report information on payments or transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers were required to begin collecting information on August 1, 2013, with the first reports due March 31, 2014. The reported data is expected to be posted in searchable form on a public website beginning September 30, 2014. Failure to submit required information may result in civil monetary penalties.

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In addition, several states now require prescription drug companies to report expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners and entities in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada and Massachusetts require pharmaceutical companies to implement compliance programs and marketing codes. Several additional states are considering similar proposals. Some of the state laws are broader in scope than federal laws. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Reimbursement

Sales of any of our product candidates that are approved will depend, in part, on the extent to which the costs of our approved products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If any of our products are approved and these third-party payors do not consider our approved products to be cost-effective compared to other therapies, they may not cover our approved products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our approved products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our approved products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, is expected to have a significant impact on the health care industry. The ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements

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under the Medicare Part D program. We cannot predict the impact of the ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred. In addition, although the U.S. Supreme Court upheld the constitutionality of most of the ACA, some states have indicated that they intend to not implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal parts of the ACA. These challenges add to the uncertainty of the legislative changes enacted as part of ACA.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, product candidates launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Manufacturing and Supply

We currently contract with third parties for the manufacture of our small-molecule drug substances and drug products for preclinical studies and clinical trials and intend to continue doing so in the future. All of our clinical drug product manufacturing activities are in compliance with cGMP. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight over the contract manufacturing organizations, or CMOs, with which we contract. We rely on third-party cGMP manufacturers for scale-up and process development work and to produce sufficient quantities of development product candidates for use in clinical and preclinical trials. We currently have development contracts and quality agreements with several CMOs for the manufacturing of our small-molecule drug substances and topical drug products. We anticipate that these CMOs will have capacity to support commercial scale, but we do not have any formal agreements at this time with any of these CMOs to cover commercial production. We also may elect to pursue other CMOs for manufacturing supplies for later-stage trials and for commercialization. We currently have no plans to establish a manufacturing capability, but rather plan to continue to rely on third-party cGMP manufacturers for any future trials and commercialization of the small-molecule compounds for which we retain manufacturing responsibility. Under the UCB agreement, UCB retains all responsibilities for the manufacture of Cimzia.

Employees

As of December 31, 2015, we had 62 regular full-time employees, including 38 in research and development. We had one employee located outside of the United States as of December 31, 2015. From time to time, we also retain independent contractors to support our organization. Our employees are not represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our employees to be good.

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, CA 94025, and our telephone number is

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(650) 421-7200. Our website address is www.dermira.com. The information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K.

Available Information

Our website address is www.dermira.com. The information contained on, or that can be accessed through, our website is not a part of this report. Investors should not rely on any such information in deciding whether to purchase our common stock. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, reports filed pursuant to Section 16 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, proxy and information statements and amendments to items filed pursuant to Sections 13(a), 14, 15(d) and 16 of the Exchange Act are filed with the U.S. Securities and Exchange Commission, or the SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. Such documents and other information filed by the Company with the SEC are available free of charge on the Investor section of our website when such reports are available on the SEC's website.

The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at *www.sec.gov*.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on the "Investors" page of our website. Corporate governance information, including the charters for the committees of our board of directors, codes of business conduct and ethics and corporate governance guidelines, is also available on the "Investors" page of our website located at http://investor.dermira.com.

In addition to SEC filings, press releases, public conference calls and webcasts, we use our website (www.dermira.com), and LinkedIn page (https://www.linkedin.com/company/dermira-inc-) as channels of distribution of information about our company, our product candidates, our planned financial and other announcements, our attendance at upcoming investor and industry conferences, and other matters. It is possible that the information we post on our website and through our LinkedIn page could be deemed material information. We may use these channels to comply with our disclosure obligations under Regulation FD. Therefore, investors should monitor our website and our LinkedIn page in addition to following our press releases, SEC filings, public conference calls and webcasts.

The contents of the websites referred to above are not incorporated into this report. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Executive Officers

The following table sets forth the names, ages as of February 28, 2016, and positions of our executive officers:

Name	Age	Position
Thomas G. Wiggans	64	Chief Executive Officer and Chairman of the Board
Eugene A. Bauer, M.D.	73	Chief Medical Officer and Director
Christopher M. Griffith	39	Vice President, Corporate Development & Strategy
Andrew L. Guggenhime	47	Chief Operating Officer and Chief Financial Officer
Luis C. Peña	53	Chief Development Officer

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Eugene A. Bauer, M.D. Dr. Bauer founded our company in August 2010, has served as a member of our board of directors since August 2010 and has served as our Chief Medical Officer since October 2011. Dr. Bauer served on the board of directors of Vyteris, Inc. from February 2010 until June 2012. From June 2006, Dr. Bauer served as a member of board of directors of Peplin, Inc., a biotechnology company, and in October 2008, he became its President and Chief Medical Officer, and he served in these positions until Peplin's acquisition by LEO Pharma A/S in November 2009. From November 2004 to October 2008, Dr. Bauer was Chief Executive Officer of Neosil Inc., a dermatology company that was acquired by Peplin in October 2008. In 1993, Dr. Bauer co-founded Connetics Corporation, a biotechnology company, where he served as a member of the board of directors until October 2005. Dr. Bauer served as Dean of the Stanford University School of Medicine from 1995 to 2001 and as Chair of the Department of Dermatology at the Stanford University School of Medicine from 1988 to 1995. Dr. Bauer is a Lucy Becker Professor, Emeritus, in the School of Medicine at Stanford University, a position he has held since 2002. In addition, he is a member of the boards of directors of Medgenics, Inc., Dr. Tattoff, Inc., First Wave Technologies, Inc., Cerecor, Inc., and Kadmon Corporation, LLC. Dr. Bauer also previously served as a member of the boards of directors of Protalex, Inc., PetDRx, Inc., Arbor Vita Corp., Patient Safety Technologies, Inc., MediSync Bioservices and Modigene Inc. (later re-named PROLOR Biotech, Inc.). Dr. Bauer was a U.S. National Institutes of Health, or NIH, funded investigator for 25 years and has served on review groups for the NIH. Dr. Bauer has been elected to several societies, including the National Academy of Medicine of the United States. Dr. Bauer received a B.S. in medicine and an M.D. from Northwestern University. Our board of directors believes that Dr. Bauer's educational and scientific background and his product development and management experience at a number of dermatology companies, as well as his experience serving on the boards of directors of public and private companies in the life sciences industry, qualify him to serve on our board of directors.

Christopher M. Griffith founded our company in August 2010 and has served as our Vice President of Corporate Development and Strategy since August 2011, after previously serving as our Head of Corporate Development and Strategy since September 2010. From July 2005 to September 2010, Mr. Griffith worked in corporate development at Gilead Sciences, Inc., most recently as Associate Director of Corporate Development. From May 2004 to August 2004, Mr. Griffith worked in the bio-oncology strategy group at Genentech, Inc., a biotechnology company. From 2001 to 2003, Mr. Griffith worked at Bay City Capital. Mr. Griffith received B.S. and M.S. degrees in biological sciences from Stanford University and an M.B.A. degree from Harvard Business School.

Andrew L. Guggenhime has served as our Chief Operating Officer and Chief Financial Officer since April 2014. From September 2011 to April 2014, Mr. Guggenhime served as Chief Financial Officer for CardioDx, Inc., a molecular diagnostics life sciences company, where he currently serves as a director. From September 2010 to April 2011, Mr. Guggenhime served as Chief Financial Officer for Calistoga Pharmaceuticals, Inc., a biotechnology company acquired in April 2011 by Gilead. From December 2008 to June 2010, Mr. Guggenhime served as Senior Vice President and Chief Financial Officer for Facet Biotech Corporation, a biotechnology company acquired in April 2010 by Abbott Laboratories. Facet Biotech Corporation was spun off from PDL BioPharma, Inc., a biopharmaceutical company, at which Mr. Guggenhime served as Chief Financial Officer from April 2006 to December 2008. From October 2000 to March 2006, Mr. Guggenhime served as Senior Vice President and Chief Financial Officer for Neoforma, Inc., a provider of supply-chain management solutions for the healthcare industry, and from January to October 2000 he served as its Vice President, Corporate Development. Mr. Guggenhime began his career in financial services at Merrill Lynch & Co. and Wells Fargo & Company. Mr. Guggenhime holds an M.B.A. from the J.L. Kellogg Graduate School of Management at Northwestern University and a B.A. in international politics and economics from Middlebury College.

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Luis C. Peña is a co-founder and has served as our Chief Development Officer since February 2016, after previously serving as our Executive Vice President of Product Development since July 2013 and our Vice President of Product Development since June 2011. From November 2010 to June 2011, Mr. Peña served as a consultant to our company. Mr. Peña served as Vice President, Head of Global Prescription Development at Stiefel, a GSK company, from January 2010 to March 2011 and, from January 2007 to December 2009, Mr. Peña served as Senior Vice President Portfolio Planning and Management at Stiefel, prior to its acquisition by GlaxoSmithKline LLC. From 2005 to 2007, Mr. Peña served as Vice President of Portfolio Planning and Management of Connetics. From 2001 to 2005, Mr. Peña served as Vice President of Product Development of Nuvelo, Inc., a biopharmaceutical company. Previously, Mr. Peña served as Senior Director of Project Planning and Management for Theravance, Incorporated, a pharmaceutical company, and held various positions in manufacturing, research and development at Genentech. Mr. Peña currently serves as an advisor to the SPARK program for the Stanford University School of Medicine where he has been an advisor since 2012. Mr. Peña holds a B.S. in biochemistry from San Francisco State University.

Thomas G. Wiggans. Mr. Wiggans founded our company in August 2010, has served as our Chief Executive Officer and a member of our board of directors since August 2010 and has served as the Chairman of our board of directors since April 2014. Mr. Wiggans has served on the boards of various industry organizations, educational institutions and private and public companies, including service on the boards of directors of Onyx from March 2005 until its acquisition by Amgen Inc. in October 2013, Sangamo Biosciences, Inc. from June 2008 until June 2012, Somaxon Pharmaceuticals, Inc. from June 2008 until May 2012 and as Chairman of the board of directors of Excaliard Pharmaceuticals, Inc. from October 2010 until its acquisition by Pfizer Inc. in December 2011. From October 2007, Mr. Wiggans served as Chairman of the board of directors of Peplin and in August 2008, he became its Chief Executive Officer, and he served in these positions until Peplin's acquisition by LEO Pharma in November 2009. Previously, Mr. Wiggans served as Chief Executive Officer of Connetics from 1994, and as Chairman of the board of directors of Connetics from January 2006, and he served in these positions until December 2006 when Connetics was acquired by Stiefel. From 1992 to 1994, Mr. Wiggans served as President and Chief Operating Officer of CytoTherapeutics Inc., a biotechnology company. From 1980 to 1992, Mr. Wiggans served at Ares-Serono S.A. in various management positions including President of its U.S. pharmaceutical operations and Managing Director of its U.K. pharmaceutical operations. Mr. Wiggans began his career with Eli Lilly and Company, a pharmaceutical company. In addition, Mr. Wiggans is a member of the board of directors of the Biotechnology Innovation Organization and a member of the board of trustees of the University of Kansas Endowment Association. Mr. Wiggans holds a B.S. in pharmacy from the University of Kansas and an M.B.A. from Southern Methodist University. Our board of directors believes that Mr. Wiggans' depth of senior management experience and his track record of new product development and commercialization as well as his experience serving on the boards of directors of public and private companies in the life sciences industry, qualify him to serve as the Chairman of our board of directors.

ITEM 1A. RISK FACTORS

RISK FACTORS

Our operations and financial results are subject to numerous risks and uncertainties, including those described below, which may have a material and adverse effect on our business, results of operations, cash flows, financial conditions, and the trading price of our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Annual Report on Form 10-K. If any of the following risks actually occur, our business,

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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 includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or 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 other product candidates that we may in-license, acquire or develop. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;

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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 provide assurances 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 biopharmaceutical company with a limited operating history upon which investors 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 $78.4 million, $31.9 million and $22.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of $161.0 million.

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

As of December 31, 2015, we had capital resources consisting of cash and cash equivalents and investments of $215.7 million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies, non-clinical 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

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reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates.

As of December 31, 2015, we believe that existing cash and cash equivalents and investments are sufficient to meet our anticipated cash requirements for at least the next 12 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Our currently anticipated expenditures for the development and potential commercialization of our lead product candidates, Cimzia, DRM04 and DRM01, exceed our existing cash and cash equivalents and investments. We will need to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities. We have substantial contractual obligations to UCB. In the event we are unable to raise sufficient capital to fund our development and commercialization obligations to UCB, we will face significant contractual liability.

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

- the timing, rate of progress and cost of any preclinical and clinical trials and other product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our product candidates in the United States and any foreign countries;
- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including post-grant challenges or opposition to third-party patent claims;
- costs associated with prosecuting or defending any litigation that we may become involved in and any damages payable by us that result from such litigation;

costs associated with any product recall that could occur;

costs of operating as a public company;

the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;

costs associated with any acquisition or in-license of products and product candidates, technologies or businesses; and

personnel, facilities and equipment requirements.

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

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

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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.

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

discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;

lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;

slower than expected rates of subject recruitment and enrollment rates in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, such as psoriasis, or clinical trials for indications for which patients do not as commonly seek treatment, such as hyperhidrosis;

difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;

difficulty in obtaining IRB approval for studies to be conducted at each site;

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delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;

inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;

changes in applicable laws, regulations and regulatory policies;

delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third-party contractors;

inability to add a sufficient number of clinical trial sites;

uncertainty regarding proper dosing;

failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;

failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;

scheduling conflicts with participating clinicians and clinical institutions;

failure to design appropriate clinical trial protocols;

inability or unwillingness of medical investigators to follow our clinical protocols;

difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or

insufficient data to support regulatory approval.

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.

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

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

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

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;

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- the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials, including the number of subjects in the safety database, sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;

- the FDA or the applicable foreign regulatory body may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;

- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other applicable regulatory filing;

- the FDA or the applicable foreign regulatory body may require additional preclinical studies or clinical trials;

- the FDA or the applicable foreign regulatory agency may identify deficiencies in the formulation, manufacturing, quality control, labeling or specifications of our current or future product candidates;

- the FDA or the applicable foreign regulatory agency may require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;

- the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials;

- the FDA or the applicable foreign regulatory agency also may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;

- the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;

- the FDA or the applicable foreign regulatory body may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract;

- the FDA or the applicable foreign regulatory body may not approve or grant marketing clearance of a device intended to be used in combination with our product candidates, such as an auto-injector with Cimzia; or

- 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 or DRM04. 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

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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 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 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 moderate-to-severe chronic plaque psoriasis and DRM04 for primary axillary 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

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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;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or REMS;
- the effectiveness of our sales, marketing and distribution efforts;

adverse publicity about our product candidates or favorable publicity about competitive products; and

potential product liability claims.

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

We are uncertain whether the market for injectable biologics for the treatment of moderate-to-severe plaque psoriasis, 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 chronic 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

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Enbrel. Even if approved for moderate-to-severe chronic 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, or OTC, 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. (a division of Johnson & Johnson), Johnson & Johnson, LEO Pharma A/S, Eli Lilly and Company, Maruho Co., Ltd., Merck & Co., Inc., Miramar Labs, Inc., Mitsubishi Tanabe Pharma Corporation, Mylan Inc., Novartis International AG, Pfizer Inc., Regeneron Pharmaceuticals, Inc., Revance Therapeutics, Inc., Takeda Pharmaceutical Company Limited, Teva Pharmaceutical Industries Ltd. and Valeant Pharmaceuticals International. The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Certain of our product candidates, if approved, would present novel therapeutic approaches for the approved indications and would 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. The competition we face could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

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

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Cimzia faces intense competition. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete.

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, which 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 OTC product is less effective than our product candidates, a less effective generic or OTC 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 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.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. The FDA approved the first biosimilar product in the United States in May 2015. In the European Union, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued since 2005. In January 2016, Samsung Bioepis was granted marketing approval by the European Commission for Benepali, an etanercept biosimilar referencing Enbrel, for the treatment of adults with moderate-to-severe rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. In addition, biosimilar product candidates in Phase 3 development by other companies include biosimilar versions of adalimumab, a biosimilar version of etanercept and biosimilar versions of infliximab. If Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis achieves regulatory approval, we expect competition from potential future biosimilars. We cannot predict to what extent the entry of biosimilars or other competing products will impact future sales of Cimzia. Such

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competition could lead to off-label use of the biosimilar for psoriasis or reduced market share and contribute to downward pressure on pricing and reduced profit margins.

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

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

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

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

Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review. Failure to comply with applicable regulatory requirements could have a material adverse impact on our business.

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

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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;
- 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.

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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, which would likely result in additional costs to us and delay our business plan.

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, our Phase 3 clinical programs for Cimzia and DRM04 are being conducted 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, any of which may adversely impact our business, financial condition, operating results and prospects.

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 chronic plaque psoriasis, we expect that regulatory authorities will require us to include the same box warning regarding increased risk of serious infections that may lead to hospitalization or death and a potential association with increased cancer risk in TNF inhibitors, of which Cimzia is one, that is currently included in labeling for Cimzia for the treatment of other indications. Results of clinical trials could reveal a high and unacceptable severity and prevalence of one or more of these side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. In addition, the FDA recently created a Tracked Safety Issue, or TSI, for all TNF inhibitors, including Cimzia, based on a potential signal of psychiatric and nervous system disorders including: anxiety, hallucination, paranoia, psychotic disorder, cognitive impairment, depression, and suicide/suicidal ideation. This TSI may have in 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

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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 provide assurances that our insurance coverage will be sufficient to cover our liability under any such cases.

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;

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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.

Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Although we have obtained product liability insurance coverage for clinical trials, 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 chronic plaque psoriasis, due to the design of our Phase 3 clinical trial comparing Cimzia to Enbrel, the prescribing information may not include data comparing the clinical performance of Cimzia and Enbrel and we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia to Enbrel in our marketing materials. Similarly, although our DRM04 product candidate, if approved, may appeal to individuals who have not been diagnosed with hyperhidrosis, we will only be able to promote DRM04 for its approved indication. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion.

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

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requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

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

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

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

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

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

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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 provide assurances that our product candidates will receive the requisite approvals for commercialization.

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

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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 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

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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.

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

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

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

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

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- 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

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respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

The manufacturing activities of our third-party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and

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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, which could have an adverse effect on our business.

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

Risks Related to Our Collaboration with UCB

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

If we consummate a change of control with a third party that is clinically developing or commercializing a biologic TNF inhibitor, UCB has the right to terminate the UCB agreement. If such termination occurs prior to the grant of regulatory approval for Cimzia for the treatment of psoriasis, we would be obligated to pay the remaining costs for which we would be responsible under the agreed development plan reduced by the amount of development milestone payments that would have been payable upon achievement of applicable development milestones if and when such milestones are achieved. This could make an acquisition of us by any such company economically unattractive,

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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 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 and any interruption in our product supply may cause serious delays in the timing of our clinical studies, increase our costs and adversely impact our financial results.

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

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

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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. If a third party claims that the intellectual property related to Cimzia infringes the intellectual property rights of such third party, we could be enjoined from performing our activities and/or exposed to substantial liability, either of which would have an adverse effect on our business.

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 provide assurances that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial

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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 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

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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 and manufacturers continue to improve production processes, certain aspects of which are complex and

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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 Chief Development Officer, 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.

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, adversely impacting our stock price.

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

delays in the commencement, enrollment and the timing of clinical testing for our product candidates;

the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;

any delays in regulatory review and approval of product candidates in clinical development;

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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;

our ability to establish and maintain collaborations, licensing or other arrangements;

our ability and third parties' abilities to protect intellectual property rights;

costs related to and outcomes of potential litigation or other disputes;

our ability to adequately support future growth;

our ability to attract and retain key personnel to manage our business effectively;

potential liabilities associated with hazardous materials;

our ability to maintain adequate insurance policies; and

future accounting pronouncements or changes in our accounting policies.

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

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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, 2015, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes of $142.0 million, $44.2 million and $3.9 million, respectively. If not utilized, the federal and California NOL carryforwards will begin expiring during the year ending December 31, 2030 and the Canadian NOL carryforwards will begin expiring during the year ending December 31, 2028. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have experienced at least one ownership change since inception and our utilization of NOL carryforwards will therefore be subject to annual limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

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.

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For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

Risks Related to Our Intellectual Property

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

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

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

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

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent

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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 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

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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 laws or the interpretations of patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

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. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

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

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

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

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

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

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

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

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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 example, any dispute with UCB relating to compliance with the terms of the UCB agreement 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. See also " Risks Related to Our Collaboration with UCB."

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 provide assurances that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

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

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

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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 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

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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 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 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 stockholders may not be able to resell their shares at or above the price at which they purchased the shares.

Prior to our initial public offering, or IPO, in October 2014, there had not been a public market for our common stock. 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;

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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;

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 SEC, and announcements relating to acquisitions, strategic transactions, licenses, joint ventures, capital commitments, intellectual property, litigation or other disputes impacting us or our business;

developments with respect to intellectual property rights;

our commencement of, or involvement in, litigation;

FDA or foreign regulatory actions affecting us or our industry;

changes in the structure of healthcare payment systems;

the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;

changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;

ratings downgrades by any securities analysts who follow our common stock;

the development and sustainability of an active trading market for our common stock;

the size of our market float;

the expiration of market standoff or contractual lock-up agreements and future sales of our common stock by our officers, directors and significant stockholders;

recruitment or departure of key personnel;

changes in accounting principles;

other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and

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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.

During the fiscal year ended December 31, 2015, the closing sale price of our common stock on The NASDAQ Global Select Market ranged from $14.34 to $35.42 per share. Because our stock price has been volatile, investing in our common stock is risky.

If a large number of shares of our common stock are sold in the public market, the sales could reduce the trading price of our common stock, impede our ability to raise future capital and holders may have difficulty selling their shares based on current trading volumes of our stock.

Our stock is currently traded on The NASDAQ Global Select Market, but we can provide no assurance that we will be able to maintain an active trading market on The NASDAQ Global Select Market or any other exchange in the future. The trading volume of our stock tends to be low and we have several stockholders who hold substantial blocks of our stock. As of December 31, 2015, we had 29,972,845 shares of common stock outstanding, and stockholders holding at least 10% of our stock, individually or with affiliated persons or entities, collectively beneficially owned or controlled approximately 43% of such shares. If stockholders holding substantial blocks of our shares sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline and our ability to raise future capital may be adversely affected. Moreover, if there is no active trading market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares.

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, we have furnished in this Annual Report on Form 10-K a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2015. However, for as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or 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

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emerging growth company for up to five years from the date of our IPO in October 2014. 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.

Risks associated with a company-wide implementation of an enterprise resource planning, or ERP, system may adversely affect our business and results of operations or the effectiveness of internal control over financial reporting.

We are implementing a company-wide ERP system to handle the business and financial processes within our operations and corporate functions. ERP implementations are complex and time-consuming projects that involve substantial expenditures on system software and implementation activities that can continue for several years. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system. Our business and results of operations may be adversely affected if we experience operating problems or cost overruns during the ERP implementation process, or if the ERP system and the associated process changes do not give rise to the benefits that we expect. If we do not effectively implement the ERP system as planned or if the system does not operate as intended, our business, results of operations, and internal controls over financial reporting may be adversely affected.

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 IPO 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.

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Future sales of our common stock or securities convertible into our common stock will result in additional dilution of the percentage ownership of our stockholders.

On November 2, 2015, we filed a shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to $300 million of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock and debt securities, subscription rights to purchase our common stock, preferred stock and debt securities, and units consisting of all or some of these securities. Our shelf registration statement was declared effective by the SEC on November 24, 2015. Up to $75 million of the maximum aggregate offering price of $300 million under the registration statement may be issued and sold pursuant to an "at-the-market" offering for sales of our common stock pursuant to a sales agreement between us and Cowen and Company, LLC, or Cowen. Subject to certain limitations in the sales agreement and compliance with applicable law, we have the discretion to deliver a sales notice to Cowen at any time throughout the term of the sales agreement, which has a term equal to the term of the registration statement on Form S-3 unless otherwise terminated earlier by us or Cowen pursuant to the terms of the sales agreement. The number of shares that are sold by Cowen after delivering a sales notice will fluctuate based on the market price of our common stock during the sales period and limits we set with Cowen. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible at this stage to predict the number of shares that will be ultimately issued. If we sell common stock, preferred stock, convertible securities and other equity securities in transactions pursuant to our shelf registration statement on Form S-3, existing investors may be materially diluted by such subsequent sales and new investors could gain rights superior to our existing stockholders.

Our directors and executive officers, together with their affiliates, will be able to exert significant influence over us and could impede a change of corporate control.

As of December 31, 2015, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 18% of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to exert significant influence on matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of us.

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

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

- our board of directors is classified into three classes of directors with staggered three-year terms, with directors removable from office only for cause, so that not all members of our board of directors are elected at one time;

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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 stockholders to elect directors of their choosing so as to cause us to take certain corporate actions they desire.

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

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

Because management has broad discretion as to the use of the net proceeds from our previous and future sales of securities, stockholders 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 our previous and future sales of securities and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock, or with which our stockholders otherwise disagree. 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. Pending their use, we may invest the net proceeds from our previous and future sales of securities in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

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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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease approximately 18,651 square feet of office space in Menlo Park, California. We will lease an additional three suites in the same building consisting of an additional 26,541 square feet of space, beginning December 2016. The term of the lease for our existing office space and the additional space expires in December 2021. We have an option to renew the lease for an additional five-year term to 2026. We use our current facilities for our research and development and general and administrative personnel. We believe that our existing facilities, together with additional space and facilities available on commercially reasonable terms, are sufficient for our current and near-term needs, and that our facilities are in good condition and are adequate and suitable for their purposes.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Price of Our Common Stock

Our common stock has been listed on The NASDAQ Global Select Market under the symbol "DERM" since October 3, 2014. Prior to that date, there was no public trading market for our common stock. Our initial public offering, or IPO, was priced at $16.00 per share on October 3, 2014. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Global Select Market:

	Low	High
Fiscal Year ended December 31, 2015		
Fourth Quarter	$ 22.39	$ 35.75
Third Quarter	17.50	32.13
Second Quarter	14.20	18.01
First Quarter	14.57	21.27
Fiscal Year ended December 31, 2014		
Fourth Quarter (beginning October 3, 2014)	$ 12.68	$ 22.94

On February 29, 2016, the last reported sale price of our common stock as reported on The NASDAQ Global Select Market was $23.06 per share.

Holders of our Common Shares

As of February 29, 2016, there were 29,972,845 shares of our common stock issued and outstanding with 27 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our available funds and future earnings, if any, will be used for the operation and growth of our business. Any future determination to declare cash dividends would be subject to the discretion of our board of directors and would depend upon various factors, including our results of operations, financial condition and capital requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

The information concerning our equity compensation plans required by this item is incorporated by reference herein to the section in the definitive Proxy Statement for our 2016 Annual Meeting of Stockholders entitled "Equity Compensation Plan Information."

Use of Proceeds from IPO

On October 2, 2014, the Securities and Exchange Commission, or SEC, declared our registration statement on Form S-1 (File No. 333-198410) effective for our IPO, which closed on October 8, 2014. The offering did not terminate before all of the securities registered in the registration statement were sold. Citigroup Global Markets Inc. and Leerink Partners LLC acted as joint book-running managers

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for the offering and Guggenheim Securities, LLC and Needham & Company, LLC acted as co-managers.

In conjunction with the IPO, we registered 7,812,500 shares of our common stock. All of the shares sold in our IPO were sold by us, at a price to the public of $16.00 per share. The aggregate public offering price of the offering amount registered was $125.0 million. As a result of our sale of 7,812,500 shares of our common stock in the IPO, we received net proceeds of $112.8 million, after deducting total expenses of $12.2 million, consisting of underwriting discounts and commissions of $8.7 million and offering-related expenses of $3.5 million. No payments were made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC on October 3, 2014 pursuant to Rule 424(b). Our management has broad discretion in the application of the net proceeds from the IPO and investors will be relying on the judgment of our management regarding the application of the proceeds.

Unregistered Sales of Equity Securities

We made no sales of unregistered securities during the quarter ended December 31, 2015 that we have not previously reported.

Issuer Purchases of Equity Securities

None.

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Stock Performance Graph

The following stock performance graph compares our total stock return with the total return for (1) The NASDAQ Composite Index and (2) The NASDAQ Biotechnology Index for the period from October 3, 2014 (the date our common stock commenced trading on The NASDAQ Global Select Market) through December 31, 2015. The figures represented below assume an investment of $100 in our common stock at the closing price of $15.55 on October 3, 2014 and in The NASDAQ Composite Index and The NASDAQ Biotechnology Index on October 3, 2014 and the reinvestment of dividends into shares of common stock; however, no dividends have been declared on our common stock to date. The comparisons in the table are required by the SEC, and are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing, except to the extent we specifically incorporate it by reference into such filing.

CUMULATIVE TOTAL RETURN

Among Dermira, Inc., The NASDAQ Composite Index
and The NASDAQ Biotechnology Index

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with the section of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015 and 2014 are derived from our audited financial statements included elsewhere in this report. The selected consolidated statements of operations data for the year ended December 31, 2012 and the selected consolidated balance sheet data as of December 31, 2013 and 2012 have been derived from our audited consolidated financial statements and accompanying notes that are not included in this Annual Report on Form 10-K. We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements.

	Year Ended December 31,			
	2015	2014	2013	2012
	(in thousands, except share and per share amounts)			
Collaboration revenue from a related party	$ 7,300	$ 7,300	$	$
Operating expenses:				
Research and development	66,831	30,710	17,937	17,055
General and administrative	17,721	8,288	4,366	3,148
Impairment of intangible assets	2,394			
Total operating expenses	86,946	38,998	22,303	20,203
Loss from operations	(79,646)	(31,698)	(22,303)	(20,203)
Interest and other income (expense), net	896	7	(38)	(51)
Interest expense	(147)	(153)	(9)	
Loss on extinguishment of debt	(124)			
Loss before taxes	(79,021)	(31,844)	(22,350)	(20,254)
(Benefit) provision for income taxes	(622)	31		
Net loss	$ (78,399)	$ (31,875)	$ (22,350)	$ (20,254)
Net loss per share, basic and diluted(1)	$ (2.93)	$ (4.96)	$ (27.03)	$ (27.99)
Weighted-average common shares used to compute net loss per share, basic and diluted	26,727,392	6,426,022	826,757	723,607

(1) Per share information presented in the above four-year summary has been adjusted to reflect the 5.8-for-1 reverse stock split of each share of our outstanding capital stock on September 18, 2014.

	As of December 31,		
2015	2014	2013	2012
	(in thousands)		

Consolidated Balance Sheet Data:				
Cash and cash equivalents and short-term investments	$ 214,693	$ 97,151	$ 22,144	$ 7,872
Working capital	191,337	93,573	17,973	3,647
Long-term investments	1,019	66,483		
Total assets	221,932	178,221	26,871	12,514
Convertible preferred stock			59,588	35,089
Additional paid-in capital	346,590	236,414	970	678
Accumulated deficit	(161,048)	(82,649)	(50,774)	(28,424)
Total stockholders' equity (deficit)	185,475	153,579	(49,803)	(27,745)

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2015, included elsewhere in this Form 10-K for the year ended December 31, 2015 and other disclosures (including the disclosures under "Part I Item 1A. Risk Factors") included in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "potential," "predict," "project," "estimate," or "continue," and similar expressions or variations. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Factors that could cause or contribute to these differences include those set forth elsewhere in this report, particularly in Part I Item 1A. Risk Factors, that could cause actual results to differ materially from historical results or anticipated results. Except as may be required by law, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. Our management team has extensive experience in product development and commercialization, having served in leadership roles at several leading dermatology companies. Our portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or acne.

Since our founding in 2010, we have executed three transactions resulting in our portfolio of product candidates. In August 2011, we acquired Valocor Therapeutics, Inc., which gave us rights to a portfolio of intellectual property and product candidates to treat acne and inflammatory skin diseases. In April 2013, we entered into agreements with Rose U LLC and Stiefel Laboratories, Inc., a GSK company, or Stiefel, to obtain rights to intellectual property related to DRM04 for the treatment of hyperhidrosis. In March 2014, we entered into an agreement to collaborate with UCB to develop and commercialize Cimzia in dermatology.

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 in multiple countries, including the United States. In March 2014, we entered into a development and commercialization agreement with UCB to develop Cimzia for the treatment of moderate-to-severe chronic 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. We commenced a Phase 3 clinical program for Cimzia in moderate-to-severe chronic plaque psoriasis in December 2014. We completed enrollment in the three clinical trials comprising the Phase 3 program in September 2015, November 2015 and December 2015 and expect to announce topline results from these trials by the end of the first quarter of 2017.

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DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of primary axillary hyperhidrosis. 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 U.S. Food and Drug Administration, or FDA, in April 2015, we commenced a Phase 3 clinical program in patients with primary axillary hyperhidrosis in July 2015. We completed enrollment in the two pivotal clinical trials comprising the Phase 3 program in February 2016 and expect to announce topline results from these trials in the second quarter of 2016.

DRM01, a novel, topical, small-molecule sebum inhibitor we are developing for the treatment of acne. 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 study in April 2015. We completed enrollment in the clinical trial comprising the Phase 2b program in January 2016 and we expect to announce topline results from this trial in the second quarter of 2016.

Key Developments

Following is a summary of selected key developments affecting our business that have occurred since December 31, 2014.

Completed patient enrollment for DRM04 Phase 3 pivotal clinical trials in patients with hyperhidrosis. In February 2016, we completed patient enrollment in the ATMOS-1 and ATMOS-2 Phase 3 pivotal clinical trials of DRM04 in patients with primary axillary hyperhidrosis.

Completed patient enrollment for Cimzia Phase 3 clinical program in patients with psoriasis. In September 2015, November 2015 and December 2015, we completed patient enrollment in the global CIMPASI-2, CIMPASI-1 and CIMPACT Phase 3 clinical trials of Cimzia, respectively, in patients with moderate-to-severe chronic plaque psoriasis. Completion of patient enrollment for the CIMPASI-2 clinical trial in September 2015 triggered a milestone payment of $7.3 million to us by UCB.

Completed patient enrollment for DRM01 Phase 2b clinical program in patients with acne. In January 2016, we completed enrollment in the DRM01 Phase 2b clinical trial.

Presented Phase 2a clinical results for DRM01 in patients with acne. In October 2015, June 2015 and March 2015, data were presented from our 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial, demonstrating statistical significance for DRM01 versus vehicle in the study's primary efficacy endpoints.

Closed follow-on public offering of common stock. In August 2015, we closed an underwritten follow-on public offering, or Follow-on Offering, of 5,175,000 shares of our common stock sold by us, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price to the public of $21.50 per share. The gross proceeds to us from the Follow-on Offering were $111.3 million, and the net proceeds to us after deducting underwriting discounts and commissions of $6.7 million and offering expenses of approximately $0.6 million were approximately $104.0 million.

Initiated Phase 3 program for DRM04 in patients with 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 designed to enroll 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 submission to the FDA. The Phase 3 program also includes an open-label study, ARIDO, assessing the long-term safety of DRM04.

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Completed end-of-Phase 2 meeting for DRM04. In April 2015, we held an end-of-Phase 2 meeting with the FDA based on the results of our Phase 2 program and in advance of the initiation of our Phase 3 program.

Initiated 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, designed to enroll approximately 400 patients, for DRM01 in patients with facial acne. 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.

Achieved positive Phase 2b results for DRM04 in hyperhidrosis. In February 2015, we announced positive Phase 2b study results for DRM04 in patients with primary axillary hyperhidrosis.

Initiated Phase 3 program for Cimzia, with UCB, in psoriasis. In January 2015, we and UCB announced that the first patients had been dosed in the Phase 3 clinical program designed to evaluate the efficacy and safety of Cimzia in adult patients with moderate-to-severe chronic plaque psoriasis. The Cimzia Phase 3 clinical program consists of three studies, CIMPASI-1, CIMPASI-2 and CIMPACT, designed to enroll a total of approximately 1,000 patients.

Financial Overview

For the year ended December 31, 2015, net loss increased 146% to $78.4 million from $31.9 million for 2014. We recognized collaboration revenue from UCB, a related party, of $7.3 million for each of the years ended December 31, 2015 and 2014 for the achievement of two separate substantive milestones pursuant to our agreement with UCB. Research and development expenses increased 118% to $66.8 million for the year ended December 31, 2015 compared to 2014 due primarily to the advancement of our product candidates. General and administrative expenses increased 114% to $17.7 million for the year ended December 31, 2015 compared to 2014, driven by headcount growth and incentive compensation expenses, as well as public company costs following our initial public offering, or IPO, in October 2014. We also recorded an impairment charge of $2.4 million against certain intangible assets for the year ended December 31, 2015 as a result of the discontinuation of two early-stage research and development programs.

As of December 31, 2015, we had cash and cash equivalents and investments of $215.7 million.

Since our inception, we have devoted substantially all of our efforts to developing our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. We have financed our operations primarily through the sale of equity securities and convertible debt securities, including the sale of common stock in our IPO and Follow-on Offering. We do not have any approved products and have never generated any revenue from product sales. Other than the revenue we may generate in connection with our agreements with UCB and Maruho Co., Ltd., we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaboration agreements with third parties for the development or license of those product candidates.

We have never been profitable and may never be profitable. As of December 31, 2015, we had an accumulated deficit of $161.0 million. We incurred net losses of $78.4 million, $31.9 million and $22.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. We expect to continue to incur net losses for the foreseeable future as we advance our current and potential additional product candidates through clinical development, seek regulatory approval for them and prepare for and proceed to commercialization. We expect to incur significant commercialization costs in advance of any of our product candidates receiving regulatory approval. As a result, we will need

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substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential collaboration or licensing agreements. Our failure to obtain sufficient funds on acceptable terms as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Results of Operations

	Year Ended December 31,			Change from 2014 to 2015		Change from 2013 to 2014	
	2015	2014	2013	$	%	$	%
	(in thousands, except percentages)						
Collaboration revenue from a related party	$ 7,300	$ 7,300	$	$	*	$ 7,300	*
Operating expenses:							
Research and development	66,831	30,710	17,937	36,121	118%	12,773	71%
General and administrative	17,721	8,288	4,366	9,433	114	3,922	90
Impairment of intangible assets	2,394			2,394	*		
Total operating expenses	86,946	38,998	22,303	47,948	123	16,695	75
Loss from operations	(79,646)	(31,698)	(22,303)	(47,948)	151	(9,395)	42
Interest and other income (expense), net	896	7	(38)	889	*	45	*
Interest expense	(147)	(153)	(9)	6	(4)	(144)	*
Loss on extinguishment of debt	(124)			(124)	*		*
Loss before taxes	(79,021)	(31,844)	(22,350)	(47,177)	148	(9,494)	42
(Benefit) provision for income taxes	(622)	31		(653)	*	31	*
Net loss	$ (78,399)	$ (31,875)	$ (22,350)	$ (46,524)	146%	$ (9,525)	43%

* Percentage not meaningful

Revenue. Revenue consists of collaboration revenue for the achievement of development milestones pursuant to our development and commercialization agreement with UCB, a related party. Under the UCB agreement, we may generate revenue from development-, regulatory- and sales-based milestone payments and royalties. Under our Right of First Negotiation Agreement with Maruho Co., Ltd., or Maruho, if we enter into an exclusive license to develop and commercialize any of our product candidates with Maruho, we may generate license revenue. Other than the revenue we may generate in connection with these agreements, we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaborative agreements with third parties.

During the years ended December 31, 2015 and 2014, we recognized collaboration revenue from a related party of $7.3 million per year for milestone achievements pursuant to our agreement with UCB, specifically the completion of patient enrollment in the first Phase 3 clinical trial for Cimzia in September 2015 and the dosing of the first patient in the Phase 3 program for Cimzia in December 2014.

We did not recognize any revenue for the year ended December 31, 2013.

Research and Development. Research and development expenses include external costs incurred for the development of our product candidates, including third-party expenses necessary for conducting clinical studies and costs to develop and manufacture clinical trial supplies, and internal expenses consisting primarily of salaries and related costs, including stock-based compensation, for personnel in

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our research and development functions. We track external research and development costs incurred for each of our product candidates. We do not track our internal research and development costs by product candidate, as these costs are typically spread across multiple product candidates. We expense research and development expenses to operations as they are incurred.

The following table summarizes our research and development expenses incurred during the respective periods:

	Phase of Development as of December 31, 2015	Year Ended December 31,			$ Change from 2014 to 2015	$ Change from 2013 to 2014
		2015	2014	2013		
		(in thousands)				
External costs incurred by product candidate:						
Cimzia(1)	Phase 3	$ 25,827	$ 5,629	$	$ 20,198	$ 5,629
DRM04(2)	Phase 3	16,444	10,294	3,809	6,150	6,485
DRM01(3)	Phase 2b	9,499	3,286	2,988	6,213	298
Other research and development expenses(4)		259	3,143	6,328	(2,884)	(3,185)
Internal costs		14,802	8,358	4,812	6,444	3,546
Total research and development expenses		$ 66,831	$ 30,710	$ 17,937	$ 36,121	$ 12,773

(1) We acquired the rights to develop Cimzia under our collaboration agreement with UCB in March 2014 and commenced a Phase 3 clinical program in December 2014.

(2) In July 2015, we commenced a Phase 3 clinical program for DRM04.

(3) In April 2015, we commenced a Phase 2b clinical program for DRM01.

(4) Amount consists of costs for early-stage product candidates.

Research and development expenses increased $36.1 million, or 118%, for the year ended December 31, 2015 compared to the year ended December 31, 2014. This increase was due to a $32.6 million increase in external costs to advance our Cimzia, DRM04, and DRM01 product candidates and a $6.4 million increase in internal costs related primarily to headcount growth and incentive compensation expenses. These increases in research and development expenses were partially offset by a $2.9 million decrease in external costs associated with our early-stage product candidates.

Research and development expenses increased $12.8 million, or 71%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. This increase was primarily due to a $12.1 million increase in external costs to advance our DRM04 and Cimzia product candidates and a $3.5 million increase in internal costs related primarily to headcount growth and incentive compensation expenses. These increases in research and development expenses were partially offset by a $3.2 million decrease in external costs associated with our early-stage product candidates.

We expect our research and development expenses to increase as we continue development of our product candidates. The timing and amount of expenses incurred will depend largely upon the outcomes of current or future clinical studies for our product candidates as well as the related regulatory requirements and manufacturing costs.

General and Administrative. General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in our general and administrative

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functions. Other general and administrative expenses include professional fees for audit, tax, legal, market research and commercial planning services.

General and administrative expenses increased $9.4 million, or 114%, for the year ended December 31, 2015 compared to the year ended December 31, 2014. This increase was primarily due to a $5.5 million increase in personnel-related expenses resulting from headcount growth and incentive compensation expenses, a $2.3 million increase in public company costs following our IPO in October 2014 and a $2.2 million increase in market research and planning expenses. These increases in general and administrative expenses were partially offset by $0.8 million of legal and consulting fees incurred in 2014, but not in 2015, for the evaluation, due diligence and negotiations associated with the UCB collaboration transaction.

General and administrative expenses increased $3.9 million, or 90%, for the year ended December 31, 2014 compared to the year ended December 31, 2013. This increase reflects a $2.7 million increase in personnel-related expenses due to increased headcount and incentive compensation expenses, $0.8 million of legal and consulting services incurred in the evaluation, due diligence and negotiations associated with the UCB collaboration transaction in the first quarter of 2014 and a $0.6 million increase in audit and accounting consultation expenses. These increases in general and administrative expenses in 2014 were partially offset by a transaction advisory fee of $0.5 million incurred in 2013, but not in 2014, in connection with the agreement we entered into with Maruho.

We expect our general and administrative expenses to increase substantially in the future as we expand our operating activities and prepare for potential commercialization of our product candidates, increase our headcount, and support our operations as a public company.

Impairment of Intangible Assets. In December 2015 and February 2016, we received the results from certain research and development experiments related to our DRM05 and DRM02 early-stage product candidates, respectively. Based on the results of these experiments, we made the decision to discontinue further efforts on these programs. As a result, we recorded a corresponding impairment charge of $2.4 million against certain intangible assets for the year ended December 31, 2015 in the consolidated statement of operations.

No impairment charge was recorded during the years ended December 31, 2014 and 2013.

Interest and Other Income (Expense), Net. Interest and other income (expense), net increased $0.9 million for the year ended December 31, 2015 compared to the year ended December 31, 2014, primarily due to an increase in interest income earned from our cash equivalents and investments.

Interest and other income (expense), net was constant for the year ended December 31, 2014 compared to the year ended December 31, 2013 and the amount was insignificant in both periods.

Interest Expense. Interest expense remained constant for the year ended December 31, 2015 compared to the year ended December 31, 2014 and included interest incurred on the borrowings of $2.0 million under a bank term loan entered into in December 2013. The loan was fully repaid in December 2015.

Interest expense increased $0.1 million for the year ended December 31, 2014 compared to the year ended December 31, 2013 due to a full year of interest incurred on borrowings of $2.0 million under the bank term loan in 2014.

Loss on Extinguishment of Debt. In December 2015, we repaid the outstanding balance of $2.0 million under our bank term loan. In connection with this transaction, we recorded a loss on extinguishment of debt of $0.1 million to account for the portion of the unamortized final payment fee, offset by the write-off of the remaining debt discount.

There was no extinguishment of debt for the years ended December 31, 2014 or 2013.

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(Benefit) Provision for Income Taxes. The $0.6 million benefit for income tax in 2015 relates to the decrease in deferred tax liability resulting from the impairment charge recorded during the year. The deferred tax liability was originally established for the book-tax differences related to the indefinitely lived intangible assets at the time of Valocor acquisition in 2011. The provision for income tax in 2014 relates to an increase in the deferred tax liability of our Canadian subsidiary as a result of a change in the Canadian corporate tax rate.

No provision was recorded in 2013.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the issuance and sale of equity securities and convertible debt securities.

On August 11, 2015, we closed an underwritten Follow-on Offering of 5,175,000 shares of our common stock, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price to the public of $21.50 per share. The gross proceeds to us from the Follow-on Offering were $111.3 million, and the net proceeds to us, after deducting underwriting discounts and commissions of $6.7 million and offering expenses of approximately $0.6 million, were approximately $104.0 million.

On November 2, 2015, we filed a shelf registration on Form S-3 with the SEC for the issuance and sale of up to an aggregate offering of $300 million of shares of our common stock, preferred stock, debt securities, warrants to purchase our common stock, preferred stock or debt securities, subscription rights to purchase our common stock, preferred stock or debt securities, and/or units consisting of some or all of these securities. The shelf registration also provides that we may issue and sell up to an aggregate offering of up to $75 million of our common stock through an at-the-market sales agreement with Cowen and Company. As of December 31, 2015, no sales had been made under this facility, and $75 million of common stock remained available to be sold, subject to certain conditions as specified in the agreement.

As of December 31, 2015, we had $215.7 million of cash and cash equivalents and investments. Our cash and cash equivalents and investments are held in a variety of interest-bearing instruments, including money market funds, repurchase agreements and corporate debt. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Our primary use of cash is to fund our operating expenses. As of December 31, 2015, we had an accumulated deficit of $161.0 million. We expect to incur additional losses in the future as we conduct research and development and pre-commercialization activities, and potential commercialization and marketing activities, and to support the administrative and reporting requirements of a public company.

Cash Flows

The following table shows a summary of our cash flows for each of the years ended December 31, 2015, 2014 and 2013 (in thousands):

	2015	2014	2013
Net cash (used in) provided by:			
Operating activities	$ (48,442)	$ (31,404)	$ (12,157)
Investing activities	(2,603)	(109,480)	(50)
Financing activities	102,929	174,098	26,479
Net increase in cash and cash equivalents	$ 51,884	$ 33,214	$ 14,272

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Operating Activities. Net cash used in operating activities was $48.4 million for the year ended December 31, 2015 and consisted primarily of our net loss of $78.4 million, partially offset by $9.7 million in non-cash charges and a $20.2 decrease in net operating assets. Non-cash charges included $5.1 million of stock-based compensation expense, $2.4 million of impairment charge against certain intangible assets and $2.0 million of amortization of premiums on available-for-sale securities. The decrease in net operating assets was driven primarily by a $10.4 million increase in accrued liabilities, a $7.3 million decrease in collaboration receivable from a related party and a $3.6 million increase in accounts payable, partially offset by a $1.2 million increase in prepaid expenses and other current assets.

Net cash used in operating activities was $31.4 million for the year ended December 31, 2014 and consisted primarily of our net loss of $31.9 million and a $1.5 million increase in net operating assets, partially offset by $2.0 million in non-cash charges. Non-cash charges consisted primarily of $1.6 million of stock-based compensation expense. The increase in net operating assets was driven primarily by an increase in collaboration receivable from a related party of $7.3 million associated with our collaboration revenue earned under the UCB agreement and a $1.8 million increase in prepaid expenses and other assets as a result of higher prepaid directors and officers insurance and higher accrued interest associated with our investments and restricted cash associated with our building lease agreement, partially offset by $4.3 million and $3.2 million increases in accrued liabilities and accounts payable, respectively. The increases in accounts payable and accrued liabilities were primarily due to higher research and development costs and employee compensation accruals.

Net cash used in operating activities was $12.2 million for the year ended December 31, 2013 and consisted primarily of our net loss of $22.4 million, partially offset by $0.3 million in non-cash charges and a $9.9 million decrease in net operating assets. Non-cash charges included $0.3 million of stock-based compensation expense. The decrease in net operating assets was driven primarily by a $10.0 million increase in deferred revenue related to our agreement with Maruho.

Investing Activities. Net cash used in investing activities for the year ended December 31, 2015 was $2.6 million, which resulted primarily from purchases of investments of $60.3 million, partially offset by proceeds from maturities of investments of $57.9 million.

Net cash used in investing activities for the year ended December 31, 2014 was $109.5 million primarily due to purchases of investments from the proceeds received in our IPO and private placement in October 2014.

Net cash used in investing activities for the years ended December 31, 2013 was $50,000. The amounts were for purchases of property and equipment.

Financing Activities. Net cash provided by financing activities was $102.9 million for the year ended December 31, 2015 and consisted primarily of $104.0 million of net proceeds from the sale of our common stock in our Follow-on Offering in August 2015, partially offset by $2.1 million from the repayment of our bank term loan.

Net cash provided by financing activities of $174.1 million for the year ended December 31, 2014 was primarily due to net proceeds of $112.8 million and $7.5 million from the sale of common stock in our IPO and concurrent private placement, respectively, in October 2014, $48.8 million from the sale of our Series C convertible preferred stock in August 2014 and $5.0 million from the sale of our Series B convertible preferred stock in April 2014.

Net cash provided by financing activities was $26.5 million for the year ended December 31, 2013 and consisted primarily of the net proceeds of $24.5 million from the sale of our Series B convertible preferred stock in March 2013 and borrowings of $2.0 million under our bank term loan.

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Operating and Capital Expenditure Requirements

We have incurred losses since our inception and anticipate that we will continue to generate losses for the foreseeable future. We expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. We believe that existing cash and cash equivalents and investments on hand as of December 31, 2015 are sufficient to meet our anticipated cash requirements through 2017. However, we expect we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. We cannot ensure that additional financing will be available to us in the amounts we need or that such financing will be available on terms acceptable to us, if at all. 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 other aspects of our business plan or relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available, any of which could have a material adverse effect on our business, results of operations and financial condition. Please see "Risk Factors" for additional risks associated with our substantial capital requirements.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2015:

	Payment Due by Period				
	Total	Less than One Year	1 - 3 Years	3 - 5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations(1)	$ 16,083	$ 1,213	$ 5,439	$ 6,200	$ 3,231
Total Contractual obligations	$ 16,083	$ 1,213	$ 5,439	$ 6,200	$ 3,231

(1) Operating lease obligations include total future minimum rent payments, assuming we do not exercise our termination option, under an operating lease agreement dated July 4, 2014, as amended, for our facilities in Menlo Park, California December 4, 2015. See Note 9 to our consolidated financial statements for further details regarding the terms of our lease agreement.

Pursuant to the UCB agreement, we are responsible for paying all development costs specified under the UCB agreement and incurred in connection with the development plan up to a specified amount greater than $75.0 million and less than $95.0 million, plus our internal development costs. Development costs include the costs of Cimzia and etanercept clinical trial materials used in the Phase 3 clinical program. UCB is responsible for providing these clinical trial materials and we reimburse UCB for such costs. Any development costs in excess of $95.0 million or for any required clinical trials in pediatric patients will be shared equally. Development costs for any EMA-specific post-approval studies will be borne solely by UCB. UCB is obligated to pay us up to an aggregate of $36.0 million if certain development milestones are met, and up to an additional aggregate of $13.5 million upon the grant of regulatory approval, including pricing and reimbursement approval, in certain European countries. To date, we have received two payments of $7.3 million each from UCB for the achievement of two development milestones: the dosing of the first patient in the Phase 3 program for Cimzia, which occurred in December 2014, and the completion of patient enrollment in

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the CIMPASI-2 clinical trial, which occurred in September 2015. We are eligible to receive up to $21.4 million in remaining development milestone payments.

Per the terms of our agreement with our CRO for the Cimzia Phase 3 program, or the Cimzia CRO, the Cimzia CRO can earn bonus payments or incur penalties (which are adjusted from the total amount payable pursuant to the agreement) based on the achievement of milestones specified in the agreement. The Cimzia CRO can earn a maximum aggregate bonus of $3.6 million and incur a maximum aggregate penalty of $3.2 million. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, we would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup the applicable amount if it achieves a subsequent milestone, and the Cimzia CRO would adjust subsequent billings as necessary to reflect such penalty and any recouped amount. If the Cimzia CRO incurs a penalty prior to the expiration of the right of recoupment, we would maintain the full amount owed to the Cimzia CRO in accrued liabilities in our consolidated balance sheet until (1) the right of recoupment has expired, at which time we would reflect the amount as a reduction in operating expenses and eliminate the liability, or (2) the Cimzia CRO has recouped the penalty, at which time we would increase the payment to the Cimzia CRO by the recouped amount and eliminate the liability. These amounts are not included in the table above.

In addition, we have certain obligations under licensing agreements with third parties contingent upon achieving various development, regulatory and commercial milestones. Pursuant to our license agreement with Rose U and related agreement with Stiefel with respect to our DRM04 product candidate, we are required to pay additional amounts totaling up to $4.4 million upon the achievement of specified development, commercialization and other milestones under these agreements. In addition, we are obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments we are obligated to pay Rose U directly upon the events or sales triggering such payments. These amounts are not included in the table above.

Segment Information

We have one primary business activity and operate in one reportable segment.

Loan and Security Agreement

In December 2013, we entered into a loan and security agreement, or the Loan Agreement, with Square 1 Bank, or the Bank, which provided for two term loans available to us: $2.0 million under the first term loan, or Term Loan A, and $5.5 million under the second term loan, or Term Loan B. Borrowings under the term loans bore interest at a rate equal to the greater of: (1) 5.10% above the treasury rate in effect on the date that a term loan was funded; or (2) 5.50%, which rate was fixed on the date of funding of the term loan. We had the option to prepay borrowings without paying a penalty or premium.

On the closing date of the Loan Agreement, we borrowed $2.0 million under Term Loan A. The amount borrowed under Term Loan A had a maturity date in December 2018 and was secured by all of our assets other than our intellectual property, subject to certain limited exceptions, and bore interest at a rate of 5.77% per annum. In December 2015, we repaid Term Loan A in full and we recorded a loss on the extinguishment of debt of $0.1 million.

There were no amounts borrowed under Term Loan B. Our ability to borrow funds under Term Loan B expired on September 30, 2015.

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As a result of our repayment in full of Term Loan A in December 2015, our Loan Agreement terminated and we have no continuing obligations or liens related to the Loan Agreement.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. The JOBS Act permits us, as an emerging growth company, to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies and thereby allows us to delay the adoption of those standards until those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Critical Accounting Polices and Significant Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses and related disclosures. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. In many instances, we could have reasonably used different accounting estimates, and in other instances changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ significantly from management's estimates. To the extent that there are material differences between these estimates and actual results, our future consolidated financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are described in the notes to our consolidated financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported consolidated financial results, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We generate revenue from activities under our collaboration agreement with UCB, a related party, for the development and commercialization of one of our product candidates. All revenue recognized to date under the agreement with UCB is non-refundable.

Collaboration and license agreements may include non-refundable upfront payments or partial reimbursement of research and development costs, contingent consideration payments based on the achievement of defined milestones and royalties on sales of commercialized products. Performance obligations under the collaboration include the transfer of intellectual property rights, such as licenses, obligations to provide research and development services, obligations to provide regulatory approval services and obligations to participate on certain development and/or commercialization committees with the collaborators. Upfront payments are recorded as deferred revenue in the consolidated balance sheet and are recognized as collaboration revenue over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the collaboration agreement. We regularly review the estimated periods of performance related to our collaborations based on the progress made under the arrangement. The estimated performance period may change over the course of the collaboration term. Such a change could have a material impact on the amount

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of revenue recorded in future periods. We recognize revenue when: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Payments received in advance of work performed are recorded as deferred revenue and recognized when earned.

Multiple Element Arrangements

We evaluate revenue from our agreement with UCB to determine whether the components of the arrangement represent separate units of accounting. We consider whether components of an arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer. Factors considered include whether the deliverable is proprietary to us, whether the customer can use the license or other deliverables for its intended purpose without the receipt of the remaining elements and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. To date, our agreement with UCB has two deliverables that represent two units of accounting, which are (1) the delivery of services related to the development of Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis and (2) the marketing services needed to commercialize Cimzia in the United States and Canada. At the date of the execution of this arrangement, potential future payments eligible to be received upon the achievement of development and regulatory milestones were all considered to be substantive. As such, payments will be recognized in their entirety in the period in which the milestone event is achieved and collectability is reasonably assured. Royalties and sales-based milestone payments will be recognized as revenue when earned and realizable. Non-refundable fees for which we have no continuing performance obligations are recognized as revenue when collection is reasonably assured and all other revenue recognition criteria have been met.

Milestone and Other Contingent Payments

We have adopted the milestone method as described in Accounting Standards Codification ("ASC") 605-28, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone will be recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (1) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved; (2) the event can only be achieved based in whole or in part on either the company's performance or a specific outcome resulting from the company's performance; and (3) if achieved, the event would result in additional payments being due to the company. Contingent payments which do not meet the definition of a milestone are recognized in the same manner as the consideration for the combined unit of accounting. If we have no remaining performance obligations under the combined unit of accounting, any contingent payments would be recognized as revenue upon the achievement of the triggering event.

Our agreement with UCB provides for payments to be paid to us upon the achievement of development, regulatory and sales milestones. Given the challenges inherent in developing biologic products, there was substantial uncertainty as to whether any such milestones would be achieved at the time the agreement was executed. We evaluate whether the development and regulatory milestones meet all of the conditions to be considered substantive. The conditions include: (1) the consideration is commensurate with either of the following: (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (2) the consideration relates solely to past performance; and (3) the consideration is reasonable relative to all the deliverables and payment

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terms within the arrangement. Substantive milestones are recognized as revenue upon achievement of the milestone and when collectability is reasonably assured.

Accrued Research and Development Expenses

We record accruals for estimated costs of research, preclinical, non-clinical and clinical studies and manufacturing development, which are a significant component of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers, including CROs. Our contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. We accrue the costs incurred under agreements with these third parties based on actual work completed in accordance with the respective agreements. In certain cases, we can be financially responsible for unused drug supplies remaining at study sites at the conclusion of a study. We accrue for the potential amounts due if they are both probable and estimable. In the event we make advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

The Cimzia CRO can earn bonuses or incur penalties based on the Cimzia CRO's achievement of certain milestones specified in the agreement. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, we would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup such penalty if it achieves a subsequent milestone. In this case, we would continue to maintain the full amount owed to the Cimzia CRO until the right of recoupment has expired.

We make significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different from amounts actually incurred, the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. To date, there have been no material differences between our accrued estimated expenses and the actual clinical trial expenses. However, variations in the assumptions used to estimate accruals, including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our consolidated financial condition and results of operations.

Stock-Based Compensation

We maintain an equity incentive plan under which incentive stock options may be granted to employees, and nonqualified stock options, restricted stock awards, restricted stock units and stock appreciation rights may be granted to employees, officers, directors, consultants and advisors. In addition, we maintain an employee stock purchase plan under which employees may purchase shares of the Company's common stock through payroll deductions.

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures, using the Black-Scholes option pricing model. The grant date fair value of the stock-based awards is recognized over

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the requisite service period, which is generally the vesting period of the respective awards. Stock-based compensation expenses are classified in the consolidated statements of operations and comprehensive loss based on the functional area to which the related recipients belong.

We estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of the employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2015	2014	2013
Expected term (years)	6.1	6.0	6.1
Expected volatility	64.1%	66.0%	76.0%
Risk-free interest rate	1.9%	1.9%	1.3%
Expected dividend rate	0.0%	0.0%	0.0%

The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions that determine the fair value of options. These assumptions are as follows:

Expected term: We determine the expected term using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected volatility: Prior to our IPO, our common stock had never been publicly traded. The expected volatility was derived from the average historic volatilities of several unrelated public companies within our industry that we considered to be comparable to our business over a period equivalent to the expected term of the option. As a public company, we will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

Risk-Free Interest Rate: We determine the risk-free interest rate based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

Expected Dividend Rate: We have never paid any dividends and do not anticipate paying any dividends in the foreseeable future, and therefore, have used an expected dividend rate of zero in the valuation model.

In addition to the assumptions used in the Black-Scholes option pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation for our options. Our forfeiture rate is based on an analysis of our actual forfeitures. We will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover and other factors. Quarterly changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation as the cumulative effect of adjusting the rate is recognized in the period in which we change the forfeiture estimate. If a revised forfeiture rate is higher than the previously estimated forfeiture rate, we make an adjustment that will result in a decrease to the stock-based compensation recognized in our consolidated financial statements. If a revised forfeiture rate is lower than the previously estimated forfeiture rate, we make an adjustment that will result in an increase to the stock-based compensation recognized in our consolidated financial statements.

We will continue to use judgment in evaluating the expected term, expected volatility and forfeiture rate related to our stock-based compensation calculations on a prospective basis. As we continue to accumulate additional data related to our common stock, we may make refinements to the estimates of our expected terms, expected volatility and forfeiture rates that could materially impact our future stock-based compensation.

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Impairment of Long-Lived Assets

We assess changes in the performance of our product candidates in relation to our expectations, and industry, economic, and regulatory conditions and make assumptions regarding estimated future cash flows in evaluating the value of our property and equipment, goodwill and in-process research and development, or IPR&D.

We periodically evaluate whether current facts or circumstances indicate that the carrying values of our long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets is compared to the carrying value to determine whether impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, we will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of the net assets acquired in connection with the acquisition of Valocor. We test goodwill for impairment on an annual basis as of October of each year, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the goodwill is less than its carrying amount. Some of the factors considered in the assessment include general macro-economic conditions, conditions specific to the industry and market, and the successful development of our product candidates. If we conclude it is more likely than not that the fair value of the goodwill is less than its carrying amount, a quantitative fair value test is performed.

IPR&D represents the fair value assigned to incomplete research projects that we acquired through the acquisition of Valocor which, at the time of acquisition, had not reached technological feasibility. The amount was capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the project. We test IPR&D for impairment annually as of October of each year, or more frequently, if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed.

We discontinued two early-stage in-process research and development programs, DRM05 and DRM02, which were acquired in the 2011 Valocor acquisition and recorded a corresponding impairment charge of $2.4 million against certain intangible assets for the year ended December 31, 2015 in the consolidated statements of operations.

Deferred Tax Assets and Liabilities and Uncertain Tax Positions

We use the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. We establish a valuation allowance when necessary to reduce deferred tax assets to the amount we expect to be realizable. Financial statement effects of uncertain tax positions are recognized when it is more likely than not, based on the technical merits of the position, that they will be sustained upon examination. If the tax positions are not more likely than not to be sustained upon examination, we record reserves against those positions. Interest and penalties related to unrecognized tax benefits are included within our provision for income tax.

As of December 31, 2015, we had net operating loss, or NOL, carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes of

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$142.0 million, $44.2 million and $3.9 million, respectively. Of these amounts, $0.5 million and $0, respectively, represent federal and state tax deductions from stock-based compensation that will be recorded as an adjustment to additional paid-in capital when such amounts reduce taxes payable. The federal and California NOL carryforwards will begin expiring during the year ended December 31, 2030 and the Canadian NOL carryforwards will begin expiring during the year ended December 31, 2028. The NOL carryforwards related to deferred tax assets do not include excess tax benefits from employee stock option exercises.

As of December 31, 2015, we also had research and development credit carryforwards of $0.8 million, $0.8 million and $0.6 million available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes, respectively. The federal and Canadian credit carryforwards will begin expiring in 2031 and the California state credit carryforwards have no expiration dates.

We have experienced at least one ownership change since inception and utilization of NOL carryforwards will therefore be subject to annual limitation, pursuant to Internal Revenue Code Section 382. Our ability to use our remaining NOL carryforwards may be further limited if we experience a Section 382 ownership change in connection with future changes in our stock ownership.

Recent Accounting Pronouncements

The information required by this item is included in Item 8, Note 2, Summary of Significant Accounting Policies in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate and foreign exchange sensitivities as follows:

Interest Rate Risk

As of December 31, 2015, we had cash and cash equivalents and investments of $215.7 million, which consisted of money market funds, repurchase agreements and corporate debt. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. We had no outstanding debt obligations as of December 31, 2015.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign Exchange Risk

Our operations are primarily conducted in the United States using the U.S. dollar. However, we conduct operations in Canada, primarily to fund our Canadian subsidiary, and engage in contracts with third-party clinical and regulatory suppliers that are denominated in currencies other than U.S. dollars, whereby settlement of our obligations for these activities are denominated in the local currency. Transactions denominated in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction with the resulting assets and liabilities being translated into the U.S. dollar at exchange rates prevailing at the balance sheet date. The resulting foreign exchange losses were $14,000, $57,000 and $43,000 for the years ended December, 2015, 2014 and 2013, respectively, are included in interest and other income (expense), net in our consolidated statements of operations. We do not use

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currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.

A hypothetical 10% change in foreign exchange rates during any of the preceding periods presented would have had an insignificant effect on our consolidated financial statements.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Dermira, Inc.

We have audited the accompanying consolidated balance sheets of Dermira, Inc. (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Dermira, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Redwood City, California
March 3, 2016

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DERMIRA, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31,	
	2015	**2014**
Assets		
Current assets:		
Cash and cash equivalents	$ 107,242	$ 55,358
Short-term investments	107,451	41,793
Collaboration receivable from a related party		7,300
Prepaid expenses and other current assets	2,540	1,012
Total current assets	217,233	105,463
Property and equipment, net	386	192
Long-term investments	1,019	66,483
Intangible assets	1,126	3,520
Goodwill	771	771
Other assets	1,397	1,792
Total assets	$ 221,932	$ 178,221
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,230	$ 5,563
Accrued liabilities	16,666	6,327
Total current liabilities	25,896	11,890
Long-term liabilities:		
Deferred revenue	10,000	10,000
Bank term loan		1,936
Deferred tax liability	194	816
Other long-term liabilities	367	
Total liabilities	36,457	24,642
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized as of December 31, 2015; no shares issued and outstanding as of December 31, 2015 and 2014		
Common stock: $0.001 par value per share; 500,000,000 shares authorized as of December 31, 2015; 29,972,845 and 24,628,670 shares issued and outstanding as of December 31, 2015 and 2014, respectively	30	25
Additional paid-in capital	346,590	236,414
Accumulated other comprehensive loss	(97)	(211)
Accumulated deficit	(161,048)	(82,649)
Total stockholders' equity	185,475	153,579
Total liabilities and stockholders' equity	$ 221,932	$ 178,221

The accompanying notes are an integral part of these consolidated financial statements.

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DERMIRA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2015	**2014**	**2013**
Collaboration revenue from a related party	$ 7,300	$ 7,300	$
Operating expenses:			
Research and development	66,831	30,710	17,937
General and administrative	17,721	8,288	4,366
Impairment of intangible assets	2,394		
Total operating expenses	86,946	38,998	22,303
Loss from operations	(79,646)	(31,698)	(22,303)
Interest and other income (expense), net	896	7	(38)
Interest expense	(147)	(153)	(9)
Loss on extinguishment of debt	(124)		
Loss before taxes	(79,021)	(31,844)	(22,350)
(Benefit) provision for income taxes	(622)	31	
Net loss	$ (78,399)	$ (31,875)	$ (22,350)
Net loss per share, basic and diluted	$ (2.93)	$ (4.96)	$ (27.03)
Weighted-average common shares used to compute net loss per share, basic and diluted	26,727,392	6,426,022	826,757

The accompanying notes are an integral part of these consolidated financial statements.

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DERMIRA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Net loss	$ (78,399)	$ (31,875)	$ (22,350)
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities	114	(211)	
Total comprehensive loss	$ (78,285)	$ (32,086)	$ (22,350)

The accompanying notes are an integral part of these consolidated financial statements.

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DERMIRA, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2012	6,572,625	$ 35,089	901,308	$ 1	$ 678		$ (28,424)	$ (27,745)
Issuance of Series B convertible preferred stock, net of issuance costs of $500	2,967,533	24,499						
Stock-based compensation					292			292
Net loss							(22,350)	(22,350)
Balance at December 31, 2013	9,540,158	59,588	901,308	1	970		(50,774)	(49,803)
Issuance of Series B convertible preferred stock	593,507	5,000						
Issuance of Series C convertible preferred stock, net of issuance costs of $2,175	5,297,041	48,825						
Conversion of preferred stock into common stock	(15,430,706)	(113,413)	15,430,706	15	113,398			113,413
Conversion of preferred stock warrants to common stock warrants					139			139
Issuance of common stock in connection with initial public offering, net of underwriting discounts, commissions and issuance costs of $12,238			7,812,500	8	112,754			112,762
Issuance of common stock in private placement			468,750	1	7,499			7,500
Exercise of common stock warrants			4,804					
Exercise of stock options			10,602		11			11
Stock-based compensation					1,643			1,643
Unrealized loss on investments						(211)		(211)
Net loss							(31,875)	(31,875)
			24,628,670	25	236,414	(211)	(82,649)	153,579

Balance at December 31, 2014						
Issuance of common stock in connection with follow-on offering, net of underwriting discounts, commissions and issuance costs of $7,216	5,175,000	5	104,042			104,047
Exercise of stock options	112,357		279			279
Purchases under employee stock purchase plan	56,818		723			723
Stock-based compensation			5,132			5,132
Unrealized gain on investments				114		114
Net loss					(78,399)	(78,399)
Balance at December 31, 2015	$ 29,972,845	$ 30	$ 346,590	$ (97)	$ (161,048)	$ 185,475

The accompanying notes are an integral part of these consolidated financial statements.

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DERMIRA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Cash flow from operating activities			
Net loss	$ (78,399)	$ (31,875)	$ (22,350)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	72	64	22
Stock-based compensation	5,132	1,643	292
Loss on disposal of property and equipment		7	2
Amortization of premiums on available-for-sale securities	2,012	190	
Revaluation of convertible preferred stock warrant liability		78	
Impairment of intangible assets	2,394		
Loss on extinguishment of debt	124		
Changes in assets and liabilities:			
Collaboration receivable from a related party	7,300	(7,300)	
Prepaid expenses and other current assets	(1,219)	(572)	(184)
Other assets	395	(1,207)	125
Accounts payable	3,607	3,209	338
Accrued liabilities	10,395	4,328	(402)
Deferred revenue			10,000
Other long-term liabilities	367		
Deferred taxes	(622)	31	
Net cash used in operating activities	(48,442)	(31,404)	(12,157)
Cash flow from investing activities			
Purchases of available-for-sale securities	(60,276)	(109,324)	
Maturities of available-for-sale securities	57,875		
Purchases of property and equipment	(202)	(156)	(50)
Net cash used in investing activities	(2,603)	(109,480)	(50)
Cash flow from financing activities			
Net proceeds from issuance of convertible preferred stock		53,825	24,499
Net proceeds from issuance of common stock	105,049	120,273	
Net borrowings from bank term loan			1,980
Payment to extinguish term loan	(2,120)		
Net cash provided by financing activities	102,929	174,098	26,479
Net increase in cash and cash equivalents	51,884	33,214	14,272
Cash and cash equivalents at beginning of period	55,358	22,144	7,872
Cash and cash equivalents at end of period	$ 107,242	$ 55,358	$ 22,144
Supplemental disclosure of cash flow information			
Interest paid	$ 123	$ 117	$

Supplemental disclosure of noncash investing and financing activities			
Conversion of preferred stock into common stock	$	$ 113,413	$
Issuance of warrants in connection with bank term loan	$	$	$ 61
Reclassification of preferred stock warrant liability into additional paid-in-capital	$	$ 139	$
Acquisition of property and equipment under accounts payable and accrued liabilities	$ 50	$ 32	$

The accompanying notes are an integral part of these consolidated financial statements.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Dermira, Inc. (the "Company") was incorporated in the State of Delaware in August 2010 under the name Skintelligence, Inc. The Company changed its name to Dermira, Inc. in September 2011. In August 2010, the Company acquired Valocor Therapeutics, Inc., which was subsequently renamed Dermira (Canada), Inc. ("Dermira Canada") and is the Company's wholly owned subsidiary. The Company is a biopharmaceutical company dedicated to identifying, developing and commercializing innovative, differentiated therapies to improve the lives of patients with dermatologic diseases. The Company's portfolio includes three late-stage product candidates that target significant unmet needs and market opportunities: Cimzia (certolizumab pegol), in Phase 3 development in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe chronic plaque psoriasis; DRM04, in Phase 3 development for the treatment of primary axillary hyperhidrosis, or excessive underarm sweating; and DRM01, in Phase 2b development for the treatment of acne vulgaris, or acne. The Company's corporate headquarters are located in Menlo Park, California.

Equity Financings

On October 3, 2014, the Company closed its initial public offering ("IPO") of 7,812,500 shares of its common stock, all of which were sold by the Company. The public offering price of shares sold in the IPO was $16.00 per share. The net proceeds from the IPO to the Company were $112.8 million, after deducting the underwriting discounts and commissions of $8.7 million and the payment of offering expenses of $3.5 million.

Concurrently with the IPO, the Company issued and sold in a private placement 468,750 shares of common stock at the public offering price of $16.00 per share, which resulted in net proceeds of $7.5 million, pursuant to a Common Stock Purchase Agreement by and between the Company and UCB, S.A., the parent company of UCB, dated September 19, 2014.

On August 11, 2015, the Company closed an underwritten follow-on public offering ("Follow-on Offering") of 5,175,000 shares of its common stock sold by the Company, including 675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock, at a price to the public of $21.50 per share. The gross proceeds to the Company from the Follow-on Offering were $111.3 million, and the net proceeds to the Company, after deducting underwriting discounts and commissions of $6.7 million and offering expenses of approximately $0.6 million, were approximately $104.0 million.

2. Summary of Significant Accounting Policies

Significant accounting policies followed in the preparation of these consolidated financial statements are as follows:

Basis of Presentation

The consolidated financial statements of the Company have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary located in Canada. All intercompany accounts and transactions have been eliminated in consolidation.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

Reverse Stock Split

The Company effected a 5.8-to-1 reverse stock split of each share of the Company's outstanding capital stock on September 18, 2014, the date that the Certificate of Amendment to the Restated Certificate of Incorporation was filed with the Delaware Secretary of State. The reverse stock split did not result in an adjustment to par value. All references to shares of common stock outstanding, average number of shares outstanding and per share amounts in these consolidated financial statements and notes to the consolidated financial statements reflect the reverse stock split.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, investments, accrued research and development expenses, goodwill, intangible assets, other long-lived assets, stock-based compensation, and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Risks and Uncertainties

The product candidates developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies prior to commercial sales in the United States or foreign jurisdictions, respectively. There can be no assurance that the Company's current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company's business and its financial condition.

The Company is subject to risks common to early-stage companies in the pharmaceutical industry, including dependence on the clinical and commercial success of its product candidates, ability to obtain regulatory approval of its product candidates, compliance with regulatory requirements, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and patients, significant competition and ability to manage third-party manufacturers, suppliers and contract research organizations ("CROs").

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include deposits, money market funds, repurchase agreements and obligations of U.S. government agencies.

Investments

The Company classifies its investments in money market funds, repurchase agreements and corporate debt as available-for-sale securities. Fixed income securities consist of repurchase agreements and corporate debt. The specific identification method is used to determine the cost basis of fixed

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

income securities sold. These securities are recorded on the consolidated balance sheet at fair value. Unrealized gains and losses on these securities are included as a separate component of accumulated other comprehensive income (loss). The cost of investment securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses and declines in fair value judged to be other than temporary, if any, are also included in interest and other income (expense), net. The Company classifies its available-for-sale securities as current or long term primarily based on the nature of the securities.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents, investments and collaboration receivable from a related party. The Company invests its excess cash in money market funds, repurchase agreements and corporate debt. Bank deposits are held by a single financial institution and these deposits may exceed insured limits. The Company is exposed to credit risk in the event of a default by the financial institution holding its cash and cash equivalents and issuers of investments to the extent recorded on the consolidated balance sheets. The Company's investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. government and its agencies, repurchase agreements, commercial paper, municipal bonds, corporate debt and places restrictions on the credit ratings, maturities and concentration by type and issuer.

Collaboration receivables are typically unsecured. Accordingly, we may be exposed to credit risk generally associated with our collaboration agreement. To date, we have not experienced any losses related to these receivables.

Fair Value Measurement

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company primarily applies the market approach for recurring fair value measurements.

The Company measures certain financial assets and liabilities at fair value based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. The carrying amount of the Company's cash and cash equivalents, investments, collaboration receivable from a related party, prepaid expenses, accounts payable and accrued liabilities approximate fair value due to their short maturities.

The Company's non-financial assets, such as intangible assets and property, plant and equipment, are only recorded at fair value if an impairment charge is recognized. See Note 7 for further details on the impairment charge against certain intangible assets recorded during the year ended December 31, 2015.

Property and Equipment

Property and equipment are stated at cost, subject to adjustments for impairments, less accumulated depreciation and amortization. Property and equipment consist primarily of computer

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

equipment, internal use software, leasehold improvements and furniture. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the related assets, ranging from three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the respective assets. Maintenance and repairs that do not extend the life of or improve an asset are expensed in the period incurred.

Internal use software costs incurred in connection with obtaining or developing internal use software are capitalized. This includes external direct costs of material and services. Capitalized internal use software costs are included in property and equipment and are amortized using the straight-line method over five years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Revenue Recognition

Collaboration and license agreements may include non-refundable upfront payments or partial reimbursement of research and development costs, contingent consideration payments based on achievement of defined milestones, and royalties on sales of commercialized products. Performance obligations under collaboration agreements may include the transfer of intellectual property rights, such as licenses, obligations to provide research and development services, obligations to provide regulatory approval services and obligations to participate on certain development and/or commercialization committees with the collaborators. Upfront payments are generally recorded as deferred revenue in the consolidated balance sheet and recognized as collaboration revenue over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the collaboration agreement. The Company regularly reviews the estimated periods of performance related to its collaborations based on the progress made under each arrangement. The estimated performance period may change over the course of the collaboration term. Such a change could have a material impact on the amount of revenue recorded in future periods. The Company generates revenue from its activities under the collaboration agreement with UCB, a related party, for the development and commercialization of one of its product candidates. All revenue recognized to date under the agreement with UCB is non-refundable and has been classified as collaboration revenue from a related party.

Multiple Element Arrangements

The Company evaluates revenue from its agreement with UCB to determine whether the components of the arrangement represent separate units of accounting. Management considers whether components of an arrangement represent separate units of accounting based upon whether certain criteria are met, including whether the delivered element has stand-alone value to the customer. Factors considered include whether the deliverable is proprietary to the Company, whether the customer can use the license or other deliverables for their intended purpose without the receipt of the remaining elements and whether there are other vendors that can provide the undelivered items. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. To date, the Company's agreement with UCB has two deliverables that represent two units of accounting, which are (1) the delivery of services related to the development of Cimzia for the treatment of moderate-to-severe chronic plaque psoriasis and (2) the marketing services needed to commercialize Cimzia in the United States and Canada. At the date of execution of this arrangement, potential future

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

payments eligible to be received upon the achievement of development and regulatory milestones were all considered to be substantive. As such, payments will be recognized in their entirety in the period in which the milestone event is achieved and collectability is reasonably assured. Royalties and sales-based milestone payments will be recognized as revenue when earned and realizable. Non-refundable fees for which the Company has no continuing performance obligations are recognized as revenue when collection is reasonably assured and all other revenue recognition criteria have been met.

Milestones and Other Contingent Payments

The Company has adopted the milestone method as described in Accounting Standards Codification ("ASC") 605-28, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone will be recognized in its entirety in the period in which the milestone is achieved. A milestone is defined as an event having all of the following characteristics: (1) there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved; (2) the event can only be achieved based in whole or in part on either the Company's performance or a specific outcome resulting from the Company's performance; and (3) if achieved, the event would result in additional payments being due to the Company. Contingent payments which do not meet the definition of a milestone are recognized in the same manner as the consideration for the combined unit of accounting. If the Company has no remaining performance obligations under the combined unit of accounting, any contingent payments would be recognized as revenue upon the achievement of the triggering event.

The Company's agreement with UCB provides for payments to be paid to the Company upon the achievement of development, regulatory and sales milestones. Given the challenges inherent in developing biologic products, there was substantial uncertainty as to whether any such milestones would be achieved at the time the agreement was executed. The Company evaluates whether the development and regulatory milestones meet all of the conditions to be considered substantive. The conditions include: (1) the consideration is commensurate with either of (a) the vendor's performance to achieve the milestone or (b) the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor's performance to achieve the milestone; (2) the consideration relates solely to past performance; and (3) the consideration is reasonable relative to all the deliverables and payment terms within the arrangement. Substantive milestones are recognized as revenue upon achievement of the milestone and when collectability is reasonably assured.

Impairment of Long-Lived Assets

The Company assesses changes in the performance of its product candidates in relation to its expectations, and industry, economic and regulatory conditions and makes assumptions regarding estimated future cash flows in evaluating the value of its property and equipment, goodwill and in-process research and development ("IPR&D").

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets is compared to the carrying value to determine whether impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of the net assets acquired in connection with the acquisition of Valocor. The Company tests goodwill for impairment on an annual basis as of October of each year, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the goodwill is less than its carrying amount. Some of the factors considered by the Company in its assessment include general macro-economic conditions, conditions specific to the industry and market, and the successful development of its product candidates. If the Company concludes it is more likely than not that the fair value of the goodwill is less than its carrying amount, a quantitative fair value test is performed.

IPR&D represents the fair value assigned to incomplete research projects that the Company acquired through the acquisition of Valocor which, at the time of acquisition, had not reached technological feasibility. The amount was capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment annually as of October of each year, or more frequently, if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the Company discontinues or abandons a program related to IPR&D and determines that there are no other indicators of value, the Company will impair the entire amount of the related intangible asset.

See Note 7 for further details on the impairment charge against certain intangible assets recorded during the year ended December 31, 2015.

Offering Costs

Offering costs, consisting of legal, accounting, filing and other directly related fees, are offset against proceeds from each offering. Offering costs incurred prior to the completion of an offering are initially recorded in other assets, evaluated each period for likelihood of completion and subsequently reclassified to additional paid-in capital upon completion of the offering.

Research and Development Expenses

The Company expenses research and development costs as they are incurred. The Company's research and development expenses consist primarily of costs incurred for the development of its product candidates and include: (1) expenses incurred under agreements with CROs, investigative sites and consultants to conduct clinical trials and preclinical and non-clinical studies; (2) costs to acquire, develop and manufacture supplies for clinical trials and other studies, including fees paid to contract manufacturing organizations ("CMOs"); (3) salaries and related costs, including stock-based compensation and travel expenses, for personnel in research and development functions; (4) costs related to compliance with drug development regulatory requirements; (5) depreciation and other allocated facility-related and overhead expenses; and (6) licensing fees and milestone payments incurred under product license agreements.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical, non-clinical and clinical studies, and manufacturing development, which are a significant component of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, including CROs. The Company's contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on actual work completed in accordance with the respective agreements. In certain cases, the Company can be financially responsible for unused drug supplies remaining at study sites at the conclusion of a trial. The Company accrues for the potential amounts due if they are both probable and estimable. In the event the Company makes advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

The Company's CRO for the Cimzia Phase 3 program (the "Cimzia CRO") can earn bonuses or incur penalties based on the Cimzia CRO's achievement of certain milestones specified in the agreement. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, the Company would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup such penalty if it achieves a subsequent milestone. In this case, the Company would continue to maintain the full amount owed to the Cimzia CRO until the right of recoupment has expired.

The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. To date, there have been no material differences between the Company's accrued estimated expenses and the actual clinical trial expenses. However, variations in the assumptions used to estimate accruals, including, but not limited to the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from the Company's estimates, resulting in adjustments to clinical trial expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its consolidated financial condition and results of operations.

Income Taxes

The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. Financial statement effects of uncertain tax positions are recognized when it is more-likely-than-not, based on the technical merits of the position, that it will be sustained upon examination. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax. The Company has not been subject to any interest or penalties through the year ended December 31, 2015.

Stock-Based Compensation

The Company maintains an equity incentive plan under which incentive stock options may be granted to employees, and nonqualified stock options, restricted stock awards, restricted stock units and stock appreciation rights may be granted to employees, officers, directors, consultants and advisors. In addition, the Company maintains an employee stock purchase plan ("ESPP") under which employees may purchase shares of the Company's common stock through payroll deductions.

For stock options granted to employees and directors, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair values, net of an estimated forfeiture rate using the Black-Scholes option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The Company estimates its forfeiture rate based on an analysis of its actual forfeitures and the experience of other companies in the same industry, and will continue to evaluate the adequacy of the forfeiture rate assumption based on actual forfeitures, analysis of employee turnover and other related factors.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards vest over the time period during which the non-employee provides services to the Company.

Stock compensation expense related to the ESPP is recognized based on the fair value of each award estimated on the first day of the offering period using the Black-Scholes option pricing model and recorded as expense over the service period using the straight-line method, net of estimated forfeitures.

Deferred Rent

Rent expense is recognized on a straight-line basis over the non-cancelable term of the Company's operating lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for dilutive potential shares of common stock. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive for all periods presented.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share is as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2015	2014	2013
Net loss per share:			
Numerator:			
Net loss	$ (78,399)	$ (31,875)	$ (22,350)
Denominator:			
Weighted-average shares of common stock outstanding used in the calculation of basic and diluted net loss per share	26,727,392	6,429,553	901,308
Less: Weighted-average shares subject to repurchase		(3,531)	(74,551)
Denominator for basic and diluted net loss per share	26,727,392	6,426,022	826,757
Net loss per share, basic and diluted	$ (2.93)	$ (4.96)	$ (27.03)

The following dilutive potential shares of common stock outstanding were excluded from the computations of diluted net loss per share for the periods presented, as the effect of including such securities would be antidilutive:

	Outstanding as of December 31,		
	2015	2014	2013
Convertible preferred stock, as converted to common stock			9,540,158
Warrant to purchase convertible preferred stock, as converted to a common stock warrant			11,276
Options to purchase common stock and estimated shares issuable under the ESPP	3,918,963	3,401,395	1,743,590
Common stock subject to repurchase			9,788
	3,918,963	3,401,395	11,304,812

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-2, *Leases.* ASU 2016-2 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This ASU is effective for the Company's interim and annual reporting periods during the year ending December 31, 2019, and all annual and interim reporting periods thereafter. Early adoption is permitted. The Company is currently evaluating the impact that the adoption ofthis ASU will have on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued ASU2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. This ASU made modifications to how certain financial instruments should be measured and disclosed, including using the exit price notion when measuring the fair value, separating the presentation of financial assets and financial liabilities by measurement category on the balance

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of Significant Accounting Policies (Continued)

sheet and eliminating the requirement to disclose the method and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods. The Company will evaluate the guidance and present the required disclosures in its consolidated financial statements at the time of adoption.

In November 2015, FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, requiring all deferred tax assets and liabilities, and any related valuation allowance, to be classified as non-current on the balance sheet. The classification change for all deferred taxes as non-current simplifies entities' processes, as it eliminates the need to separately identify the net current and net non-current deferred tax asset or liability in each jurisdiction and allocate valuation allowances. The Company early adopted this standard on a prospective basis in the fourth quarter of fiscal 2015. Prior periods were not retrospectively adjusted upon adoption.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements Going Concern* (*Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance was initially effective for the fiscal years and interim reporting periods beginning after December 15, 2016, however, in July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). This ASU's effective date for the Company will be the first quarter of fiscal year 2018, using one of two retrospective application methods. The Company has not selected a transition method and is currently assessing the future impact of this ASU on its consolidated financial statements.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting guidance for fair value establishes a three-level hierarchy for disclosure of fair value measurements, as follows:

Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Fair Value Measurements (Continued)

Level 2 Inputs (other than quoted market prices included in Level 1) that are either directly or indirectly observable, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the instrument's anticipated life.

Level 3 Unobservable inputs that are supported by little or no market activity and reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following tables set forth the fair value of the Company's financial instruments that were measured at fair value on a recurring basis (in thousands):

	As of December 31, 2015			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 203	$	$	$ 203
Repurchase agreements		106,635		106,635
Corporate debt		108,470		108,470
Total financial assets	$ 203	$ 215,105	$	$ 215,308

	As of December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 10,088	$	$	$ 10,088
Repurchase agreements		70,000		70,000
Corporate debt		83,276		83,276
Total financial assets	$ 10,088	$ 153,276	$	$ 163,364

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates fair value by using quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to benchmark yields, reported trades and broker/dealer quotes. The Company classifies repurchase agreements and corporate debt as Level 2. There were no transfers between Level 1 and Level 2 during the periods presented.

See Note 4 for further details on the financial instruments that were measured at fair value.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Fair Value Measurements (Continued)

See Note 7 for further details on the impairment charge against certain intangible assets recorded during the year ended December 31, 2015. This adjustment falls within Level 3 of the fair value hierarchy.

4. Investments

Investments include available-for-sale securities and investment securities classified as cash equivalents. Investment securities consisted of the following (in thousands):

	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$ 203	$	$	$ 203
Repurchase agreements	106,635			106,635
Corporate debt	108,567	17	(114)	108,470
Total investments	$ 215,405	$ 17	$ (114)	$ 215,308

	As of December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets:				
Money market funds	$ 10,088	$	$	$ 10,088
Repurchase agreements	70,000			70,000
Corporate debt	83,487	2	(213)	83,276
Total investments	$ 163,575	$ 2	$ (213)	$ 163,364

As of December 31, 2015, investments (excluding money market funds) had the following contractual maturities (in thousands):

	Amortized Cost	Fair Value
Mature in less than one year	$ 214,180	$ 214,086
Mature in more than one year	1,022	1,019
Total	$ 215,202	$ 215,105

The Company did not hold any investment securities exceeding a two-year maturity.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Investments (Continued)

The securities in an unrealized loss position consisted of the following (in thousands):

	As of December 31, 2015					
	Securities in an unrealized loss position for less than 12 months		Securities in an unrealized loss position for more than 12 months		Total	
	Gross unrealized losses	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses	Fair value
Corporate debt	$ (107)	$ 84,458	$ (7)	$ 6,337	$ (114)	$ 90,795
Total	$ (107)	$ 84,458	$ (7)	$ 6,337	$ (114)	$ 90,795

	As of December 31, 2014					
	Securities in an unrealized loss position for less than 12 months		Securities in an unrealized loss position for more than 12 months		Total	
	Gross unrealized losses	Fair value	Gross unrealized losses	Fair value	Gross unrealized losses	Fair value
Corporate debt	$ (213)	$ 79,438	$	$	$ (213)	$ 79,438
Total	$ (213)	$ 79,438	$	$	$ (213)	$ 79,438

The unrealized losses on the available-for-sale investments are related to corporate debt securities. The Company determined these unrealized losses to be temporary. Factors considered in determining whether a loss is temporary include the length of time and extent to which the investment's fair value has been less than the cost basis; the financial condition and near-term prospects of the investee; the extent of the loss related to the credit of the issuer; the expected cash flows from the security; and the Company's intent to sell the security and whether or not the Company will be required to sell the security before the recovery of its amortized cost. The Company does not intend to sell the securities and it is not more likely than not that the Company will be required to sell the investments before recovery of the amortized cost bases. There were no realized gains or losses on the available-for-sale securities during year ended December 31, 2015.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Computer and other equipment	$ 69	$ 60
Internal use software(1)	239	
Leasehold improvements	71	76
Office furniture	82	72
Total property and equipment	461	208
Less accumulated depreciation and amortization	(75)	(16)
Property and equipment, net	$ 386	$ 192

(1) As of December 31, 2015, the internal use software was not being depreciated as it had not been placed into service.

Property and equipment depreciation and amortization expense for the years ended December 31, 2015, 2014 and 2013 was $59,000, $47,000 and $22,000, respectively.

6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2015	December 31, 2014
Accrued outside research and development services	$ 12,373	$ 3,670
Accrued compensation	3,848	2,463
Accrued professional and consulting services	297	108
Other	148	86
	$ 16,666	$ 6,327

7. Intangible Assets

In-Process Research and Development

In connection with the acquisition of Valocor in 2011, the Company acquired intangible assets that were associated with IPR&D projects relating to preclinical product candidates. The acquisition-date fair value of these intangible assets was $3.5 million. These assets are considered to be indefinite-lived and are not amortized, but are tested for impairment on an annual basis, as well as between annual tests if changes in circumstances indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives.

During the year ended December 31, 2015, the Company recorded an impairment charge of $2.4 million to IPR&D in the consolidated statement of operations. In December 2015 and February 2016, the Company received the results from certain research and development experiments related to its DRM05 and DRM02 early-stage product candidates, respectively. Based on the results of these

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Intangible Assets (Continued)

experiments, the Company made the decision to discontinue further efforts on these programs. The intangible assets related to these product candidates were written off in full. There was no impairment charge against intangible assets in the year ended December 31, 2014. DRM02 is a PDE4 inhibitor that was under preclinical development for the treatment of inflammatory skin diseases, and DRM05 is a photodynamic therapy that was under preclinical development for the treatment of acne. Both of these compounds were acquired in the Valocor acquisition in 2011.

Goodwill

The Company recorded the goodwill resulting from the Valocor acquisition separately on its consolidated balance sheet as of the acquisition date. Goodwill is tested for impairment on an annual basis, as well as between annual tests if there are changes in circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

The net book value of intangible assets and goodwill was as follows (in thousands):

	December 31, 2015	December 31, 2014
Intangible assets IPR&D	$ 1,126	$ 3,520
Goodwill	771	771
Total intangible assets with indefinite lives	$ 1,897	$ 4,291

8. Loan Agreement

In December 2013, the Company entered into a loan and security agreement (the "Loan Agreement") with Square 1 Bank (the "Bank") that provided for two term loans available to the Company: $2.0 million under the first term loan ("Term Loan A") and $5.5 million under the second term loan ("Term Loan B").

On the closing date of the Loan Agreement, the Company borrowed $2.0 million under Term Loan A. The amount borrowed under Term Loan A had a maturity date in December 2018 and was secured by all assets of the Company other than the Company's intellectual property, subject to certain limited exceptions, and bore interest at a rate of 5.77% per annum. In December 2015, the Company repaid Term Loan A in full, plus a final repayment fee of $120,000, and recorded a loss on extinguishment of debt of $0.1 million during the year ended December 31, 2015, which consisted of the write-off of the debt discount and accrued final repayment fee. The loss is included in the consolidated statements of operations as a loss on debt extinguishment. The Company incurred interest expense in connection with Term Loan A totaling $147,000, $153,000 and $9,000 for the years ended December 31, 2015, 2014 and 2013, respectively.

There were no amounts borrowed under Term Loan B, and the Company's ability to borrow funds under Term Loan B expired on September 30, 2015.

As a result of the Company's repayment in full of Term Loan A in December 2015, the Loan Agreement terminated and the Company has no continuing obligations or liens related to the Loan Agreement.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Commitments and Contingencies

Facility Lease

The Company leases its corporate headquarters in Menlo Park, California under a non-cancelable operating lease agreement entered into in July 2014 and amended in September 2014 and December 2015. The leased space currently totals approximately 18,651 square feet and consists of one suite in a multi-suite building. Rent payments include the base rent plus additional fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance and maintenance. The base rent was approximately $97,918 per month during the first year of the lease and increases by three percent annually. The estimated amount of the additional fees was approximately $22,381 per month during the first year of the lease.

In connection with the lease amendment entered into in December 2015, the Company will lease an additional three suites in the current building consisting of 26,541 square feet of space, effective December 2016. The base rent for the new expanded space will be approximately $135,426 per month during the first year, and increases by three percent annually. The estimated amount of the additional fees for the expanded space will be approximately $30,954 per month during the first year of the lease.

Pursuant to the December 2015 lease amendment, the term of the lease for the original 18,651 square feet of space and the additional 26,541 square feet expires on December 31, 2021. The Company has an option to renew the lease for an additional five-year term.

The Company may terminate the lease with respect to two of the suites in the expanded space if on or prior to September 30, 2016 (1) the results from certain clinical trials of the Company are negative and, as a consequence thereof, the Company determines not to proceed to the next phase of development for either trial, and (2) the Company provides the lessor with written notice of the same and its intent to terminate the lease with respect to the two suites in the expansion space. If the Company exercises its termination option, it must pay a termination fee equal to six months' rent, payable on a monthly basis commencing December 1, 2016. The termination fee is subject to reduction if the landlord leases the space during such six-month period.

Pursuant to the terms of the lease agreement, the Company provided the lessor with a $500,000 letter of credit in August 2014, which is collateralized by a money market account. The letter of credit may be used by or drawn upon by the lessor in the event of the Company's default of certain terms of the lease agreement. If no such event of default has occurred or then exists, the letter of credit may be reduced to $350,000 after May 1, 2019. The collateralized money market account is restricted cash and recorded in the Company's consolidated balance sheet in other assets.

Rent expense for the years ended December 31, 2015, 2014 and 2013 was $1.5 million, $0.6 million and $0.3 million, respectively. The terms of the facility lease provide for rental payments on a monthly basis on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Commitments and Contingencies (Continued)

As of December 31, 2015, the aggregate total future minimum lease payments under the Menlo Park non-cancelable operating lease were as follows (in thousands):

Year Ending December 31,		
2016	$	1,213
2017		2,473
2018		2,966
2019		3,055
2020 and thereafter		6,376
Total payments	$	16,083

The table above includes the scheduled base rent payments for all suites, including the expansion space suites, assuming the termination option described above is not exercised. It excludes approximately $3.7 million of additional rent due over the period of the operating lease to cover the Company's share of facility expenses, including utilities, property taxes, insurance and maintenance.

CRO Agreement

Per the terms of the Company's agreement with its CRO for the Cimzia Phase 3 program, the Cimzia CRO can earn bonus payments or incur penalties (which are adjusted from the total amount payable pursuant to the agreement) based on the achievement of milestones specified in the agreement. The Cimzia CRO can earn a maximum aggregate bonus of $3.6 million and incur a maximum aggregate penalty of $3.2 million. If, in any period, it becomes probable that the Cimzia CRO would earn a bonus and the amount is estimable, the Company would recognize the full amount of such bonus in that same period as an expense, even if the bonus would not be earned by and paid to the Cimzia CRO until the milestone is achieved. If the Cimzia CRO incurs a penalty, it has the right to recoup the applicable amount if it achieves a subsequent milestone, and the Cimzia CRO would adjust subsequent billings as necessary to reflect such penalty and any recouped amount. If the Cimzia CRO incurs a penalty prior to the expiration of the right of recoupment, the Company would maintain the full amount owed to the Cimzia CRO in either accrued liabilities or other long-term liabilities, as appropriate, in its consolidated balance sheet until (1) the right of recoupment has expired, at which time the Company would reflect the amount as a reduction in operating expenses and eliminate the liability, or (2) the Cimzia CRO has recouped the penalty, at which time the Company would increase the payment to the Cimzia CRO by the recouped amount and eliminate the liability. As of December 31, 2015, the Company has not recognized an increase in expense for a bonus earned, or a decrease in expense for a penalty incurred, under the agreement in its consolidated statements of operations.

Contingencies

Pursuant to the UCB agreement, the Company is responsible for paying all development costs specified under the UCB agreement and incurred in connection with the development plan up to a specified amount greater than $75.0 million and less than $95.0 million, plus its internal development costs. Development costs include the costs of Cimzia and etanercept clinical trial materials used in the Phase 3 clinical program. UCB is responsible for providing these clinical trial materials and the Company reimburses UCB for such costs. In addition to clinical trial materials used in the study, the

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Commitments and Contingencies (Continued)

Company is financially responsible for unused clinical drug supplies remaining at study sites at the conclusion of the study. At this time, the Company cannot determine the amounts of unused clinical drug supplies until all patients have completed treatment. Based on currently available data, the Company estimates that the loss contingency related to unused clinical drug supplies over the next six months ranges from $0.5 million to $1.0 million. As a result, the Company recorded a charge of $0.5 million to research and development expense for the year ending December 31, 2015 and a corresponding accrual of the same amount to accrued liabilities as of December 31, 2015. There were no contingency losses or accruals related to unused clinical drug supplies recorded in 2014 or 2013.

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company would accrue a liability for such matters when it is probable that future expenditures would be made and such expenditures could be reasonably estimated. The Company is not subject to any current pending legal matters or claims.

Indemnification

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

No amounts associated with such indemnifications have been recorded to date.

10. Technology and Financing Agreements

Maruho Agreement

In March 2013, the Company entered into a Right of First Negotiation Agreement with Maruho Co., Ltd. Under the terms of the agreement, the Company provided Maruho with certain information and the right to negotiate an exclusive license to develop and commercialize certain of the Company's product candidates in specified territories. In connection with the entry into this agreement, Maruho paid the Company a non-refundable upfront payment of $10.0 million, which will be credited against certain payments payable by Maruho to the Company if the two parties enter into an exclusive license for any of the Company's products. If the parties do not enter into such an arrangement, the Company will be entitled to keep the funds without further obligation. As of December 31, 2015 and 2014, the Company recorded the $10.0 million as deferred revenue on its consolidated balance sheet. The revenue will be recognized in connection with and pursuant to a future license arrangement, if any,

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Technology and Financing Agreements (Continued)

or at the time the parties decide not to enter into such a license, at which point the entire amount would be recognized as revenue.

In connection with the execution of the Right of First Negotiation Agreement, Maruho purchased 1,187,014 shares of the Company's Series B convertible preferred stock for an aggregate purchase price of $10.0 million

Rose U Agreement

In April 2013, the Company entered into an exclusive license agreement with Rose U, LLC to license certain patents, patent applications and know-how related to its DRM04 program. This agreement includes a sublicense and assignment of certain know-how licensed and assigned to Rose U by Stiefel Laboratories, Inc., a GSK company, or Stiefel, the prior licensee of such patents. In connection with this agreement, the Company also entered into a letter agreement with Stiefel. As of December 31, 2015 the Company has paid license and other fees of $0.5 million to Rose U and is required to pay additional amounts totaling up to $4.4 million upon the achievement of specified development, commercialization and other milestones under these agreements to Rose U and Stiefel. In addition, the Company is also obligated to pay Rose U low-to-mid single-digit royalties on net product sales and low double-digit royalties on sublicense fees and certain milestone, royalty and other contingent payments received from sublicensees, to the extent such amounts are in excess of the milestone and royalty payments the Company is obligated to pay Rose U directly upon the events or sales triggering such payments.

UCB (a Related Party) Agreement

In March 2014, the Company entered into a development and commercialization agreement with UCB, a related party (the "UCB agreement"), which provides that the Company will develop Cimzia for the treatment of psoriasis in order for UCB to seek regulatory approval from the FDA, European Medicines Agency ("EMA") and the Canadian federal department for health ("Health Canada"), and upon the grant of regulatory approval in the United States and Canada, for the Company to promote sales of Cimzia to dermatologists and conduct related medical affairs activities in the United States and Canada. Unless earlier terminated, the term of the UCB agreement is 12.5 years following the first commercial launch following regulatory approval of Cimzia for the treatment of psoriasis in the United States or Canada.

The Company has agreed with UCB on a development plan to obtain regulatory approval from the FDA, the EMA and Health Canada, which may be amended as necessary to meet the requirements of these regulatory authorities for approval. The Company is responsible for development costs under the development plan up to a specified cap greater than $75.0 million and less than $95.0 million, plus its internal development costs. Development costs under the development plan include the costs of clinical trial materials, which are supplied by UCB and paid by the Company. Any development costs in excess of $95.0 million or for any required clinical trials in pediatric patients will be shared equally. Development costs for any EMA-specific post-approval studies will be borne solely by UCB. The Company incurred expenses related to clinical materials supplied by UCB totaling $3.4 million and $0 for the years ended December 31, 2015 and 2014. The Company recorded $0.9 million and $2.4 million in accounts payable and accrued liabilities, respectively, due to UCB as of December 31, 2015. There

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Technology and Financing Agreements (Continued)

were no amounts recorded in accounts payable and accrued liabilities due to UCB as of December 31, 2014.

UCB is obligated to pay the Company up to an aggregate of $36.0 million if certain development milestones are met, and up to an additional aggregate of $13.5 million upon the grant of regulatory approval, including pricing and reimbursement approval, in certain European countries. In December 2014, the Company earned the first development milestone of $7.3 million for dosing of the first patient in the Phase 3 clinical program for Cimzia and recorded the amount as collaboration revenue from a related party in the consolidated statements of operations for the year ended December 31, 2014. In September 2015, the Company earned the second development milestone of $7.3 million for the completion of patient enrollment in a Phase 3 clinical trial for Cimzia and recorded the amount as collaboration revenue from a related party in the consolidated statements of operations for the year ended December 31, 2015. As a result of achieving this milestone, there is $21.4 million in remaining development milestone payments that the Company is eligible to receive.

Under the terms of the UCB agreement, the Company will have the exclusive rights upon regulatory approval of the psoriasis indication to promote Cimzia to dermatologists in the United States and Canada. Following such regulatory approval, UCB will book sales and is obligated to pay the Company royalties representing a percentage of the annual gross profits (after subtracting the costs of certain commercialization support services to be provided by UCB) from Cimzia sales attributed to dermatologists in all indications in the United States and Canada. In each year, the royalties payable to the Company are tiered based upon increasing levels of annual net sales attributed to dermatologists in such year, with UCB retaining between 10% and, above $150.0 million of such annual net sales in such year, 50%, and the Company receiving the balance, of such annual gross profits. In addition, UCB is obligated to pay the Company up to an aggregate of $40.0 million upon the achievement of tiered milestones based on annual net sales of Cimzia attributed to dermatologists in the United States and Canada.

In connection with the UCB agreement, UCB purchased $5.0 million of shares of the Company's Series B convertible preferred stock in April 2014, $7.5 million of shares of the Company's Series C convertible preferred stock in August 2014 and $7.5 million of shares of the Company's common stock in a private placement concurrent with the Company's IPO, at the IPO price. As of December 31, 2015, UCB beneficially owned 1,841,234 shares, or approximately 6%, of the Company's outstanding common stock. One of the members of the Company's Board of Directors is an Executive Vice President and the Chief Operating Officer of UCB S.A.

11. Stockholders' Equity

Preferred Stock

As of December 31, 2015, the Company was authorized to issue up to 10,000,000 shares of preferred stock, par value $0.001 per share. Upon completion of the IPO, all shares of the Company's issued and outstanding convertible preferred stock were automatically converted into shares of common stock. The Company had no shares of preferred stock issued or outstanding as of December 31, 2015 or 2014.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Stockholders' Equity (Continued)

Common Stock

As of December 31, 2015, the Company was authorized to issue up to 500,000,000 shares of common stock, par value $0.001 per share.

The Company had reserved shares of common stock, on an as-converted basis, for issuance as follows:

	As of December 31,		
	2015	**2014**	**2013**
Share-based payments outstanding under stock incentive plans	3,814,342	3,401,395	1,743,590
Conversion of convertible preferred stock			9,540,158
Issuances upon exercise of convertible preferred stock warrant			11,276
Shares available for future stock option grants	1,154,895	941,339	142,506
Shares available for future issuance under employee stock purchase plan	491,192	301,724	
	5,460,429	4,644,458	11,437,530

12. Stock-Based Compensation

In 2010, the Company adopted the 2010 Equity Incentive Plan (the "2010 Plan") which provided for the granting of stock options to employees, directors and consultants of the Company. In September 2014, the Company's Board of Directors approved the 2014 Equity Incentive Plan (the "2014 EIP"), which became effective on October 1, 2014, the day prior to the effective date of the Company's registration statement on Form S-1. As of the effective date of the 2014 EIP, the 2010 Plan was terminated and no further stock awards will be granted pursuant to the 2010 Plan. Outstanding stock options granted under the 2010 Plan will continue to be governed by the provisions of the 2010 Plan until the earlier of the stock option's expiration or exercise.

Equity Incentive Plan

The 2014 EIP authorizes the reservation of 1,896,551 shares of the Company's common stock, plus any shares reserved or remaining for issuance, or that become available upon forfeiture of outstanding options or repurchase by the Company of shares granted pursuant to an equity award, in each case, under the 2010 Plan. On January 1 of each of the first 10 years commencing after the effective date of the IPO, the number of shares of the Company's common stock reserved for issuance under the 2014 EIP will increase automatically by an amount equal to 4% of the number of shares of the Company's common stock outstanding on the preceding December 31, unless the Company's Board of Directors elects to authorize a lesser number of shares. The Company's Board of Directors did not elect a lesser number of shares prior to December 31, 2015.

The 2014 EIP provides for the granting of stock options to employees, officers, directors, consultants and advisors of the Company. Options granted under the 2014 EIP may be either incentive stock options or nonqualified stock options. Incentive stock options ("ISOs") may be granted only to Company employees, including officers and directors who are also employees. Nonqualified stock options ("NSOs") may be granted to Company employees, officers, directors, consultants and advisors. The exercise price of options granted under the 2014 EIP must be at least equal to the fair market

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Stock-Based Compensation (Continued)

value of the common stock on the date of grant, except that an ISO granted to an employee who owns more than 10% of the shares of the Company's common stock shall have an exercise price of no less than 110% of the fair value per share on the grant date and expire five years from the date of grant. The maximum term of options granted under the 2014 EIP is 10 years, unless subject to the provisions regarding 10% stockholders. Options granted by the Company to new employees generally vest over four years at a rate of 25% upon the first anniversary of the issuance date and monthly thereafter. All other options granted by the Company to employees generally vest monthly over four years. As of December 31, 2015, the Company had reserved 2,846,896 shares of common stock for issuance under the 2014 EIP. Effective January 1, 2016, an additional 1,198,913 shares of common stock were reserved for issuance.

The following table reflects a summary of stock option activity for the specified periods (in thousands, except share and per share amounts):

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2014	941,339	3,401,395	$ 6.88		
Additional shares reserved under plan	738,860				
Options granted	(560,425)	560,425	$ 22.05		
Options exercised		(112,357)	$ 2.49		
Options forfeited	35,121	(35,121)	$ 12.15		
Options outstanding at December 31, 2015	1,154,895	3,814,342	$ 9.19	7.9	$ 96,954
Vested and expected to vest as of December 31, 2015		3,719,506	$ 9.07	7.8	$ 95,004
Exercisable as of December 31, 2015		1,917,616	$ 4.39	7.0	$ 57,947

The following table summarizes information with respect to stock options outstanding and exercisable as of December 31, 2015:

Exercise Price	Options Outstanding Number of Options Outstanding	Options Outstanding Weighted-Average Remaining Contractual Life (in years)	Options Outstanding Weighted-Average Exercise Price	Options Exercisable Number of Options Exercisable
$ 0.00 to $0.99	823,598	5.79	$ 0.96	813,792
$ 1.00 to $4.99	832,061	7.24	$ 1.43	570,618
$ 5.00 to $15.99	565,267	8.56	$ 7.24	181,024
$ 16.00 to $21.99	1,257,477	8.81	$ 16.17	341,413
$ 22.00 to $28.44	335,939	9.73	$ 25.76	10,769
	3,814,342	7.86	$ 9.19	1,917,616

The total estimated grant date fair value of options vested during the years ended December 31, 2015, 2014 and 2013 was $4.7 million, $0.8 million and $0.1 million, respectively. The total intrinsic

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Stock-Based Compensation (Continued)

value of options exercised during the years ended December 31, 2015 and 2014 was $3.6 million and $0.2 million, respectively. There were no options exercised during the year ended December 31, 2013.

Stock Options Granted to Employees

During the years ended December 31, 2015, 2014 and 2013, the Company granted stock options to employees and non-employee directors to purchase shares of common stock with a weighted-average grant date fair value of $12.49, $7.50 and $0.93 per share, respectively, and a weighted-average exercise price of $22.05, $7.13 and $1.40 per share, respectively. As of December 31, 2015, 2014 and 2013, there was total unrecognized compensation expense of $13.4 million, $10.9 million and $0.7 million, respectively, to be recognized over a period of approximately 2.84 years, 2.57 years and 2.48 years, respectively.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of the employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2015	2014	2013
Expected term (years)	6.1	6.0	6.1
Expected volatility	64.1%	66.0%	76.0%
Risk-free interest rate	1.9%	1.9%	1.3%
Expected dividend rate	0.0%	0.0%	0.0%

Expected Term: The Company determines the expected term using the simplified method (based on the midpoint between the vesting date and the end of the contractual term).

Expected Volatility: Prior to the IPO, the Company's common stock had never been publicly traded. The expected volatility was derived from the average historic volatilities of several public companies within the Company's industry that the Company considered to be comparable to its business over a period equivalent to the expected term of the option. As a public company, the Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate: The Company determines the risk free interest rate based on the U.S. Treasury yield in effect at the time of the grant for zero coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

Expected Dividend Rate: The Company has never paid any dividends and does not anticipate paying any dividends in the foreseeable future, and therefore used an expected dividend rate of zero in the valuation model.

Stock Options Granted to Non-employees

Stock-based compensation expense related to stock options granted to non-employees is recognized as the stock options are earned. During the year ended December 31, 2015, the Company did not grant

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Stock-Based Compensation (Continued)

options to non-employees. During the year ended December 31, 2014, the Company granted options to purchase 4,310 shares of common stock to persons other than employees and non-employee members of the Company's Board of Directors with an exercise price of $16.00 per share. During the year ended December 31, 2013, the Company granted options to purchase 36,031 shares of common stock to non-employees with an exercise price of $1.74 per share.

Compensation expense related to these options during the years ended December 31, 2015, 2014, and 2013 was approximately $253,000, $304,000 and $38,000, respectively.

The Company believes that the fair value of the stock options is more reliably measurable than the fair value of services received. The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2015	2014	2013
Expected term (in years)	7.3	7.6	8.3
Expected volatility	61.3%	66.0%	72.0%
Risk-free interest rate	1.9%	2.1%	2.4%
Expected dividend rate	0.0%	0.0%	0.0%

Employee Stock Purchase Plan

On September 9, 2014, the Company's Board of Directors adopted and approved the 2014 Employee Stock Purchase Plan (the "2014 ESPP"), which became effective on October 2, 2014, the day that the Company's Registration Statement on Form S-1 was declared effective. The 2014 ESPP authorizes the reservation of 301,724 shares of the Company's common stock for issuance thereunder. On January 1 of each of the first 10 years commencing after the effective date of the IPO, the number of shares of the Company's common stock reserved for issuance under the 2014 ESPP will increase automatically by an amount equal to 1% of the number of shares of the Company's common stock outstanding on the preceding December 31, unless the Company's Board of Directors or compensation committee elects to authorize a lesser number of shares. The Company's Board of Directors and compensation committee did not elect a lesser number of shares on January 1, 2016. Subject to certain limitations, the Company's employees may elect to have 1% to 15% of their compensation withheld through payroll deductions to purchase shares of common stock under the 2014 ESPP. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of the two-year offering period. As of December 31, 2015, the Company had reserved 548,010 shares of common stock for issuance under the 2014 ESPP. Compensation expense related to the 2014 ESPP for the years ended December 31, 2015 and 2014 was approximately $417,000 and $57,000, respectively.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Stock-Based Compensation (Continued)

The fair value of each employee stock purchase right grant is estimated using the Black-Scholes option pricing model and is recognized as expense using the straight-line method. The weighted-average estimated fair value of employee stock purchase rights granted pursuant to the ESPP during 2015 and 2014 was $8.03 and $5.09 per share, respectively, and was based on the following assumptions:

	Year ended December 31,	
	2015	2014
Expected term (in years)	1.3	1.3
Expected volatility	56.0%	54.0%
Risk-free interest rate	0.4%	0.1%
Expected dividend rate	0.0%	0.0%

Total Stock-Based Compensation

Total stock-based compensation expense related to the 2010 Plan, the 2014 EIP and the 2014 ESPP was allocated as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Research and development	$ 1,984	$ 836	$ 196
General and administrative	3,148	807	96
Total stock-based compensation expense	$ 5,132	$ 1,643	$ 292

There were no capitalized stock-based compensation costs or recognized stock-based compensation tax benefits during the years ended December 31, 2015, 2014 and 2013.

13. Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its employees. This plan provides for tax-deferred salary deductions for all employees. Employee contributions are voluntary. Employees may contribute up to 100% of their annual compensation to this plan, as limited by an annual maximum amount as determined by the Internal Revenue Service. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. The Company made no contributions to the plan for the years ended December 31, 2015, 2014 and 2013.

14. Income Taxes

The Company has a benefit for income taxes of $0.6 million for the year ended December 31, 2015. The benefit for income tax relates to the reduction in the deferred tax liability resulting from the impairment charge to IPR&D, which is not recognized for tax purposes. The Company had a provision for income taxes of $31,000 for the year ended December 31, 2014. The provision for income tax relates to the deferred tax liability of the Company's Canadian subsidiary as a result of a change in the Canadian corporate tax rate. There was no provision for income taxes for the year ended December 31, 2013.

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Income Taxes (Continued)

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2015 and 2014 consisted of the following (in thousands):

	Year Ended December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$ 51,703	$ 24,395
Depreciation and amortization	510	529
Research and development tax credits	1,910	1,345
Deferred Revenue		3,423
Accruals and stock-based compensation expense	2,638	1,101
Total deferred tax assets	56,761	30,793
Deferred tax asset valuation allowance	(56,761)	(30,793)
Net deferred tax assets		
Deferred tax liabilities:		
Acquired IPR&D	(194)	(816)
Net deferred tax assets prior to valuation allowance	(194)	(816)
Net deferred tax liabilities	$ (194)	$ (816)

Reconciliations of the statutory federal income tax benefit rate to the Company's effective tax for the years ended December 31, 2014, 2013 and 2012 are as follows:

	Year Ended December 31,		
	2015	2014	2013
Tax (benefit) at statutory federal rate	34.0%	34.0%	34.0%
State tax (benefit), net of federal benefit		0.2	5.8
Foreign tax, net of federal benefit	(1.1)	(0.2)	(1.1)
Permanent differences	(0.8)	(0.9)	(0.4)
Research and development credits	0.7	1.2	0.9
Change in valuation allowance	(32.0)	(34.4)	(39.2)
Effective tax rate	0.8%	(0.1)%	%

A valuation allowance is provided when it is more likely than not that the deferred tax assets will not be realized. The Company has established a valuation allowance to offset net deferred tax assets as of December 31, 2015 and 2014 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets. The Company's valuation allowance increased by approximately $26.0 million and $11.0 million for the years ended December 31, 2015 and 2014, respectively.

As of December 31, 2015, the Company had net operating loss ("NOL") carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes of $142.0 million, $44.2 million and $3.9 million, respectively. Of these amounts, $0.5 million and $0, respectively, represent federal and state tax deductions from stock-based compensation that will be

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Income Taxes (Continued)

recorded as an adjustment to additional paid-in capital when such amounts reduce taxes payable. The federal and California NOL carryforwards will begin expiring during the year ended December 31, 2030 and the Canadian NOL carryforwards will begin expiring during the year ended December 31, 2028. The NOL carryforwards related to deferred tax assets do not include excess tax benefits from employee stock option exercises.

As of December 31, 2015, the Company also had research and development credit carryforwards of $0.8 million, $0.8 million and $0.6 million available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes, respectively. The federal and Canadian credit carryforwards will begin expiring in 2031 and the California state credit carryforwards has no expiration date.

In general, if the Company experiences a greater than 50 percentage point aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards is subject to an annual limitation under Section 382 of the Internal Revenue Code (California has similar laws). The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long- term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company has experienced at least one ownership change since inception and utilization of NOL carryforwards will therefore be subject to annual limitation. In addition, the ability of the Company to use its remaining NOL carryforwards may be further limited if the Company experiences a Section 382 ownership change in connection with future changes in its stock ownership.

The Company recognizes uncertain tax positions when it is more likely than not, based on the technical merits, that the position will not be sustained upon examination. The guidance also clarifies the financial statement classification of tax-related penalties and interest and sets forth new disclosure regarding unrecognized tax benefits. The Company's policy is to include interest and penalties, if any, related to unrecognized tax benefits within the Company's provision for income taxes.

As the Company has a full valuation allowance against its deferred tax assets, the unrecognized tax benefits will reduce the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to change in the next 12 months. A summary of the activity of the unrecognized tax benefits is as follows (in thousands):

Balance as of December 31, 2012	$	122
Addition based on tax position related to current year		155
Increase related to tax positions taken during a prior period		53
Balance as of December 31, 2013		330
Addition based on tax position related to current year		305
Balance as of December 31, 2014		635
Addition based on tax position related to current year		437
Balance as of December 31, 2015	$	1,072

The Company files income tax returns in the United States, California and Canada. The Company is not currently under examination by income tax authorities in federal, state, Canadian or other

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Income Taxes (Continued)

jurisdictions. All tax returns for 2011 and later will remain open for examination by the federal, state and Canadian authorities for three, four and four years, respectively. The federal and state taxing authorities may choose to audit tax returns for tax years beyond the statute of limitation period due to significant tax attribute carryforwards from prior years, making adjustments only to carryforward attributes.

On December 18, 2015, legislation, which will extend over 50 expired provisions of the tax code, was signed into law. Among the extended provisions is the Section 41 research credit for qualified research expenditures incurred through the end of 2015, which is now a permanent tax credit. The benefit of the reinstated credit did not impact the consolidated statements of operations in the period of enactment, which was the fourth quarter of 2015, as the research and development credit carryforwards are offset by a full valuation allowance.

15. Quarterly Results of Operations (Unaudited)

The following table contains quarterly financial information for 2015 and 2014. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	2015			
(Amounts in thousands, except share and per share amounts)	**First Quarter**	**Second Quarter**	**Third Quarter**	**Fourth Quarter**
Collaboration revenue from a related party	$	$	$ 7,300	$
Operating expenses:				
Research and development	10,088	13,495	18,890	24,358
General and administrative	4,146	3,848	4,684	5,043
Impairment of intangible assets				2,394
Total operating expenses	14,234	17,343	23,574	31,795
Loss from operations	(14,234)	(17,343)	(16,274)	(31,795)
Interest and other income (expense), net	237	222	259	178
Interest expense	(38)	(38)	(39)	(32)
Loss on extinguishment of debt				(124)
Loss before taxes	(14,035)	(17,159)	(16,054)	(31,773)
(Benefit) for income taxes				(622)
Net loss	$ (14,035)	$ (17,159)	$ (16,054)	$ (31,151)
Net loss per share, basic and diluted	$ (0.57)	$ (0.69)	$ (0.58)	$ (1.04)
Weighted-average common shares used to compute net loss per share, basic and diluted	24,655,011	24,694,920	27,553,952	29,938,543

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DERMIRA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. Quarterly Results of Operations (Unaudited) (Continued)

	2014			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Collaboration revenue from a related party	$	$	$	$ 7,300
Operating expenses:				
Research and development	6,685	6,963	6,028	11,034
General and administrative	1,812	1,740	1,688	3,048
Total operating expenses	8,497	8,703	7,716	14,082
Loss from operations	(8,497)	(8,703)	(7,716)	(6,782)
Interest and other income (expense), net	(9)	(25)	(84)	125
Interest expense	(33)	(34)	(47)	(39)
Loss before taxes	(8,539)	(8,762)	(7,847)	(6,696)
Provision for income taxes				31
Net loss	$ (8,539)	$ (8,762)	$ (7,847)	$ (6,727)
Net loss per share, basic and diluted	$ (9.56)	$ (9.72)	$ (8.66)	$ (0.29)
Weighted-average common shares used to compute net loss per share, basic and diluted	893,542	901,140	906,239	22,822,844

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate, to allow for timely decisions regarding required or necessary disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost- benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2015. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f). Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework

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in Internal Control Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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PART III. OTHER INFORMATION.

Certain information required by Part III is omitted from this annual report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, or the Proxy Statement, which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2015.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Pursuant to General Instruction G(3) of Form 10-K, the information required by this Item 10 relating to our executive officers is included under the caption "Executive Officers" in Part I of this Form 10-K. The other information required by this item is incorporated herein by reference to information contained in the Proxy Statement for our 2016 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated herein by reference to information contained in the Proxy Statement for our 2016 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated herein by reference to information contained in the Proxy Statement for our 2016 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated herein by reference to information contained in the Proxy Statement for our 2016 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated herein by reference to information contained in the Proxy Statement for our 2016 Annual Meeting of Stockholders.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

The following documents are filed as part of this report:

(1)

Financial Statements

Our Consolidated Financial Statements are listed in the "Index to Consolidated Financial Statements" under Part II. Item 8 of this Annual Report on Form 10-K.

(2)

Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the consolidated financial statements or related notes thereto.

(b)

Exhibits. The list of exhibits filed with this report is set forth in the Exhibit Index following the signature pages and is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in Menlo Park, California, on the 3rd day of March 2016.

DERMIRA, INC.

By: /s/ THOMAS G. WIGGANS

Thomas G. Wiggans
Chief Executive Officer and Chairman of the Board (Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas G. Wiggans and Andrew L. Guggenhime, jointly and severally, as his or her true and lawful attorneys-in-fact, proxies and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, proxies and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact, proxies and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ THOMAS G. WIGGANS Thomas G. Wiggans	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 3, 2016
/s/ ANDREW L. GUGGENHIME Andrew L. Guggenhime	Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer)	March 3, 2016
/s/ EUGENE A. BAUER M.D. Eugene A. Bauer	Chief Medical Officer and Director	March 3, 2016
/s/ DAVID E. COHEN, M.D., M.P.H. David E. Cohen, M.D., M.P.H.	Director	March 3, 2016

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Signature	Title	Date
/s/ FRED B. CRAVES Fred B. Craves	Lead Independent Director	March 3, 2016
/s/ MATTHEW K. FUST Matthew K. Fust	Director	March 3, 2016
/s/ MARK D. MCDADE Mark D. McDade	Director	March 3, 2016
/s/ JAKE R. NUNN Jake R. Nunn	Director	March 3, 2016
/s/ WILLIAM R. RINGO William R. Ringo	Director	March 3, 2016
/s/ KATHLEEN SEBELIUS Kathleen Sebelius	Director	March 3, 2016

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EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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	08/27/2014	
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	08/27/2014	
10.1#	Form of Indemnity Agreement.	S-1	333-198410	10.1	09/19/2014	
10.2#	2010 Equity Incentive Plan and forms of award agreements.	S-1	333-198410	10.2	08/27/2014	
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	08/27/2014	
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	03/25/2015	
10.7#	Amended and Restated Employment Agreement, dated August 4, 2011, by and between the Registrant and Eugene A. Bauer	S-1	333-198410	10.6	08/27/2014	
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	09/29/2014	
10.9	Exclusive License Agreement, dated April 26, 2013, by and between the Registrant and Rose U LLC.	S-1	333-198410	10.10	09/29/2014	
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	03/25/2015	
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	09/29/2014	
10.12	Lease Agreement, dated July 24, 2014, as amended, by and between the Registrant and Middlefield Park.	S-1	333-198410	10.13	09/12/2014	

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Exhibit Number	Description of Document	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.13	Second Amendment to Lease, dated December 4, 2015, by and between the Registrant and Middlefield Park.					X
10.14#	Form of Severance and Change in Control Agreement.	S-1	333-198410	10.14	09/12/2014	
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of independent registered public accounting firm.					X
24.1	Power of Attorney (see signature page to this report).					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

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.

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Represents a management contract or compensatory plan.

*

As contemplated by SEC Release No. 33-8212, these exhibits are furnished with this Annual Report on Form 10-K and are not deemed filed with the Securities and Exchange Commission and are not incorporated by reference in any filing of Dermira, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filings.

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