

Dermira, Inc.
Form 424B4
October 03, 2014

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**Filed Pursuant to Rule 424(b)(4)
Registration No. 333-198410**

PROSPECTUS

7,812,500 Shares

Dermira, Inc.

Common Stock

\$16.00 per share

This is an initial public offering of shares of our common stock. We are selling 7,812,500 shares of common stock in this offering. The initial public offering price of our common stock is \$16.00 per share. Concurrently with the closing of this offering, entities affiliated with UCB Pharma S.A. will purchase from us in a private placement 468,750 shares of our common stock with an aggregate purchase price of \$7.5 million, at a price per share equal to the initial public offering price.

We have granted the underwriters an option to purchase up to 1,171,875 additional shares of common stock to cover over-allotments.

Our common stock has been approved for listing on The NASDAQ Global Select Market under the symbol "DERM."

Investing in our common stock involves risks. See "Risk Factors" beginning on page 13.

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be eligible for reduced public company disclosure requirements. See "Summary Implications of Being an Emerging Growth Company."

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

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	Per Share	Total
Public Offering Price	\$ 16.00	\$ 125,000,000
Underwriting Discount(1)	\$ 1.12	\$ 8,750,000
Proceeds to Dermira (before expenses)	\$ 14.88	\$ 116,250,000

(1) We refer you to "Underwriting" beginning on page 190 for additional information regarding underwriting compensation.

Certain of our principal stockholders affiliated with our directors have agreed to purchase 187,500 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

The underwriters expect to deliver the shares to purchasers on or about October 8, 2014 through the book-entry facilities of The Depository Trust Company.

Citigroup

Guggenheim Securities

Leerink Partners

Needham & Company

October 2, 2014

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

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

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SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider in making your investment decision. Before deciding to invest in shares of our common stock, you should read this summary together with the more detailed information, including our consolidated financial statements and the accompanying notes, provided elsewhere in this prospectus. You should carefully consider, among other things, the matters discussed in the sections entitled "Risk Factors," "Selected Consolidated Financial Data," our consolidated financial statements and the accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included elsewhere in this prospectus. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements."

Our Company

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

Medical dermatology focuses on therapeutic solutions to treat serious skin conditions, such as psoriasis, acne, atopic dermatitis, commonly known as eczema, and hyperhidrosis. 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. Furthermore, according to multiple published studies, patients report that medical dermatology conditions affect quality of life in ways comparable to other serious diseases, such as cancer, heart disease, diabetes, epilepsy, asthma and arthritis.

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

Dermatology represents a large, growing, specialty market supported by strong patient demand.

The dermatology market is ripe for innovation with significant commercial opportunities.

The development of dermatology products can be relatively efficient in terms of time and cost.

Dermatology products can be commercialized at relatively low cost.

The needs of dermatologists and their patients have been underserved as a result of the significant consolidation of dermatology-focused companies.

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

Dermira was founded by Thomas G. Wiggans, Eugene A. Bauer, M.D., Christopher M. Griffith and Luis C. Peña with the vision of building a leading dermatology company. Several members of our management team, including Mr. Wiggans, Dr. Bauer and Mr. Peña, have extensive experience within the dermatology field, including having served in executive roles at leading dermatology companies such

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as Connetics Corporation, Peplin, Inc. and Stiefel Laboratories, Inc., a GlaxoSmithKline LLC Company, or Stiefel. This experience brings us significant insight into product and commercial opportunities, as well as a broad network of relationships with leaders within the industry and medical community.

Our Product Candidates

Our three late-stage product candidates are:

Cimzia, an injectable biologic tumor necrosis factor-alpha inhibitor, or TNF inhibitor, that is currently approved and marketed by UCB for the treatment of numerous inflammatory diseases spanning multiple medical specialties, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease, in multiple countries, including the United States. Biologic TNF inhibitors are a class of pharmaceutical products that are manufactured by biological processes and designed to exert their effect by inhibiting TNF, a naturally occurring molecule that plays an important role in promoting inflammation within the body, including in patients with psoriasis. We have entered into a development and commercialization agreement, or the UCB agreement, to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. UCB has conducted two Phase 2 clinical trials, including a 176-patient, randomized, multi-center, double-blind, placebo-controlled trial, that demonstrated significant reductions in the signs and symptoms of moderate-to-severe plaque psoriasis. We and UCB conducted an end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or the FDA, in June 2014, filed an investigational new drug application, or IND, for the treatment of moderate-to-severe plaque psoriasis with the FDA in September 2014 and intend to commence Phase 3 clinical trials in the first half of 2015.

DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of hyperhidrosis. Anticholinergics are a class of pharmaceutical products that exert their effect by blocking the action of acetylcholine, a molecule that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. DRM04 is a topical formulation of a novel form of an anticholinergic agent that has been approved for systemic administration in other indications, and it is designed to inhibit sweat production by blocking the activation of sweat glands following topical administration. Two randomized, double-blind, vehicle-controlled Phase 2 clinical trials, including a 198-patient, multi-center Phase 2b clinical trial and a 38-patient Phase 2a clinical trial, have demonstrated significant reductions in the signs and symptoms of primary axillary, or underarm, hyperhidrosis in patients treated 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. In addition, we are currently conducting a Phase 2b clinical trial in patients with primary axillary hyperhidrosis in which we are comparing DRM04 to the topical formulation of the reference agent. We expect data from this trial in the first half of 2015. If successful, we intend to commence a Phase 3 clinical program, which would include one or more Phase 3 clinical trials, in the second half of 2015.

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 a prodrug designed to inhibit the production of sebum by delivering a widely-studied lipid synthesis inhibitor to the skin following topical administration. We have completed a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial that demonstrated significant reductions in the signs and

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symptoms of acne. Based on the results of this Phase 2a clinical trial, we intend to file an IND with the FDA and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015.

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

Our Strategy

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

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

Efficiently establish proof-of-concept for our early-stage product candidates and advance promising candidates into late-stage development. We seek to rapidly and efficiently establish proof-of-concept for our early-stage product candidates. Our experienced management team is able to efficiently determine whether and how to advance product candidates into the next stages of development, which we believe increases our ability to direct resources to promising programs and enhances our likelihood of successfully developing and commercializing our product candidates. We believe that our advancement of DRM01 into late-stage development demonstrates our ability to efficiently progress promising candidates into late-stage development.

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

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

Maximize the value of our portfolio by commercializing our approved products ourselves where we can effectively do so and partnering with other companies to help us reach new markets. We currently plan to commercialize our approved products in the United States and Canada by deploying a specialized sales force targeting dermatologists in these countries. We intend to partner with third parties to help us reach other geographic markets or therapeutic specialties.

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

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exceptional opportunity to build relationships with opinion leaders, advocacy groups and medical practitioners. We intend to take advantage of this opportunity in order to accelerate the identification, in-licensing, acquisition, development and commercialization of product candidates and products that we believe can be successful in the dermatology marketplace.

Key Markets for Our Product Candidates

The Moderate-to-Severe Plaque Psoriasis Market

Psoriasis is a chronic, complex, immune-mediated disease that requires long-term treatment. It is commonly considered the most prevalent autoimmune disease in the world. According to Decision Resources, the diagnosed prevalence of psoriasis in the United States was approximately 9.3 million people, or approximately 2.8% of the population, in 2012.

According to Decision Resources, U.S. sales of psoriasis prescriptions accounted for \$3.6 billion in 2012. In the same year, U.S. sales of biologic therapies for moderate-to-severe plaque psoriasis were \$2.9 billion, of which \$2.3 billion were from TNF inhibitors. According to data provided by IMS Health National Prescription Audit and National Sales Perspectives, between 2009 and 2012, sales of biologic therapies attributable to U.S. dermatologists grew at an average annual rate of 20% and sales of TNF inhibitors attributable to U.S. dermatologists grew at an average annual rate of 9%.

We believe that there is a substantial opportunity for continued expansion of the market for biologic psoriasis therapies. 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. We believe that penetration into the psoriasis patient population may continue to increase as dermatologists become more familiar with available biologic therapies, particularly, the established safety record of TNF inhibitors, and as new biologic products reach the market. Decision Resources projects that U.S. sales of branded, systemic psoriasis therapies will increase from approximately \$3.1 billion in 2012 to \$5.7 billion by 2022.

The Hyperhidrosis Market

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

The market for products to control sweating is large and highly underpenetrated by prescription pharmaceutical products. Despite the limited efficacy of over-the-counter, or OTC, antiperspirants for the alleviation of hyperhidrosis symptoms, according to a 2003 survey, only 38% of hyperhidrosis patients had discussed their condition with a healthcare professional. We believe that this is largely a 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. While these topical antiperspirants generate over 500,000 prescriptions annually in the United States, 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.

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The Acne Market

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

According to VisionGain, acne accounted for approximately \$3.7 billion in global pharmaceutical sales in 2012. In the same year, each of the three major prescription pharmaceutical product classes that are predominantly used to treat acne generated between approximately \$670 million and \$1.9 billion in U.S. sales, according to data provided by Symphony Health Solutions, Pharmaceutical Audit Suite. 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.

Selected Risks Associated with Our Business

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

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

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

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

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

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

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

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

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

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

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

The report of our independent registered public accounting firm on our 2013 consolidated financial statements contains an explanatory paragraph regarding going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.

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.

Concurrent Private Placement

Concurrently with the closing of this offering, entities affiliated with UCB will purchase from us in a private placement 468,750 shares of our common stock with an aggregate purchase price of \$7.5 million, at a price per share equal to the initial offering price.

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 2055 Woodside Road, Redwood City, California 94061, and our telephone number is (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 prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock.

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

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

Implications of Being an Emerging Growth Company

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

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

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

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

reduced disclosure about our executive compensation arrangements; and

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

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

The JOBS Act also 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.

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The Offering

Shares of common stock offered by us	7,812,500 shares
Over-allotment option to be offered by us	1,171,875 shares
Shares of common stock sold in the concurrent private placement	Concurrently with the closing of this offering, entities affiliated with UCB will purchase from us in a private placement 468,750 shares of our common stock with an aggregate purchase price of \$7.5 million, at a price per share equal to the initial public offering price. We will receive the full proceeds from the sale and will not pay any underwriting discounts or commissions with respect to the shares that are sold in the private placement. The sale of these shares to entities affiliated with UCB will not be registered in this offering. We refer to the private placement of these shares of common stock as the concurrent private placement.
Shares of common stock to be outstanding immediately after this offering and the concurrent private placement	19,322,429 shares (20,494,304 shares if the over-allotment option is exercised in full)
Insider Participation	Certain of our principal stockholders affiliated with our directors have agreed to purchase 187,500 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.
Use of proceeds	We currently intend to use the net proceeds from this offering and the concurrent private placement for external research and development expenses associated with the development of our Cimzia, DRM04 and DRM01 product candidates, with the balance primarily used to fund internal research and development expenses associated with all of our product candidates, working capital, capital expenditures and other general corporate purposes. See "Use of Proceeds."
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ symbol	"DERM"
The number of shares of our common stock to be outstanding following this offering and the concurrent private placement is based on 11,041,179 shares of our common stock outstanding as of June 30, 2014. This number assumes the conversion of all outstanding shares of our convertible	

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preferred stock, which will occur automatically in connection with the completion of this offering, and excludes:

2,265,305 shares of our common stock issuable upon the exercise of outstanding options under the 2010 Equity Incentive Plan, or the 2010 Plan, as of June 30, 2014, with a weighted-average exercise price of \$2.15 per share;

11,276 shares of our Series B convertible preferred stock issuable upon the exercise of a warrant outstanding as of June 30, 2014, with an exercise price of \$8.4245 per share;

5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 for a price per share of \$9.628; and

2,383,549 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 55,964 shares of our common stock reserved for issuance under the 2010 Plan as of June 30, 2014, (2) 129,310 shares of our common stock reserved for issuance under the 2010 Plan after June 30, 2014, (3) 1,896,551 shares of our common stock reserved for issuance under the 2014 Equity Incentive Plan, or the 2014 Plan, which includes 1,084,835 shares of our common stock that are issuable upon the exercise of options to purchase common stock with an exercise price per share equal to the initial public offering price, which options were granted on the day that the registration statement for this offering was declared effective, and (4) 301,724 shares of our common stock reserved for issuance under the 2014 Employee Stock Purchase Plan, or the 2014 ESPP. On the date of this prospectus, any remaining shares available for issuance under the 2010 Plan will be added to the shares reserved under the 2014 Plan and we will cease granting awards under the 2010 Plan. The 2014 Plan and the 2014 ESPP also provide for automatic annual increases in the number of shares reserved thereunder, as more fully described in "Executive Compensation Employee Benefit and Stock Plans."

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

a 5.8-to-1 reverse stock split of our outstanding capital stock that was effected on September 18, 2014;

the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2014 into an aggregate of 10,133,665 shares of our common stock effective immediately upon the completion of this offering;

the automatic conversion of 5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 into an aggregate of 5,297,041 shares of our common stock effective immediately upon the completion of this offering;

the automatic conversion of an outstanding warrant exercisable for 11,276 shares of our Series B convertible preferred stock as of June 30, 2014 into a warrant exercisable for 11,276 shares of common stock, which will occur automatically in connection with the completion of this offering;

the filing of our restated certificate of incorporation and the effectiveness of our restated bylaws, which will occur upon the completion of this offering;

no exercise of outstanding options or the outstanding warrant; and

no exercise of the underwriters' over-allotment option.

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Summary Consolidated Financial Data

The following summary consolidated financial data should be read with "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, the accompanying notes and other financial information included elsewhere in this prospectus.

The following tables summarize our consolidated financial data. We derived our summary consolidated statements of operations data for the years ended December 31, 2012 and 2013 from our audited consolidated financial statements included elsewhere in this prospectus. We derived our summary consolidated statements of operations data for the six months ended June 30, 2013 and 2014 and our summary consolidated balance sheet data as of June 30, 2014 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. Our unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, on the same basis as our audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, that are necessary for the fair presentation of our consolidated financial position as of June 30, 2014 and our consolidated results of operations for the six months ended June 30, 2013 and 2014. Our historical results are not necessarily indicative of the results to be expected in the future, and the results for the six months ended June 30, 2014 are not necessarily indicative of the results to be expected for the full year or any other period. You should read the following summary consolidated financial data in conjunction with the sections entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, the accompanying notes and other financial information included elsewhere in this prospectus.

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	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
(Unaudited)				
(in thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 17,055	\$ 17,937	\$ 8,778	\$ 13,648
General and administrative	3,148	4,366	2,205	3,552
Total operating expenses	20,203	22,303	10,983	17,200
Loss from operations	(20,203)	(22,303)	(10,983)	(17,200)
Interest and other income (expense), net	(51)	(38)	12	(34)
Interest expense		(9)		(67)
Net loss	\$ (20,254)	\$ (22,350)	\$ (10,971)	\$ (17,301)
Net loss per share, basic and diluted(1)	\$ (27.99)	\$ (27.03)	\$ (13.88)	\$ (19.28)
Weighted-average common shares used to compute net loss per share, basic and diluted(1)	723,607	826,757	790,512	897,356
Pro forma net loss per share, basic and diluted (unaudited)(1)		\$ (2.31)		\$ (1.62)
Weighted-average common shares used to compute pro forma net loss per share, basic and diluted, (unaudited)(1)		9,667,715		10,706,395

(1) See Note 2 to our consolidated financial statements for an explanation of the method used to calculate our basic and diluted net loss per share, unaudited pro forma basic and diluted net loss per share and weighted-average common shares outstanding used to calculate the per share amounts.

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	As of June 30, 2014		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
	(in thousands, unaudited)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 9,774	\$ 58,587	\$ 178,887
Working capital	3,921	52,794	173,094
Total assets	16,530	65,343	185,643
Convertible preferred stock warrant liability	60		
Bank term loan, current and non-current	1,931	1,931	1,931
Convertible preferred stock	64,588		
Additional paid-in capital	1,287	114,733	235,024
Accumulated deficit	(68,075)	(68,075)	(68,075)
Total stockholders' (deficit) equity	(66,787)	46,674	166,974

- (1) The pro forma consolidated balance sheet data as of June 30, 2014 reflects: (a) the issuance of 5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 and receipt of the related net proceeds of \$48.8 million; (b) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock effective immediately upon the completion of this offering; (c) the automatic conversion of an outstanding warrant exercisable for 11,276 shares of our Series B convertible preferred stock into a warrant

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exercisable for 11,276 shares of common stock in connection with this offering; and (d) the filing of our restated certificate of incorporation and the effectiveness of our restated bylaws, as if our restated certificate of incorporation was filed and our restated bylaws had become effective on June 30, 2014.

(2)

The pro forma as adjusted column in the summary consolidated balance sheet data above reflects the effect of the sale by us of 8,281,250 shares of our common stock in this offering and the concurrent private placement, at an initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including the consolidated financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus before deciding whether to invest in shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In that event, the market price of our stock could decline, and you could lose part or all of your investment.

Risks Related to Development, Regulatory Approval and Commercialization

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

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

the ability to raise additional capital on acceptable terms, or at all;

timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;

whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;

acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;

our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy 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;

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achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;

the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;

a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates;

our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;

acceptance by physicians and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;

our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;

our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and

our ability to in-license or acquire additional product candidates or commercial-stage products that we believe can be successfully developed and commercialized.

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

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

We are a clinical-stage specialty biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred losses in each year since we commenced operations in August 2010. We have incurred net losses of \$20.3 million, \$22.4 million and \$17.3 million for the years ended December 31, 2012 and 2013 and for the six months ended June 30, 2014, respectively. As of June 30, 2014, we had an accumulated deficit of \$68.1 million.

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

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As of June 30, 2014, we had capital resources consisting of cash and cash equivalents of \$9.8 million and in August 2014, we issued shares of our Series C convertible preferred stock and received related net proceeds of \$48.8 million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, manufacturing and supply, as well as marketing and selling any products approved for sale. In particular, our Phase 3 clinical programs for our product candidates will require substantial funds to complete. We plan to finance the development and commercialization of Cimzia in part through milestone payments made by UCB under the UCB agreement. In addition, other unanticipated costs may arise. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates.

We believe that the net proceeds from this offering and the concurrent private placement and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through 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 of our lead product candidates, Cimzia, DRM04 and DRM01, exceed the net proceeds from this offering and the concurrent private placement and our existing cash and cash equivalents. We will need to raise additional capital following this offering to fund our operations and continue to support our planned research and development and commercialization activities. We have substantial contractual obligations to UCB. For more information about our collaboration with UCB, see "Business Collaborations and License Agreements Collaboration with UCB." In 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;

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costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;

costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;

costs associated with any product recall that could occur;

costs of operating as a public company;

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

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

personnel, facilities and equipment requirements.

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

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

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

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

The UCB agreement requires us to pay all development costs in order for UCB to seek approval of Cimzia for the treatment of moderate-to-severe plaque psoriasis from the FDA, the European Medicines Agency, or the EMA, as established by Regulation (EC) 2309/93 and Regulation (EC) 726/2004, and the Canadian federal department for health, or Health Canada, up to a specified 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

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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:

regulatory requirements prior to commencing a clinical trial;

the terms of agreements with prospective contract research organizations, or CROs, and trial sites, which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and other third-party contractors;

identification and maintenance of a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs;

withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;

inability to obtain institutional review board, or IRB, approval to conduct a clinical trial at prospective sites;

increase in the time and expense required to conduct clinical trials due to difficulties in recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the treatment of psoriasis; and

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

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

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

failed inspection of the clinical trial operations or trial sites by the FDA, the EMA, Health Canada or other regulatory authorities;

unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;

inability to fully enroll clinical trials; and

lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties or other reasons.

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

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Clinical drug development for our product candidates is very expensive, time-consuming, 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

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IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

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

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

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

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

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

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

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

changes in applicable laws, regulations and regulatory policies;

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

inability to add a sufficient number of clinical trial sites;

uncertainty regarding proper dosing;

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

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

scheduling conflicts with participating clinicians and clinical institutions;

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failure to design appropriate clinical trial protocols;

insufficient data to support regulatory approval;

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

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

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

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example, the dosage form for DRM04 is an API-saturated wipe, and we are not aware of previous FDA approvals of prescription drug wipes.

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

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

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

To gain approval to market a biologic product such as Cimzia or a new drug such as DRM04 or DRM01, the FDA and foreign regulatory authorities must receive preclinical and clinical 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 our Phase 2 clinical trial for Cimzia in moderate-to-severe plaque psoriasis, a six-point physical global assessment, or PGA, scale was used, and we intend to use a five-point PGA scale in the Phase 3 clinical trials. As a result, data from our Phase 2 clinical trial may not accurately predict Phase 3 results. In addition, for DRM04, the results of our Phase 2a and Phase 2b clinical trials may not accurately predict results in our Phase 3 clinical trials that will have larger numbers of patients. Even for a drug such as Cimzia that has been approved for multiple indications, regulatory review processes are lengthy and uncertain.

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

the FDA or the applicable foreign regulatory body may disagree with the design or implementation of one or more clinical trials;

the FDA or the applicable foreign regulatory body may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;

the FDA or the applicable foreign regulatory body may not find the data from preclinical studies and clinical trials 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, 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 give us marketing clearance of a device intended to be used in combination with our product candidate DRM05, or any other future product candidates; or

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the FDA or the applicable foreign regulatory body may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. For example, the FDA may not agree with our Phase 3 clinical trial protocols for Cimzia. In addition, our product candidates may not be approved by the FDA or applicable foreign regulatory agencies even though they meet specified endpoints in our clinical trials. The FDA or applicable foreign regulatory

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agencies may ask us to conduct additional costly and time-consuming clinical trials in order to obtain marketing approval or approval to enter into an advanced phase of development, or may change the requirements for approval even after such agency has reviewed and commented on the design for the clinical trials. In our collaboration with UCB, we are required to pursue development in support of UCB seeking approval from each of the FDA, the EMA and Health Canada, although we have the right to abandon pursuit of regulatory approval in Canada. If UCB is unable to obtain and retain regulatory approval for the marketing of Cimzia for psoriasis, we could lose our ability to receive royalties and regulatory- and sales-based milestone payments, which would adversely affect our financial position and business.

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

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

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

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

If Cimzia does receive regulatory approval for the treatment of psoriasis in the United States or Canada, UCB could use its final decision-making authority to direct our market access, promotional or medical affairs activities to dermatologists in ways that would adversely impact sales attributable to dermatologists, including due to a concern that such activities could adversely impact sales of Cimzia attributable to physicians other than dermatologists, for which UCB is not required to pay us royalties or milestone payments. If such limitations resulted in reduced sales of Cimzia to dermatologists, the 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 conducted a Phase 3 clinical trial before, 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 conducted a Phase 3 clinical trial before, and as a result may require more time and incur greater costs than we anticipate. For example, we intend to commence Phase 3 clinical trials for Cimzia in the first half of 2015, as more fully described in "Business Our Product Candidates Cimzia." Failure to commence or complete, or delays in, our planned clinical trials, would prevent us from or delay us in obtaining regulatory approval of and commercializing our product candidates and could prevent us from or delay us in receiving development- or regulatory-based milestone payments and commercializing Cimzia for the treatment of psoriasis, which would adversely impact our financial performance.

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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, and may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

the clinical indications for which the product is approved and patient demand for approved products that treat those indications;

the effectiveness of our product as compared to other available therapies;

the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;

the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;

acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;

physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;

in the case of hyperhidrosis, patients' perception of the condition as one for which medical treatment may be appropriate and a prescription therapy may be available;

overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;

proper training and administration of our product candidates by physicians and medical staff;

patient satisfaction with the results and administration of our product candidates and overall treatment experience;

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;

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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.

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Enbrel, Humira and Stelara, injectable biologics for the treatment of moderate-to-severe plaque psoriasis, achieved aggregate sales of \$4.0 billion in 2012 and we are uncertain whether this market, including off-label use of other injectable biologics for the treatment of psoriasis, has peaked or may still grow and whether we could displace any existing market share if Cimzia is approved for the treatment of moderate-to-severe plaque psoriasis. In particular, Cimzia's administration schedule may not be perceived as advantageous and its theoretical advantages may not lead to a perception of Cimzia being safer or comparably effective to Humira or Enbrel. Even if approved for moderate-to-severe plaque psoriasis, we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia relative to other TNF inhibitors or biologics in our marketing materials and may not be able to promote any theoretical advantages that are not in our approved product labeling.

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

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

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

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

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

If approved for the treatment of psoriasis, Cimzia will face direct competition from numerous other injected products such as Enbrel, Humira, Remicade and Stelara, and the existence of these products may limit the market size for Cimzia. In addition, Cimzia will compete against oral systemic treatments for psoriasis, which include acitretin, 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 a lower price and may offer greater efficacy or a better safety profile.

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

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

Even if Cimzia for the treatment of psoriasis achieves regulatory approval, we may face competition from biosimilars. In the United States, the Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or "biosimilar," to or "interchangeable" with an FDA-approved biological product. This new pathway could allow competitors to reference the FDA's prior determinations regarding innovative biological products and to obtain approval of a biosimilar application 12 years after the time of approval of the innovative biological product. The 12-year exclusivity period 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. In his proposed budget for fiscal year 2014, President Obama proposed to reduce this 12-year period of exclusivity to seven years and proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." It is possible that Congress may take these or other measures to reduce or eliminate periods of exclusivity. The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for Cimzia. If competitors are able to obtain marketing approval for biosimilars referencing Cimzia or other branded biologic products against which Cimzia competes, Cimzia may become subject to competition from such biosimilars. Such competition could lead to off-label use of the biosimilar for psoriasis or reduced market share and contribute to downward pressure on pricing and reduced profit margins.

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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 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 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, PROs will have an important role in the development and regulatory approval of our DRM04 product candidate. 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, and from patient to patient and site to site within a clinical trial. Furthermore, we intend to use a new PRO in our Phase 2 clinical program and pursue the use of the new PRO to measure efficacy in our planned Phase 3 clinical program for DRM04. It is possible that the FDA will not accept the new PRO or will require changes in the PRO, potentially delaying clinical development of DRM04, increasing our costs and making additional clinical trials necessary.

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

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and with the FDA's good clinical practice, or GCP, requirements and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

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

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

impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;

mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;

commence criminal investigations and prosecutions;

impose injunctions, suspensions or revocations of necessary approvals or other licenses;

impose other civil or criminal penalties;

suspend any ongoing clinical trials;

delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;

refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;

suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products or require us or our partners to initiate a product recall.

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

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

We have conducted 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 trials for Cimzia that we intend to commence in the first half of 2015 will be 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

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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

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able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

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

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

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

regulatory authorities may withdraw their approval of the product;

regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;

regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;

we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;

we may have limitations on how we promote the product;

we may be required to change the way the product is administered or modify the product in some other way;

the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

sales of the product may decrease significantly;

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we could be sued and held liable for harm caused to patients; and

our brand and reputation may suffer.

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

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

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

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;

termination of clinical trial sites or entire trial programs;

the inability to commercialize our product candidates;

decreased demand for our product candidates;

impairment of our business reputation;

product recall or withdrawal from the market or labeling, marketing or promotional restrictions;

substantial costs of any related litigation or similar disputes;

distraction of management's attention and other resources from our primary business;

substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or

loss of revenue.

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We have obtained product liability insurance coverage for clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this

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increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

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

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. For example, if Cimzia is approved for use in the United States for the treatment of moderate-to-severe plaque psoriasis, due to the design of our Phase 3 clinical trial comparing Cimzia to Enbrel, the prescribing information may not include data comparing the clinical performance of Cimzia and Enbrel and we may not be able to utilize directly comparative head-to-head data on the clinical performance of Cimzia to Enbrel in our marketing materials. Similarly, although our DRM04 product candidate, if approved, may appeal to individuals who have not been diagnosed with hyperhidrosis, we will only be able to promote DRM04 for its approved indication. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

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

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

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

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

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

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

We are currently developing one product candidate, DRM04, for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. DRM04 is a topical formulation of 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, as a result, the FDA may not permit us to use this approach to regulatory approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, 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 was 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

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risks associated with these product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

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

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

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

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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 the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act. It contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which are expected to impact existing government healthcare programs and result in the development of new programs. The Affordable Care Act, among other things, (1) increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, (2) established annual fees on manufacturers of certain branded prescription drugs and (3) enacted a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

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

More recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provides for a 0.5% change from 2013 federal payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until April 1, 2015. Congressional failure to intervene to prevent these changes in payment rates may adversely affect our revenue and operating results.

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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 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 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 new 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 healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies 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

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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 addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

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

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

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

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

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

Risks Related to Our Collaboration with UCB

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

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

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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 acquirers, 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.

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

UCB is also solely responsible for and controls all aspects of the manufacture, distribution and supply of Cimzia for commercialization, including providing any product samples that we may use in our marketing and promotion activities as well as the product that will be sold from which we would

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derive royalties and any sales-based milestone payments. If UCB experiences any interruption in product supply for any of the reasons described in the prior paragraph, or if UCB were to allocate its supplies of Cimzia to commercial sales attributable to physicians other than dermatologists, it could adversely impact the sales from which we derive such royalties and payments, and our financial results.

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

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

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

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

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

In the UCB agreement, UCB has made very limited 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

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defense of such claim, and may make different decisions than we would make, potentially exposing us to increased liability.

Risks Related to Our Dependence on Third Parties other than UCB

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

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

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

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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 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. We are currently in the process of transitioning the manufacture of certain of our APIs and product candidates to new contract manufacturers, which creates risks of additional cost and delay. 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 product candidate, 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

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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 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.

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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 drug delivery substances and techniques, production and storage methods and packaging and shipment processes;

transportation and import/export risk, particularly given the global nature of our supply chain;

delays in analytical results or failure of analytical techniques that we depend on for quality control and release of product;

natural disasters, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and

latent defects that may become apparent after product has been released and which may result in recall and destruction of product.

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

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

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factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

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

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

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

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, 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;

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develop a marketing, sales and distribution capability;

manage our commercialization activities for our product candidates effectively and in a cost-effective manner;

establish and maintain relationships with development and commercialization partners;

manage our preclinical and clinical trials effectively;

manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and

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

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

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

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

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend

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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 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.

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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;

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.

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

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

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

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. From time to time, we may enter into collaboration agreements and license agreements with other companies that include development funding and significant upfront and milestone expenditures and payments, and we expect that amounts earned from or paid pursuant to these agreements will be a significant source of our capital 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 our products and making it more difficult for us to raise funds if necessary, and our stock price may

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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.

The report of our independent registered public accounting firm on our 2013 consolidated financial statements contains an explanatory paragraph regarding going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources in the foreseeable future. These conditions raise substantial doubt about our ability to continue as a going concern without additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our 2013 consolidated financial statements with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing.

We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our 2013 consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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, 2013, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California and Canadian income tax purposes of \$43.8 million, \$43.8 million and \$3.0 million, respectively. If not utilized, the federal and California NOL carryforwards will begin expiring during the year ended December 31, 2031 and the Canadian NOL carryforwards will begin expiring during the year ended December 31, 2029. 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 believe that, with our initial public offering and other transactions that have occurred over the past three years, we may have triggered an "ownership change" 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 Redwood City, 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

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adverse effect on our business, financial condition, operating results and prospects. In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates, our business, financial condition, operating results and prospects would suffer.

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

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

Risks Related to Our Intellectual Property

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

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

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

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization 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

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enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

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

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

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

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;

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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.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. The issued U.S. patents relating to DRM04 will expire between 2020 and 2029. The issued U.S. patents relating to Cimzia will expire between 2014 and 2024.

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

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

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

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of 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 U.S. Patent and Trademark Office, or USPTO, is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, 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

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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 USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;

if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

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

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

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

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

Interference, derivation or other proceedings 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.

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

There has been no prior public market for our common stock, the stock price of our common stock may be volatile or may decline and you may not be able to resell your shares at or above the initial public offering price.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock was determined through negotiations between the underwriters and us and may vary from the market price of our common stock following this offering. If you purchase shares of our common stock in this offering, you may not be able to resell those shares at or above the initial public offering price. An active or liquid market in our common stock might not develop upon the closing of this offering or, if it does develop, it might not be sustainable. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

the development status of our product candidates, including whether any of our product candidates receive regulatory approval;

regulatory or legal developments in the United States and foreign countries;

the results of our clinical trials and preclinical studies;

the clinical results of our competitors or potential competitors;

the success of, and fluctuations in, the commercial sales of products approved for commercialization, if any;

the execution of our partnering and manufacturing arrangements;

our execution of collaboration, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;

variations in the level of expenses related to our preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;

variations in the level of expenses related to our commercialization activities, if any product candidates are approved;

the performance of third parties on whom we rely for clinical trials, manufacturing, marketing, sales and distribution, including their ability to comply with regulatory requirements;

overall performance of the equity markets;

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;

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the public's response to press releases or other public announcements by us or third parties, including our filings with the Securities and Exchange Commission, or the SEC, and 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;

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

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

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

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

the size of our market float;

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

recruitment or departure of key personnel;

changes in accounting principles;

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

any other factors discussed in this prospectus.

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.

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 controls over financial reporting are 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 controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with the fiscal year ending December 31, 2015. However, for as long as we are an "emerging growth company" under the 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 emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls

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could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and will be 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. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. In addition, our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We will also need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and will need to establish an internal audit function. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. This could also make it more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

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

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering and the concurrent private placement, we will have 24,619,470 outstanding shares of common stock, based on the number of shares outstanding as of September 1, 2014, that may be sold after the expiration of lock-up agreements at least 180 days after the date of this prospectus, unless held by an affiliate of ours, as more fully described in the section entitled "Shares Eligible for Future Sale." Moreover, we also intend to register all shares of common stock that we may issue after this offering under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described above and in the section entitled "Shares Eligible for Future Sale Lock-Up/Market Standoff

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Agreements." If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital. Citigroup Global Markets Inc. and Leerink Partners LLC, however, may permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the end of the lock-up period.

Our directors, executive officers and principal stockholders will continue to exert significant influence over us after this offering and the concurrent private placement and could impede a change of corporate control.

Upon completion of this offering and the concurrent private placement, our directors, executive officers and holders of more than 5% of our common stock, together with their affiliates, will beneficially own, in the aggregate, 49.5% of our outstanding common stock, including the 187,500 shares of common stock that certain of our principal stockholders affiliated with our directors have agreed to purchase in this offering at the initial public offering price of \$16.00 per share. 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, would have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

delaying, deferring or preventing a change of control of us;

impeding a merger, consolidation, takeover or other business combination involving us; or

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

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

Delaware law and provisions in our restated certificate of incorporation and restated bylaws that will be in effect at the closing of our initial public offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Following the closing of our initial public offering, 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 that will be in effect at the closing of our initial public offering will contain provisions that may make the acquisition of our company more difficult, including the following:

establish a classified board of directors consisting of 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;

provide that only our board of directors will have 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;

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provide that only our chairman of our board of directors, our chief executive officer, our president or a majority of our board of directors will be authorized to call a special meeting of stockholders;

require that certain litigation against us can only be brought in Delaware;

authorize 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;

prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

provide that our board of directors is expressly authorized to make, alter or repeal our bylaws; and

establish advance notice requirements for nominations for elections to our board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

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

We qualify as an "emerging growth company" as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We qualify as 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 our fiscal year following the fifth anniversary of the date of the completion of this offering, (3) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

Our management will have considerable discretion over the use of proceeds from this offering and the concurrent private placement. We currently intend to use the net proceeds from this offering and the concurrent private placement for external research and development expenses associated with the development of our Cimzia, DRM04 and DRM01 product candidates, with the balance primarily used to fund internal research and development expenses associated with all of our product candidates, working capital, capital expenditures and other general corporate purposes. In addition, a portion of the net proceeds may also be used to acquire or in-license, as applicable, product candidates, technologies, compounds, other assets or complementary businesses. However, our management will have broad discretion in the application of the net proceeds from this offering and the concurrent private placement and could spend the proceeds in ways that do not necessarily improve our operating

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results or enhance the value of our common stock, or that you otherwise do not agree with. You will be relying on the judgment of our management concerning these uses and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The failure of our management to apply these funds effectively could, among other things, result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

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

If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share after giving effect to this offering and the concurrent private placement of \$9.39 per share as of June 30, 2014, based on the initial public offering price of \$16.00 per share, because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased shares of our capital stock. You will experience additional dilution upon exercise of the outstanding warrant and outstanding stock options and other equity awards that may be granted under our equity incentive plans, and when we otherwise issue additional shares of our common stock. For more information, see "Dilution."

The sale of shares to entities affiliated with UCB in the concurrent private placement will reduce the available public float for our shares.

Entities affiliated with UCB will purchase from us in a concurrent private placement 468,750 shares of our common stock with an aggregate purchase price of \$7.5 million, at a price per share equal to the initial public offering price. As of September 1, 2014, entities affiliated with UCB beneficially owned approximately 8.4% of our outstanding capital stock. The sale of these shares to entities affiliated with UCB will not be registered in this offering. Following this offering and the concurrent private placement, the number of shares beneficially owned by entities affiliated with UCB after this offering will be as set forth in the beneficial ownership table in "Principal Stockholders" elsewhere in this prospectus. In addition, the concurrent private placement will reduce the available public float for our shares because these entities will be restricted from selling the shares pursuant to lock-up agreements they have entered into with the underwriters in this offering and pursuant to restrictions under applicable securities laws. As a result, the sale of shares in the concurrent private placement will reduce the liquidity of our common stock relative to what it would have been had these shares been sold in this offering and been purchased by investors that were not affiliated with us.

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

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

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements contained in this prospectus other than statements of historical fact, including statements regarding our future consolidated results of operations and financial position, our business strategy and plans, market growth, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "potentially," "continue," "anticipate," "intend," "expect," "could," "would," "project," "plan" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our consolidated financial condition, consolidated results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. We undertake no obligation to update any of these forward-looking statements for any reason after the date of this prospectus or to conform these statements to actual results or revised expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

INDUSTRY AND MARKET DATA

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

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USE OF PROCEEDS

We estimate that the net proceeds from our sale of 7,812,500 shares of our common stock in this offering, excluding the proceeds from the concurrent private placement, at the initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$112.8 million. If the underwriters' over-allotment option is exercised in full, we estimate that we will receive additional net proceeds of \$17.4 million. We also expect to receive \$7.5 million from the sale by us of 468,750 shares of our common stock in the concurrent private placement, at the initial public offering price, for an aggregate amount to be raised by us in this offering and the concurrent private placement of \$120.3 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. For more information, please see "Certain Relationships and Related Party Transactions Concurrent Private Placement."

The principal purposes of this offering are to create a public market for our common stock, obtain additional capital, facilitate our future access to the public equity markets and increase awareness of our company.

As of June 30, 2014, we had cash and cash equivalents of \$9.8 million and received an additional \$48.8 million in net proceeds from the sale of shares of our Series C convertible preferred stock in August 2014. We currently intend to use the net proceeds we receive from this offering and the concurrent private placement, together with our existing cash and cash equivalents, as follows:

approximately \$50 million to fund external research and development expenses associated with the development of our Cimzia product candidate, net of development milestone payments we expect to receive from our partner UCB Pharma S.A.;

approximately \$30 million to fund external research and development expenses associated with the development of our DRM04 product candidate;

approximately \$15 million to fund external research and development expenses associated with the development of our DRM01 product candidate; and

the balance used to fund internal research and development expenses associated with all of our product candidates, working capital, capital expenditures and other general corporate purposes.

Additionally, we may use a portion of the net proceeds from this offering and the concurrent private placement to expand our current business by in-licensing or acquiring, as the case may be, commercial products, product candidates, technologies, compounds, other assets or complementary businesses, using cash or shares of our common stock. However, we have no current plans, commitments or obligations to do so.

We believe that the net proceeds from this offering and the concurrent private placement, together with our existing cash and cash equivalents, will be sufficient to meet our anticipated cash requirements for at least the next 12 months, including for the initiation of Phase 3 clinical trials for Cimzia and a Phase 2b clinical program for DRM01, and through the receipt of data from our ongoing Phase 2b clinical trial for DRM04. This expected use of the net proceeds from this offering and the concurrent private placement represents our intentions based upon our current plans and business conditions. We cannot specify with certainty all of the particular uses of the net proceeds that we will receive from this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures will depend on numerous factors, including the ongoing status of and results from clinical trials and other studies, as well as any strategic collaborations that we may enter into with third parties for our product candidates, any in-licensing transactions or acquisitions, any unforeseen cash needs and the performance of our investments.

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We will have broad discretion over the uses of the net proceeds of this offering and the concurrent private placement and investors will be relying on the judgment of our management regarding the application of the proceeds. Pending these uses, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing securities such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government.

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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 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. In addition, the terms of our loan and security agreement with Square 1 Bank currently restrict our ability to pay dividends.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2014 on:

an actual basis;

a pro forma basis to give effect to (1) the issuance of 5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 and receipt of the related net proceeds of \$48.8 million, (2) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock effective immediately upon the completion of this offering, (3) the automatic conversion of an outstanding warrant exercisable for 11,276 shares of our Series B convertible preferred stock into a warrant exercisable for 11,276 shares of common stock in connection with this offering and (4) the filing of our restated certificate of incorporation and the effectiveness of our restated bylaws, as if our restated certificate of incorporation was filed and our restated bylaws had become effective on June 30, 2014; and

a pro forma as adjusted basis, giving effect to the pro forma adjustments described above and the sale by us of 8,281,250 shares of our common stock in this offering and the concurrent private placement, at the initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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You should read this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Description of Capital Stock" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2014		
	Actual	Pro Forma	Pro Forma
	(in thousands, except share and per share amounts)		
	(unaudited)		
Cash and cash equivalents	\$ 9,774	\$ 58,587	\$ 178,887
Convertible preferred stock warrant liability	\$ 60	\$	\$
Bank term loan, current and non-current	1,931	1,931	1,931
Convertible preferred stock, \$0.001 par value: 10,700,619 shares authorized, 10,133,665 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma or pro forma as adjusted	64,588		
Stockholders' deficit			
Preferred stock, \$0.001 par value: no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.001 par value: 23,965,517 shares authorized, 907,514 shares issued and outstanding, actual; 500,000,000 shares authorized, 16,338,220 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 24,619,470 shares issued and outstanding, pro forma as adjusted	1	16	25
Additional paid-in capital	1,287	114,733	235,024
Accumulated deficit	(68,075)	(68,075)	(68,075)
Total stockholders' (deficit) equity	(66,787)	46,674	166,974
Total capitalization	\$ (208)	\$ 48,605	\$ 168,905

The number of shares of our common stock to be outstanding following this offering and the concurrent private placement is based on 11,041,179 shares of our common stock outstanding as of June 30, 2014. This number assumes the conversion of all outstanding shares of our convertible preferred stock, which will occur automatically in connection with the completion of this offering, and excludes:

2,265,305 shares of common stock issuable upon the exercise of outstanding options under the 2010 Equity Incentive Plan, or the 2010 Plan, as of June 30, 2014, with a weighted-average exercise price of \$2.15 per share;

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11,276 shares of our Series B convertible preferred stock issuable upon the exercise of a warrant outstanding as of June 30, 2014, with an exercise price of \$8.4245 per share;

5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 for a price per share of \$9.628; and

2,383,549 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 55,964 shares of our common stock reserved for issuance under the 2010 Plan as of June 30, 2014, (2) 129,310 shares of our common stock reserved for issuance under the 2010 Plan after June 30, 2014, (3) 1,896,551 shares of our common stock

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reserved for issuance under the 2014 Equity Incentive Plan, or the 2014 Plan, which includes 1,084,835 shares of our common stock that are issuable upon the exercise of options to purchase common stock with an exercise price per share equal to the initial public offering price, which options were granted on the day that the registration statement for this offering was declared effective, and (4) 301,724 shares of our common stock reserved for issuance under the 2014 Employee Stock Purchase Plan, or the 2014 ESPP. On the date of this prospectus, any remaining shares available for issuance under the 2010 Plan will be added to the shares reserved under the 2014 Plan and we will cease granting awards under the 2010 Plan. The 2014 Plan and the 2014 ESPP also provide for automatic annual increases in the number of shares reserved thereunder, as more fully described in "Executive Compensation Employee Benefit and Stock Plans."

Table of Contents**DILUTION**

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

As of June 30, 2014, our pro forma net tangible book value was \$42.4 million, or \$2.59 per share of common stock. Pro forma net tangible book value per share represents the amount of our tangible assets less our liabilities divided by the total number of shares of our common stock outstanding, after giving effect (1) the issuance of 5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 and receipt of the related net proceeds of \$48.8 million, (2) the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock effective immediately upon the completion of this offering, (3) the automatic conversion of an outstanding warrant exercisable for 11,276 shares of our Series B convertible preferred stock into a warrant exercisable for 11,276 shares of common stock in connection with this offering and (4) the filing of our restated certificate of incorporation and the effectiveness of our restated bylaws, as if our restated certificate of incorporation was filed and our restated bylaws had become effective on June 30, 2014.

Our pro forma as adjusted net tangible book value as of June 30, 2014 was \$162.7 million, or \$6.61 per share of common stock. Pro forma as adjusted net tangible book value per share reflects the pro forma adjustments described above and the sale by us of 8,281,250 shares of our common stock in this offering and the concurrent private placement, at our initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This represents an immediate increase in pro forma as adjusted net tangible book value of \$4.02 per share to existing stockholders and immediate dilution of \$9.39 per share to new investors purchasing shares in the offering and the concurrent private placement.

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

Initial public offering price per share	\$ 16.00
Pro forma net tangible book value per share as of June 30, 2014	\$ 2.59
Increase in pro forma net tangible book value per share attributable to new investors in this offering and the concurrent private placement	4.02
Pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement	6.61
Dilution per share to new investors in this offering and the concurrent private placement	\$ 9.39

If the underwriters exercise their over-allotment option in full, our pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement would be \$6.98 per share, and the dilution in pro forma net tangible book value per share to new investors in this offering and the concurrent private placement would be \$9.02 per share of common stock.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2014, the differences between the number of shares of common stock purchased from us by existing stockholders, by investors in the concurrent private placement and by new investors participating in this offering, the total cash consideration and the average price per share paid to us by existing stockholders, by investors in the concurrent private placement and by new investors purchasing shares in this offering, at

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the initial public offering price of \$16.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Average
	Number	Percent	Amount	Percent	Price Per Share
Existing stockholders	16,338,220	66.4%	\$ 115,016,457	46.5%	\$ 7.04
Concurrent private placement investors	468,750	1.9	7,500,000	3.0	16.0
New public investors	7,812,500	31.7	125,000,000	50.5	16.0
Total	24,619,470	100%	\$ 247,516,457	100%	

If the underwriters exercise their over-allotment option in full, the number of shares of common stock held by existing stockholders will be reduced to 63.3% of the total number of shares of common stock to be outstanding after this offering and the concurrent private placement, and the number of shares of common stock held by investors participating in this offering and the concurrent private placement will be further increased to 36.7% of the total number of shares of common stock to be outstanding after this offering and the concurrent private placement.

Certain of our existing stockholders affiliated with our directors have agreed to purchase 187,500 shares of our common stock in this offering at the initial public offering price.

The table and discussion above are based on 11,041,179 shares of our common stock outstanding as of June 30, 2014. This number assumes the conversion of all outstanding shares of our convertible preferred stock, which will occur automatically in connection with the completion of this offering, and excludes:

2,265,305 shares of common stock issuable upon the exercise of outstanding options under the 2010 Equity Incentive Plan, or the 2010 Plan, as of June 30, 2014, with a weighted-average exercise price of \$2.15 per share;

11,276 shares of our Series B convertible preferred stock issuable upon the exercise of a warrant outstanding as of June 30, 2014, with an exercise price of \$8.4245 per share;

5,297,041 shares of our Series C convertible preferred stock that were issued after June 30, 2014 for a price per share of \$9.628; and

2,383,549 shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 55,964 shares of our common stock reserved for issuance under the 2010 Plan as of June 30, 2014, (2) 129,310 shares of our common stock reserved for issuance under the 2010 Plan after June 30, 2014, (3) 1,896,551 shares of our common stock reserved for issuance under the 2014 Equity Incentive Plan, or the 2014 Plan, which includes 1,084,835 shares of our common stock that are issuable upon the exercise of options to purchase common stock with an exercise price per share equal to the initial public offering price, which options were granted on the day that the registration statement for this offering was declared effective, and (4) 301,724 shares of our common stock reserved for issuance under the 2014 Employee Stock Purchase Plan, or the 2014 ESPP. On the date of this prospectus, any remaining shares available for issuance under the 2010 Plan will be added to the shares reserved under the 2014 Plan and we will cease granting awards under the 2010 Plan. The 2014 Plan and the 2014 ESPP also provide for automatic annual increases in the number of shares reserved thereunder, as more fully described in "Executive Compensation Employee Benefit and Stock Plans."

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SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, the accompanying notes and other financial information included elsewhere in this prospectus.

We derived our selected consolidated statements of operations data for the years ended December 31, 2012 and 2013 and our selected consolidated balance sheet data as of December 31, 2012 and 2013 from our audited consolidated financial statements included elsewhere in this prospectus. We derived our selected consolidated statements of operations data for the six months ended June 30, 2013 and 2014 and our selected consolidated balance sheet data as of June 30, 2014 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. Our unaudited interim consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles on the same basis as our audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal, recurring adjustments, that are necessary for the fair presentation of our consolidated financial position as of June 30, 2014 and our consolidated results of operations for the six months ended June 30, 2013 and 2014. Our historical results are not necessarily indicative of the results to be expected in the future, and the results for the six months ended June 30, 2014 are not necessarily indicative of the results to be expected for the full year or any other period. You should read the following selected consolidated financial data in conjunction with the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, the accompanying notes and other financial information included elsewhere in this prospectus. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and is qualified in its entirety by our consolidated financial statements, the accompanying notes and other financial information included elsewhere in this prospectus.

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	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(Unaudited)			
	(in thousands, except share and per share amounts)			
Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 17,055	\$ 17,937	\$ 8,778	\$ 13,648
General and administrative	3,148	4,366	2,205	3,552
Total operating expenses	20,203	22,303	10,983	17,200
Loss from operations	(20,203)	(22,303)	(10,983)	(17,200)
Interest and other income (expense), net	(51)	(38)	12	(34)
Interest expense		(9)		(67)
Net loss	\$ (20,254)	\$ (22,350)	\$ (10,971)	\$ (17,301)
Net loss per share, basic and diluted(1)	\$ (27.99)	\$ (27.03)	\$ (13.88)	\$ (19.28)
Weighted-average common shares used to compute net loss per share, basic and diluted(1)	723,607	826,757	790,512	897,356
Pro forma net loss per share, basic and diluted (unaudited)(1)		\$ (2.31)		\$ (1.62)
Weighted-average common shares used to compute pro forma net loss per share, basic and diluted, (unaudited)(1)		9,667,715		10,706,395

(1) See Note 2 to our consolidated financial statements for an explanation of the method used to calculate our basic and diluted net loss per share, unaudited pro forma basic and diluted net loss per share and weighted-average common shares outstanding used to calculate the per share amounts.

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	As of December 31,		As of June 30,
	2012	2013	2014
(in thousands, unaudited)			
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 7,872	\$ 22,144	\$ 9,774
Working capital	3,647	17,973	3,921
Total assets	12,514	26,871	16,530
Convertible preferred stock warrant liability		61	60
Bank term loan, current and non-current		1,919	1,931
Convertible preferred stock	35,089	59,588	64,588
Additional paid-in capital	678	970	1,287
Accumulated deficit	(28,424)	(50,774)	(68,075)
Total stockholders' (deficit) equity	(27,745)	(49,803)	(66,787)

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL
CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the section entitled "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those forward-looking statements. Factors that could cause or contribute to such differences include those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this prospectus.

Overview

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

Since our founding in 2010, we have executed three significant transactions resulting in a portfolio of five 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 GlaxoSmithKline LLC 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, 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 an agreement to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. UCB has conducted two Phase 2 clinical trials, including a 176-patient, randomized, multi-center, double-blind, placebo-controlled trial, that demonstrated significant reductions in the signs and symptoms of moderate-to-severe plaque psoriasis. We and UCB conducted an end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or the FDA, in June 2014, filed an investigational new drug application, or IND, for the treatment of moderate-to-severe plaque psoriasis with the FDA in September 2014 and intend to commence Phase 3 clinical trials in the first half of 2015.

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

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by blocking the action of acetylcholine, a molecule that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. DRM04 is a topical formulation of a novel form of an anticholinergic agent that has been approved for systemic administration in other indications, and it is designed to inhibit sweat production by blocking the activation of sweat glands following topical administration. Two randomized, double-blind, vehicle-controlled Phase 2 clinical trials, including a 198-patient, multi-center Phase 2b clinical trial and a 38-patient Phase 2a clinical trial, have demonstrated significant reductions in the signs and symptoms of primary axillary, or underarm, hyperhidrosis in patients treated 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. In addition, we are currently conducting a Phase 2b clinical trial in patients with primary axillary hyperhidrosis in which we are comparing DRM04 to the topical formulation of the reference agent. We expect data from this trial in the first half of 2015. If successful, we intend to commence a Phase 3 clinical program, which would include one or more Phase 3 clinical trials, in the second half of 2015.

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 a prodrug designed to inhibit the production of sebum by delivering a widely-studied lipid synthesis inhibitor to the skin following topical administration. We have 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. Based on the results of this Phase 2a clinical trial, we intend to file an IND with the FDA and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015.

In addition, we have two early-stage programs in preclinical development:

DRM02, a novel, topical, small-molecule inhibitor of phosphodiesterase-4, or PDE4, for the treatment of inflammatory skin diseases; and

DRM05, a novel, topical photodynamic therapy, or PDT, for the treatment of acne.

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 do not have any approved products and have never generated any revenue from product sales or otherwise. We have financed our operations primarily through the sale of equity securities and convertible debt securities, from which we raised \$64.6 million of net cash from our inception through June 30, 2014 and raised an additional \$48.8 million of net cash in August 2014.

We have never been profitable and, as of June 30, 2014, we had an accumulated deficit of \$68.1 million. We incurred net losses of \$20.3 million and \$22.4 million in the years ended December 31, 2012 and 2013, respectively, and \$11.0 million and \$17.3 million for the six months ended June 30, 2013 and 2014, 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 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 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.

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Financial Operations Overview

Revenue

To date, we have not generated any revenue. Under our development and commercialization agreement with UCB, or 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.

Research and Development Expenses

We expense both internal and external research and development expenses to operations as they are incurred. We track the 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.

External research and development expenses consist primarily of costs incurred for the development of our product candidates and include:

expenses incurred under agreements with contract research organizations, or CROs, investigative sites, and consultants to conduct our clinical trials and preclinical and non-clinical studies;

costs to acquire, develop and manufacture supplies for clinical trials and other studies, including fees paid to contract manufacturing organizations, or CMOs;

costs related to compliance with drug development regulatory requirements; and

licensing fees and milestone payments incurred under product license agreements.

Internal research and development costs include:

salaries and related costs, including stock-based compensation and travel expenses, for personnel in our research and development functions;

costs for consultants who advise us on multiple product candidates; and

depreciation and other allocated facility-related and overhead expenses.

During the year ended December 31, 2012, development work was ongoing for DRM01, DRM02 and DRM05. During this period, external costs associated with DRM05 totaled \$8.2 million, or 48% of our total research and development expenses, and external costs associated with DRM01 and DRM02, combined, totaled \$4.9 million, or 29% of our total research and development expenses.

During the year ended December 31, 2013, external costs associated with DRM05 totaled \$3.7 million, or 21% of our total research and development expenses, a decrease of \$4.5 million from the prior year. During the year ended December 31, 2013, external costs associated with DRM01 and DRM02, combined, totaled \$5.7 million, or 32% of our total research and development expenses, an increase of \$0.8 million from the prior year. This increase was due to both product candidates moving forward to Phase 2a clinical trials. The addition of our DRM04 product candidate in April 2013, which we obtained through our licensing agreement with Rose U, and subsequent research and development activities, resulted in external costs of \$3.8 million, or 21% of our total research and development expenses, during the year ended December 31, 2013.

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For the six months ended June 30, 2013, external costs associated with DRM05 were \$2.9 million, or 33% of our total research and development expenses. External costs associated with DRM01 and DRM02, combined, were \$3.0 million, or 34% of our total research and development expenses.

For the six months ended June 30, 2014, external costs associated with DRM04 were \$5.8 million, or 43% of our total research and development expenses, reflecting the advancement of DRM04 into Phase 2b clinical trials. Total external costs associated with DRM01 and DRM02, combined, were \$3.8 million, or 27% of our total research and development expenses, and reflected the continuation of the Phase 2a clinical trials.

For each of the above periods, the balance of our research and development expenses were comprised primarily of internal costs.

We expect that our future research and development efforts will be focused on our late-stage clinical programs, Cimzia, DRM04 and DRM01. UCB filed an IND for Cimzia in September 2014, and we and UCB intend to commence Phase 3 clinical trials in the first half of 2015. For DRM04, we are currently conducting a Phase 2b clinical trial and expect data from this trial in the first half of 2015. If successful, we intend to initiate a Phase 3 clinical program in the second half of 2015. For DRM01, we have completed a Phase 2a clinical trial that demonstrated significant reductions in the signs and symptoms of acne. Based on the results of this clinical trial, we intend to file an IND and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015. We also expect to continue to evaluate our early-stage product candidates, DRM02 and DRM05, to determine which, if any, we would advance into later stages of development.

We expect our research and development expenses to increase substantially in the future as we continue development of our product candidates. In particular, we expect to incur substantial research and development expenses associated with Cimzia beginning in the second half of 2014 to prepare for Phase 3 clinical trials that we intend to initiate in the first half of 2015.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation and travel expenses, for personnel in our executive, finance, corporate development and other administrative functions. Other general and administrative expenses include allocated depreciation and facility-related costs, legal costs of pursuing patent protection of our intellectual property, and professional services fees for auditing, tax and general legal services.

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, including increased expenses related to legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors' and officers' liability insurance premiums and investor relations activities.

Interest and Other Income (Expense), Net

Interest income consists primarily of interest received or earned on our cash and cash equivalents balances. Other income (expense) primarily includes gains and losses from the remeasurement of our convertible preferred stock warrant liability and gains and losses on our foreign currency transactions.

We will continue to record adjustments to the estimated fair value of our convertible preferred stock warrant liability until such time as the instrument is exercised, expires or converts into a warrant to purchase shares of our common stock. At that time, our convertible preferred stock warrant liability will be reclassified to additional paid-in capital, a component of stockholders' (deficit) equity, and we

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will no longer record any related periodic fair value adjustments. See also " Critical Accounting Policies and Significant Estimates Estimated Fair Value of Convertible Preferred Stock Warrant."

Interest Expense

Interest expense consists of cash and non-cash interest costs related to our bank term loan. The non-cash interest costs consist of the amortization of the fair value of the warrant that was issued to the lender in connection with our bank term loan, with the initial fair value of the warrant being amortized to interest expense over the term of the governing agreement.

Results of Operations**Comparison of the Six Months Ended June 30, 2013 and 2014**

	Six Months Ended June 30,		Change	
	2013	2014	\$	%
	(Unaudited)			
	(in thousands, except percentages)			
Operating expenses:				
Research and development	\$ 8,778	\$ 13,648	\$ 4,870	55%
General and administrative	2,205	3,552	1,347	61
Total operating expenses	10,983	17,200	6,217	57
Loss from operations	(10,983)	(17,200)	(6,217)	57
Interest and other income (expense), net	12	(34)	(46)	383
Interest expense		(67)	(67)	*
Net loss	\$ (10,971)	\$ (17,301)	\$ (6,330)	58

*

Percentage not meaningful

Research and Development. Research and development expenses increased \$4.9 million, or 55%, for the six months ended June 30, 2014 compared to the six months ended June 30, 2013. This increase was due to a \$5.2 million increase in external costs related to our DRM04 product candidate, a \$1.2 million increase in internal costs related primarily to headcount growth and additional consulting fees and a \$0.7 million increase in external costs related to our DRM01 and DRM02 product candidates. These increases in research and development expenses were partially offset by a \$2.3 million decrease in external costs associated with our DRM05 product candidate.

General and Administrative. General and administrative expenses increased \$1.3 million, or 61%, for the six months ended June 30, 2014 compared to the six months ended June 30, 2013. This increase reflects \$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, a \$0.6 million increase in personnel expenses and a \$0.4 million increase in audit and accounting consultation expenses, which were partially offset by a transaction advisory fee of \$0.5 million incurred in the first quarter of 2013 in connection with the agreement we entered into with Maruho.

Interest and Other Income (Expense), Net. Amounts recorded in interest and other income (expense), net for both periods were primarily related to foreign currency exchange gains relating to our Canadian subsidiary and payments made to non-U.S. third-party service providers.

Interest Expense. The increase in interest expense was due to interest incurred on borrowings of \$2.0 million under the bank term loan we entered into in December 2013.

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	Year Ended December 31,		Change	
	2012	2013	\$	%
(in thousands, except percentages)				
Operating expenses:				
Research and development	\$ 17,055	\$ 17,937	\$ 882	5%
General and administrative	3,148	4,366	1,218	39
Total operating expenses	20,203	22,303	2,100	10
Loss from operations	(20,203)	(22,303)	(2,100)	10
Interest and other income (expense), net	(51)	(38)	13	(25)
Interest expense		(9)	(9)	*
Net loss	\$ (20,254)	\$ (22,350)	\$ (2,096)	10

*

Percentage not meaningful

Research and Development. Research and development expenses increased \$0.9 million, or 5%, for the year ended December 31, 2013 compared to the year ended December 31, 2012. This increase was due to increases in external costs of \$3.6 million related to our DRM04 product candidate and \$0.8 million related to our DRM01 and DRM02 product candidates, and internal costs of \$1.0 million, partially offset by a decrease in external costs of \$4.5 million related to our DRM05 product candidate.

The increase in external costs of \$3.6 million related to our DRM04 product candidate was primarily due to our preparation for, and commencement of, one Phase 2b clinical trial that we initiated for this product candidate in the fourth quarter of 2013. The increase in external costs of \$0.8 million related to our DRM01 and DRM02 product candidates was primarily due to our commencement of Phase 2a clinical trials in 2013. The increase in internal costs of \$1.0 million was primarily due to an increase in headcount. The decrease in external costs of \$4.5 million related to our DRM05 product candidate was primarily due to the completion of clinical trials in mid-2013, a decrease in costs associated with the development and manufacture of the device used as part of the photodynamic therapy, and \$1.0 million in milestone-related expenses related to a licensing agreement with QLT, Inc. that were incurred in 2012 but not in 2013.

General and Administrative. General and administrative expenses increased \$1.2 million, or 39%, for the year ended December 31, 2013 compared to the year ended December 31, 2012. This increase was primarily due to the transaction advisory fee of \$0.5 million incurred in the first quarter of 2013 related to the Maruho agreement we entered into in March 2013, professional services fees of \$0.5 million related to higher audit and legal fees, and increases in consulting and legal expenses of \$0.2 million related to the evaluation, due diligence and negotiations associated with the UCB agreement.

Interest and Other Income (Expense), Net. The \$13,000 decrease in interest and other income (expense), net for the year ended December 31, 2013 compared to the year ended December 31, 2012 was due primarily to lower foreign currency exchange losses incurred by us in 2013 relating to our Canadian subsidiary and lower payments made to our non-U.S. third-party service providers.

Interest Expense. The increase in interest expense was due to interest incurred on borrowings of \$2.0 million under the bank term loan we entered into in December 2013.

Table of Contents**Liquidity and Capital Resources**

Since our inception through June 30, 2014, we have financed our operations primarily with \$64.6 million in net proceeds from the issuance and sale of equity securities and convertible debt securities. In addition, we received \$10.0 million related to our agreement with Maruho entered into in March 2013, and \$2.0 million in bank financing under a \$7.5 million bank loan agreement entered into in December 2013. As of June 30, 2014, we had \$9.8 million of cash and cash equivalents. Our cash and cash equivalents are held in a variety of interest-bearing instruments, including money market accounts and obligations of U.S. government agencies. 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, which consist principally of research and development expenditures. As of March 31, 2014, we had an accumulated deficit of \$59.3 million and there was substantial doubt about our ability to continue as a going concern if we did not secure additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our 2013 consolidated financial statements with respect to this uncertainty.

As of June 30, 2014, we had an accumulated deficit of \$68.1 million. In August 2014, we issued 5,297,041 shares of Series C convertible preferred stock at a price of \$9.628 per share for aggregate net proceeds of \$48.8 million. In addition, we are entitled to borrow \$5.5 million under our Term Loan B as more fully described in " Loan and Security Agreement." 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. Therefore, we will need to raise additional capital to fund 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. We also may be required to 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.

We believe that our net proceeds from this offering and the concurrent private placement of our common stock, together with our existing cash and cash equivalents, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Cash Flows

The following table shows a summary of our cash flows for each of the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014 (in thousands):

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
			(Unaudited)	
Net cash (used in) provided by:				
Operating activities	\$ (17,253)	\$ (12,157)	\$ (2,388)	\$ (17,340)
Investing activities	(36)	(50)	(24)	(37)
Financing activities	12,064	26,479	24,499	5,007
Net (decrease) increase in cash and cash equivalents	\$ (5,225)	\$ 14,272	\$ 22,087	\$ (12,370)

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Operating Activities. Net cash used in operating activities was \$2.4 million for the six months ended June 30, 2013 and consisted primarily of our net loss of \$11.0 million and a \$1.5 million decrease in accounts payable and accrued liabilities primarily due to higher disbursements, partially offset by a \$10 million increase in deferred revenue related to our agreement with Maruho. Net cash used in operating activities was \$17.3 million for the six months ended June 30, 2014 and consisted primarily of our net loss of \$17.3 million and a \$0.6 million decrease in accounts payable due to higher disbursements, partially offset by a \$0.9 million increase in accrued liabilities related primarily to higher research and development accruals.

Net cash used in operating activities was \$17.3 million for the year ended December 31, 2012 and consisted primarily of our net loss of \$20.3 million, partially offset by increases in accounts payable and accrued liabilities of \$1.2 million and \$1.5 million, respectively. The increases in accounts payable and accrued liabilities were primarily due to higher clinical trial expenses. 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 a \$10.0 million increase in deferred revenue related to our agreement with Maruho.

Investing Activities. Net cash used in investing activities for the six months ended June 30, 2013 and 2014 was \$24,000 and \$37,000, respectively. The amounts were for purchases of property and equipment.

Net cash used in investing activities for the years ended December 31, 2012 and 2013 was \$36,000 and \$50,000, respectively. The amounts were for purchases of property and equipment.

Financing Activities. Net cash provided by financing activities was \$24.5 million for the six months ended June 30, 2013 and consisted of the net proceeds from the sale of our Series B convertible preferred stock in March 2013. Net cash provided by financing activities was \$5.0 million for the six months ended June 30, 2014 and related primarily to the net proceeds from the sale of shares of our Series B convertible preferred stock in April 2014.

Net cash provided by financing activities was \$12.1 million for the year ended December 31, 2012 and consisted of the net proceeds from the sale of our Series A convertible preferred stock in August 2012. 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.

Operating and Capital Expenditure Requirements

We have incurred losses since our inception. We anticipate that we will continue to generate losses for the foreseeable future, and 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. Additionally, as a public company, we will incur significant audit, legal and other expenses that we did not incur as a private company. We believe that our net proceeds from this offering and the concurrent private placement of our common stock, together with our existing cash and cash equivalents, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, 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 assure you that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our failure to obtain sufficient funds on acceptable terms when needed 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.

Table of Contents**Contractual Obligations and Other Commitments**

The following table summarizes our contractual obligations as of December 31, 2013:

	Total	Payments Due by Period			More than 5 Years
		Less than One Year	1 - 3 Years	3 - 5 Years	
			(in thousands)		
Debt obligations(1)	\$ 2,055	\$ 133	\$ 1,600	\$ 322	\$
Interest expense payments(2)	255	123	129	3	
Operating lease obligations(3)	168	168			
Total contractual obligations	\$ 2,478	\$ 424	\$ 1,729	\$ 325	\$

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- (1) Debt obligations are comprised of a bank term loan agreement that we entered into in December 2013.
- (2) Represents interest payments on our outstanding debt under our bank term loan agreement.
- (3) Operating leases include total future minimum rent payments under non-cancelable operating lease agreements.

In March 2014 and May 2014, we entered into sublease agreements for additional office space at our current location in Redwood City, California. The sublease agreements terminate in November 2014 and the total estimated cost for this space is \$165,000 over the full term of the subleases. These amounts are not included in the table above.

We entered into a lease agreement in July 2014 and an amendment in September 2014 for a facility totaling approximately 18,651 square feet in Menlo Park, California and intend to relocate our corporate headquarters to this facility in the fourth quarter of 2014. The term of the lease commences December 2014 and terminates November 2019. The total estimated lease payments for this facility over the five-year term of the lease are approximately \$8 million. This amount is not included in the table above.

In September 2014, we entered into an amendment to the bank term loan agreement, which provided for the following revisions: (1) the interest only end date was extended from October 2014 to June 2016 for Term Loan A and from December 2014 to June 2016 for Term Loan B; (2) the maturity date was extended from April 2017 to December 2018 for Term Loan A and from June 2017 to December 2018 for Term Loan B; (3) the date through which the Term Loan B is available to us was extended from October 2014 to September 2015; and (4) the fee that we are required to pay the lender upon the final repayment of the amounts borrowed under Term Loan A was increased from 2.75% to 6.00% of the original principal amount borrowed. These revisions are not included in the table above.

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. Any development costs in excess of this amount 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. These amounts are not included in the table above.

In addition to the amounts set forth in the table above, 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

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Stiefel with respect to our DRM04 product candidate, we are required to pay additional amounts totaling up to \$4.6 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. In the future, we may owe milestone- and royalty-based payments under our license agreements for two of our early-stage product candidates, DRM02 and DRM05.

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 provides for two term loans available to us of \$2.0 million and \$5.5 million, respectively. In September 2014, we entered into an amendment to the Loan Agreement. Borrowings under the term loans bear interest at the greater of: (1) 5.10% above the treasury rate in effect on the date that a term loan is funded; or (2) 5.50%, which rate will be fixed on the date of funding of the term loan. We may prepay borrowings without paying a penalty or premium.

On the closing date of the Loan Agreement, we borrowed \$2.0 million under the first term loan, or Term Loan A. Borrowings under Term Loan A mature in December 19, 2018 and are secured by all of our assets other than our intellectual property, subject to certain limited exceptions, and bear interest at a rate of 5.77% per annum. Borrowings under Term Loan A are to be repaid over a period of 60 months as follows: (1) commencing on January 11, 2014, 30 monthly payments of interest only; and (2) commencing on June 19, 2016, 30 equal monthly payments of \$66,666.67, plus interest. Upon final repayment of Term Loan A, we are required to pay the Bank a fee of \$120,000. We are accruing this fee monthly over the loan term on a straight-line basis and are recording it as interest expense in our consolidated statement of operations.

The second term loan, or Term Loan B, of \$5.5 million is available to us any time between the date on which our board of directors determines that we have achieved certain positive top-line Phase 2 clinical trial results and September 30, 2015. As of June 30, 2014, we had no borrowings under Term Loan B and were not entitled to borrow funds under Term Loan B. Subsequent to June 30, 2014, our board of directors has determined that we achieved positive top-line Phase 2 clinical trial results from two of our Phase 2 programs, which satisfied the condition to our ability to borrow funds under Term Loan B. As a result, we are now entitled to borrow funds under Term Loan B. Borrowings, if any, under Term Loan B would be repaid over a period of months as follows: (1) commencing on the 11th day following the date of Term Loan B, monthly payments of interest only to the earlier of (a) June 19, 2016 or (b) six months following the date of Term Loan B; and (2) commencing on the last day of the month immediately following the interest only end date, equal monthly payments of principal, plus interest, to the maturity date of December 19, 2018. Upon final repayment of Term Loan B, we would be required to pay the Bank a fee equal to 2.75% of the original principal amount borrowed under Term Loan B.

The Loan Agreement is subject to certain representations and warranties, certain affirmative and negative covenants, certain conditions and events of default that are customarily required for similar financings. As of December 31, 2013 and June 30, 2014, the Company was in compliance with all of the covenants.

In connection with the Loan Agreement, we agreed to issue the Bank a warrant to purchase up to 17,805 shares of our Series B convertible preferred stock, with an exercise price of \$8.4245 per share. The number of shares issuable pursuant to the warrant at any date is 8,902 shares plus 1% of the amount drawn through that date under the Loan Agreement divided by 8.4245. Following the entry into the Loan Agreement and the concurrent funding of Term Loan A, and as of December 31, 2013

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and June 30, 2014, the warrant was exercisable for 11,276 shares of Series B convertible preferred stock, consisting of the 8,902 initial shares related to the Loan Agreement and an additional 2,374 shares related to the draw-down of Term Loan A.

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.

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 June 30, 2014, we had cash and cash equivalents of \$9.8 million, which consisted of bank deposits, money market funds and obligations of U.S. government agencies. These interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. All of our outstanding debt obligations carry fixed interest rates.

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 (gains) losses, which were \$57,000, \$43,000, \$(7,000) and \$40,000 for the years ended December 31, 2012 and 2013 and the six months ended June 30, 2013 and 2014, respectively, are included in interest and other income (expense), net in our consolidated statements of operations and comprehensive loss. We do not use 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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Critical Accounting Policies 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.

Accrued Research and Development Expenses

We record accruals for estimated costs of research, preclinical and clinical studies, and drug and process manufacturing development, which are a significant component of our 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 for 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 our agreements with these third parties based on actual work completed in accordance with the respective agreements. In the event we make advance payments, the payments are recorded as a prepaid asset 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.

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, our understanding of 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 from our accrued estimated expenses to the actual expenses. However, variations in the assumptions used to estimate accruals, including variations in the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to research and development expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our financial condition and results of operations.

Common Stock Valuation and Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentive for employees, officers, directors, consultants and advisors. The plan allows for the issuance of incentive stock options to employees and nonqualified stock options, restricted stock awards, restricted stock units and stock appreciation rights to employees, officers, directors, consultants and advisors.

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We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards made to employees and directors, including employee stock options. We recognize this expense over the requisite service period. In addition, we recognize stock-based compensation expense in the consolidated statements of operations and comprehensive loss based on awards expected to vest and, therefore, the amount of expense has been reduced for estimated forfeitures. We use the straight-line method for expense attribution.

Under the applicable accounting guidance for equity incentive awards granted to non-employees, the measurement date at which the fair value of the equity incentive awards is measured is equal to the earlier of (1) the date at which a commitment for performance by the counterparty to earn the equity instrument is reached and (2) the date at which the counterparty's performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of the equity incentive awards in the consolidated statements of operations and comprehensive loss. We remeasure the fair value of options granted to consultants as the options vest.

The valuation model we used for calculating the fair value of awards for stock-based compensation expense is the Black-Scholes option-pricing model, or the Black-Scholes model. The Black-Scholes model requires us to make assumptions and judgments about the variables used in the calculation, including the expected term weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, an assumed risk-free interest rate and an estimated forfeiture rate. We use the "simplified method" to determine the expected term of the stock option. Volatility is based on an average of the historical volatilities of the common stock of publicly traded companies with characteristics similar to us. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected term of the option. Potential forfeitures of awards are estimated based on our historical forfeiture experience and an analysis of similar companies. The estimate of forfeitures will be adjusted over the service period to the extent that actual forfeitures differ, or are expected to differ, from prior estimates.

The following table summarizes the assumptions we used to determine the fair value of employee stock options:

	Year Ended December 31, 2013	Six Months Ended June 30, 2014 (Unaudited)
Expected term (years)	6.1	6.0
Expected volatility	76.0%	76.0%
Risk-free interest rate	1.3%	1.9%
Expected dividend rate	0.0%	0.0%

Fair Value of Common Stock. As discussed below, the fair value of the shares of our common stock underlying the stock options has historically been determined by our board of directors. Because there has been no public market for our common stock, our board of directors has determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors, including valuations of comparable companies, sales of our convertible preferred stock, our operating and financial performance, the lack of liquidity of our convertible preferred stock, and general and industry-specific economic outlooks.

Expected Term. The expected term of stock options represents the weighted-average period that our stock options are expected to remain outstanding. Since we have insufficient historical information regarding our stock options to provide a basis for estimate of expected term, we use the simplified method, which is the average of the weighted-average vesting period and contractual term of the option, to estimate the expected life of our stock option awards.

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Expected Volatility. Since there has been no public market for our common stock and lack of company specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we consider factors such as industry, stage of life cycle and size.

Risk-free Interest Rate. The risk-free interest rate is 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 assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

Estimated Forfeitures. We are required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data and the experience of other companies in the same industry to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, we record the difference as a cumulative adjustment in the period that the estimates are revised.

Service Period. We amortize all stock-based compensation over the requisite service period of the awards, which is generally the same as the vesting period of the awards. We amortize the fair value cost on a straight-line basis over the expected service periods. We estimate when and if performance-based grants will be earned. If we consider the award to be probable, we recognize expense over the estimated service period, which would be the estimated period of performance. If we do not consider the awards probable of achievement, we recognize no amount of stock-based compensation.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. We currently estimate when and if performance-based grants will be earned. If we do not consider the awards probable of achievement, we recognize no amount of stock-based compensation. If we consider the award to be probable, we record expense over the estimated service period. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Our intent has been to grant all options with an exercise price not less than the fair value of our common stock underlying those options on the date of grant. We have determined the estimated fair value of our common stock at each valuation date in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our board of directors, with the assistance of management, developed these valuations using significant judgment and taking into account numerous factors, including developments at our company, market conditions and contemporaneous independent third-party valuations.

For all option grant dates through June 30, 2014, our board determined the enterprise value based on the Market Approach using the Option Pricing Method, or OPM, and the Income Approach using the Probability Weighted Expected Return Method, or PWERM.

Under the Market Approach, we estimate the value based upon analysis of similar companies. We then apply these derived multiples or values to our financial metrics to estimate our market value. The Income Approach, or Discounted Cash Flow Method, estimates value based on the expectation of future net cash flows, which are then discounted back to the present using a rate of return derived from companies of similar type and risk profile. The allocation of these enterprise values to each part of our capital structure, including our common stock, was done under the Market Approach based on OPM. OPM treats the rights of the holders of preferred and common stock as equivalent to call

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options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the common stock can be determined by estimating the value of its portion of each of these call option rights. OPM derives the implied equity value of a company from a recent transaction involving the company's own securities issued on an arms-length basis. Under the PWERM, the value is estimated based upon analysis of future values for the enterprise under varying scenarios, and probabilities are ascribed to these scenarios based on expected future outcomes.

For valuations completed following the closing of this initial public offering, the fair value of our common stock will be determined based on the closing price of our common stock as reported on The NASDAQ Global Select Market on the date of grant.

The following table summarizes by grant date the number of shares of common stock subject to options granted from January 1, 2013 through August 25, 2014, the per share exercise price of the award, the fair value of our common stock on each grant date:

Grant Date	Number of Shares Granted	Exercise Price Per Share	Estimated Fair Value Per Share of Common Stock
January 4, 2013	508,060	\$ 1.218	\$ 1.218
July 11, 2013	290,208	1.74	1.74
October 3, 2013	1,724	1.74	1.74
December 10, 2013	23,275	1.74	1.74
January 13, 2014	12,931	1.74	1.74
February 7, 2014	16,378	1.74	1.74
June 5, 2014	504,646	5.51	5.51

We determined, after consultation with the underwriters, that our initial public offering price range would be \$14.00 to \$16.00 per share. As of the dates of the January 13, 2014, February 7, 2014 and June 5, 2014 stock option grants, our board of directors had determined the fair value of our common stock to be \$1.74 per share (for the January and February 2014 grants) and \$5.51 per share (for the June 2014 grants). The determination was based upon the objective and subjective factors described above. We believe the difference between the fair value of our common stock for the January, February and June 2014 grants, in each case as determined by our board of directors, and the initial offering price range is a result of the following factors:

the price range necessarily assumed that the initial public offering has occurred and a public market for our common stock has been created, and therefore excludes any marketability or illiquidity discount for our common stock, which was appropriately taken into account in our board of directors' fair value determinations;

differences in the valuation methodologies, assumptions and inputs used by the underwriters in their valuation analysis discussed with our management, which assume a successful initial public offering with no weighting attributed to any other outcome, compared to the valuation methodologies, assumptions and inputs used in the valuations considered by our board of directors, which were based on the market approach for the January and February 2014 grants and the income approach for the June 2014 grants, as described above;

differences in comparable companies in the dermatology and biopharmaceutical markets discussed between us and the underwriters as compared to the more narrow prior analysis applied and comparable companies used by our board of directors;

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our completed sale of shares of Series C convertible preferred stock at a price of \$9.628 per share for an aggregate purchase price of \$51.0 million, which shares of convertible preferred stock have certain rights, preferences and privileges senior to shares of our common stock; and

advancements in the development of our product candidates and, in particular, the following:

the effectiveness of the UCB agreement in August 2014;

our agreement with UCB of the terms of a planned Phase 3 clinical program for Cimzia in July 2014;

the receipt of clinical trial data from a Phase 2a clinical trial for DRM01 on June 27, 2014 that demonstrated significant reductions in the signs and symptoms of acne; and

the receipt of clinical trial data from a Phase 2b clinical trial for DRM04 in August 2014 that demonstrated statistically significant improvements relative to vehicle in both primary efficacy endpoints.

In September and October 2014, our compensation committee or board of directors approved equity awards for an aggregate of 1,084,835 shares of our common stock that are issuable upon the exercise of options to purchase common stock with an exercise price per share equal to the initial public offering price, which options were granted on the day that the registration statement for this offering was declared effective.

We expect to continue to grant stock options in the future, and to the extent that we do, our actual stock-based compensation expense recognized in future periods likely will increase.

Estimated Fair Value of Convertible Preferred Stock Warrant

Our outstanding convertible preferred stock warrant is classified as a liability on our consolidated balance sheets at fair value as it is contingently redeemable because it may obligate us to transfer assets to the holders at a future date under certain circumstances, such as a deemed liquidation event. We remeasure our convertible preferred stock warrant to fair value at each balance sheet date and record the corresponding gain or loss from the adjustment in our consolidated statements of operations and comprehensive loss as interest income and other income (expense), net. We will continue to record adjustments to the fair value of the convertible preferred stock warrant until it is exercised, converted into a warrant to purchase common stock or expires, at which time the warrant will no longer require remeasurement.

We estimate the fair values of our convertible preferred stock warrant using an option-pricing model or a hybrid of the option-pricing model and the probability-weighted expected return method. The option-pricing model is based on inputs as of the valuation measurement dates, including our estimates regarding the equity value at the valuation measurement dates, the volatility of the price of our convertible preferred stock, the remaining contractual term of the warrant, and the risk-free interest rates. The hybrid methodology is applied to various exit scenarios and each scenario is weighted based on our estimate of the probability of the scenario occurring.

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

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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 at least an annual basis, 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 at least annually, 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 have not recorded any impairment of our long-lived assets to date.

Net Operating Loss Carryforwards

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, 2013, 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 \$43.8 million, \$43.8 million and \$3.0 million, respectively. The federal and California NOL carryforwards will begin expiring during the year ended December 31, 2031 and the Canadian NOL carryforwards will begin expiring during the year ended December 31, 2029. The NOL carryforwards related to deferred tax assets do not include excess tax benefits from employee stock option exercises.

As of December 31, 2013, we also had research and development credit carryforwards of \$0.2 million, \$0.3 million and \$0.5 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 2032 and the California state credit carryforwards have no expiration date.

Our future utilization of our NOL carryforwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Section 382, as a result of ownership changes that may have occurred previously or that could occur in the future.

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Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, or ASU 2013-11, that provides for disclosure requirements related to unrecognized tax benefits in certain situations. We adopted ASU 2013-11 in the first quarter of 2014 and adoption of this standard did not have material impact on our consolidated results of operations or financial position.

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, 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 is effective for the fiscal years and interim reporting periods beginning after December 15, 2016. We are currently evaluating the impact that the adoption of ASU 2014-09 will have on our consolidated financial statements and related disclosures.

On June 10, 2014, the FASB issued ASU 2014-10, *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*, or ASU 2014-10, which eliminates the definition of a development stage entity, eliminates the development stage presentation and disclosure requirements under Accounting Standards Codification, or ASC, 915 *Development Stage Entities*, or ASC 915, and amends provisions of existing variable interest entity guidance under ASC 810 *Consolidation*. As a result of the changes, entities which meet the former definition of a development stage entity will no longer be required to: (1) present inception-to-date information in the statements of income, cash flows, and stockholder equity; (2) label the financial statements as those of a development stage entity; (3) disclose a description of the development stage activities in which the entity is engaged; and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. Furthermore, ASU 2014-10 clarifies disclosures about risks and uncertainties under ASC Topic 275, *Risks and Uncertainties*, that apply to companies that have not commenced planned principal operations. Finally, variable interest entity rules no longer contain an exception for development stage entities and, as a result, development stage entities will have to be evaluated for consolidation in the same manner as non-development stage entities.

Under ASU 2014-10, entities are no longer required to apply the presentation and disclosure provisions of ASC 915 during annual periods beginning after December 15, 2014. In addition, the revisions to the consolidation standards are effective for annual periods beginning after December 15, 2015 for public entities and are effective for annual periods beginning after December 15, 2016 for nonpublic entities. Early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities).

We have adopted ASU 2014-10 effective as of its issuance date. Adoption of this standard had no impact on our financial position, results of operations, or cash flows; however, the presentation of the consolidated financial statements and related disclosures in the notes to the consolidated financial statements has been changed to eliminate the disclosures that are no longer required.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the consolidated financial statements as a result of future adoption.

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BUSINESS

Overview

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

Medical dermatology focuses on therapeutic solutions to treat serious skin conditions, such as psoriasis, acne, atopic dermatitis, commonly known as eczema, and hyperhidrosis. 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. Furthermore, according to multiple published studies, patients report that medical dermatology conditions affect quality of life in ways comparable to other serious diseases, such as cancer, heart disease, diabetes, epilepsy, asthma and arthritis.

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

Dermatology Represents a Large, Growing, Specialty Market Supported by Strong Patient Demand. According to VisionGain, the medical dermatology market was valued at over \$21 billion in global pharmaceutical sales in 2012. In the same year, the psoriasis market alone accounted for approximately \$6.1 billion in global pharmaceutical sales, which was estimated to increase by 15% to approximately \$7.0 billion in 2013, and the acne market alone accounted for approximately \$3.7 billion in global pharmaceutical sales. The symptoms of medical dermatology diseases are often visible, and as a result, patients can be particularly motivated and willing to pay out of pocket for treatments. We believe that the willingness of patients to pay for dermatology treatments will help support pricing within the dermatology market despite trends toward declining reimbursement from healthcare insurers.

The Dermatology Market Is Ripe for Innovation with Significant Commercial Opportunities. We believe that an overall lack of innovation in the research and development of new dermatology products has resulted in a limited number of treatment options, severely underserving dermatologists and their patients across a number of medical dermatology conditions. For example, the three mechanisms of action most commonly used to treat acne have been available for over 30 years. However, the few truly innovative therapies launched over the past few decades have resulted in significant sales. For example, the launch of injectable, immune-modifying, biologic therapies targeting specific inflammatory mediators for the treatment of moderate-to-severe plaque psoriasis beginning in 2002 has created a growing, global market representing approximately \$4.0 billion in sales in 2012, according to Decision Resources. Recent advances in the understanding of skin disease biology are creating significant new opportunities for innovative product development, as illustrated by the recent development and commercial success of these biologics. We believe that companies focused on medical dermatology can accelerate the pace of innovation in this field.

The Development of Dermatology Products Can Be Relatively Efficient in Terms of Time and Cost. In comparison to many other segments of the biopharmaceutical industry, we believe that product development in dermatology can be relatively efficient in terms of time and cost. In many cases, efficacy can be determined based on short durations of therapy using comparatively small sample

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sizes, patients can be rapidly enrolled in clinical trials and the cost of monitoring study populations treated with topical, as opposed to systemic, therapies can be relatively low. In many dermatology indications, product development is further streamlined by well-established regulatory pathways. In addition, the same or similar efficacy endpoints can often be used to measure success in early- and late-stage clinical trials, which increases the predictability of late-stage clinical trial outcomes based on early-stage results. We believe that the development of our product candidates may benefit from one or more of these efficiencies.

Dermatology Products Can Be Commercialized at Relatively Low Cost. Our customer base is relatively concentrated compared to many other medical specialties. In 2010, there were approximately 10,800 dermatologists practicing in the United States, compared to approximately 215,600 internal and general practice physicians, 40,400 obstetricians and gynecologists and 21,800 cardiologists, according to the Association of American Medical Colleges. As a result, we believe that we can utilize a targeted, specialty sales force to commercialize our product candidates. In the experience of our management team, dermatologists tend to be highly motivated to work with dermatology-focused companies to bring innovative new therapies to patients who need them. Due to the high level of engagement between dermatologists and dermatology companies, we believe that dermatology products tend to be particularly sensitive to promotion. These factors make the dermatology market relatively accessible to small companies like ours by limiting capital requirements.

The Needs of Dermatologists and Their Patients Have Been Underserved as a Result of the Significant Consolidation of Dermatology-Focused Companies. We believe that a market opportunity exists for companies with a singular focus on dermatology. The significant consolidation of dermatology-focused companies that has occurred over the past decade has resulted in a marked reduction in the number of companies focused on marketing to dermatologists and, we believe, the number of products being developed to address unmet patient needs.

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

Dermira was founded by Thomas G. Wiggans, Eugene A. Bauer, M.D., Christopher M. Griffith and Luis C. Peña with the vision of building a leading dermatology company. Several members of our management team, including Mr. Wiggans, Dr. Bauer and Mr. Peña, have extensive experience within the dermatology field, including having served in executive roles at leading dermatology companies such as Connetics Corporation, Peplin, Inc. and Stiefel Laboratories, Inc., a GSK Company, or Stiefel. This experience brings us significant insight into product and commercial opportunities, as well as a broad network of relationships with leaders within the industry and medical community. Our team has extensive experience with products representing a variety of therapeutic modalities, including biologics and small molecules, and routes of administration, including systemic and topical products. At Connetics, members of our senior management team secured five marketing approvals for new dermatology products from the U.S. Food and Drug Administration, or the FDA, within seven years and successfully built a new product category across a number of highly competitive markets characterized by extensive branded and generic competition. For more information on our management, see "Management Executive Officers and Directors."

Since our founding in 2010, we have executed three significant transactions resulting in a portfolio of five 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 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.

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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. We have entered into an agreement to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval, to market Cimzia to dermatologists in the United States and Canada. UCB has conducted two Phase 2 clinical trials, including a 176-patient, randomized, multi-center, double-blind, placebo-controlled trial, that demonstrated significant reductions in the signs and symptoms of moderate-to-severe plaque psoriasis. We and UCB conducted an end-of-Phase 2 meeting with the FDA in June 2014, filed an investigational new drug application, or IND, for the treatment of moderate-to-severe plaque psoriasis with the FDA in September 2014 and intend to commence Phase 3 clinical trials in the first half of 2015.

DRM04, a topical, small-molecule anticholinergic product we are developing for the treatment of hyperhidrosis. 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. Two randomized, double-blind, vehicle-controlled Phase 2 clinical trials, including a 198-patient, multi-center Phase 2b clinical trial and a 38-patient Phase 2a clinical trial, have demonstrated significant reductions in the signs and symptoms of primary axillary, or underarm, hyperhidrosis in patients treated 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. In addition, we are currently conducting a Phase 2b clinical trial in patients with primary axillary hyperhidrosis in which we are comparing DRM04 to the topical formulation of the reference agent. We expect data from this trial in the first half of 2015. If successful, we intend to commence a Phase 3 clinical program, which would include one or more Phase 3 clinical trials, in the second half of 2015.

DRM01, a novel, topical, small-molecule sebum inhibitor we are developing for the treatment of acne. DRM01 is a prodrug designed to inhibit the production of sebum by delivering a widely-studied lipid synthesis inhibitor to the skin following topical administration. We have 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. Based on the results of this Phase 2a clinical trial, we intend to file an IND with the FDA and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015.

In addition, we have two early-stage programs in preclinical development:

DRM02, a novel, topical, small-molecule inhibitor of phosphodiesterase-4, or PDE4, for the treatment of inflammatory skin diseases; and

DRM05, a novel, topical photodynamic therapy, or PDT, for the treatment of acne.

Our Strategy

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

Rapidly Develop Our Late-Stage Product Candidates. We completed our end-of-Phase 2 meeting for Cimzia with the FDA within three months of establishing our collaboration with UCB, and we intend to commence Phase 3 clinical trials in the first half of 2015. We commenced our two Phase 2b clinical trials within one year and produced positive results from the first Phase 2b clinical trial within 16 months of licensing intellectual property related to DRM04 from Rose U

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and Stiefel. We produced positive Phase 2a clinical trial results within one year of initiating our first clinical trial of DRM01 and intend to commence a Phase 2b clinical program in the first half of 2015. We believe that our team's expertise in designing and executing product development programs in dermatology, combined with the relative efficiencies of dermatology product development, will enable us to rapidly develop our late-stage product candidates.

Efficiently Establish Proof-of-Concept for Our Early-Stage Product Candidates and Advance Promising Product Candidates into Late-Stage Development. In developing our early-stage product candidates, we focus on translating ongoing advances in the understanding of the biology of skin diseases into innovative solutions for unmet needs in medical dermatology by leveraging established pharmacology and current scientific tools. We seek to rapidly and efficiently establish proof-of-concept for these product candidates. Using this approach, our experienced management team is able to efficiently determine whether and how to advance product candidates into the next stages of development, which we believe increases our ability to direct resources to promising programs and enhances our likelihood of successfully developing and commercializing our product candidates. We believe that our advancement of DRM01 into late-stage development demonstrates our ability to efficiently progress promising candidates into late-stage development.

In-License and Acquire New Product Candidates and, Potentially, Commercial-Stage Products. Since our founding in 2010, we have executed three significant transactions resulting in a portfolio of five product candidates. We intend to continue to identify, evaluate, in-license and acquire product candidates from a number of sources by leveraging the insights, network and experience of our management team. Our objective is to maintain a well-balanced portfolio by in-licensing or acquiring additional product candidates across various stages of development. We intend to focus on product candidates that we believe have expeditious clinical development and regulatory pathways, including product candidates that we believe have demonstrated attractive profiles in early clinical testing and that we can advance into late-stage development, as well as earlier-stage product candidates targeting substantial commercial opportunities that we can quickly and efficiently advance through proof-of-concept studies. We may also seek to in-license and acquire dermatology products that have received regulatory approval for marketing in order to accelerate our entry into the market or expand the portfolio of products we can market to dermatologists.

Build a Specialized Sales and Marketing Organization of Highly Experienced Professionals Who Can Effectively Communicate the Benefits of Our Approved Products and Support Dermatologists and Their Patients. We believe that we can compete effectively in the dermatology market by having a specialized sales and marketing organization focused solely on dermatologists and their patients. Based on the commercial experience of members of our team, we believe that dermatologists place significant value on trusted relationships with, and scientifically-oriented commercial support from, the biopharmaceutical industry. To commercialize any approved products we may successfully develop or acquire, we intend to build a specialized sales and marketing organization that will provide high levels of customer support and scientific expertise to dermatologists and their patients. We believe that our targeted customer base would respond positively to a dermatology-focused approach, particularly in light of the recent consolidation in the number of companies focused on marketing to dermatologists.

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 intend to partner with third parties to help us reach other geographic markets or therapeutic specialties. We have an exclusive license to market Cimzia to dermatologists in the United States and

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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. We intend to take advantage of these opportunities in order to accelerate the identification, in-licensing, acquisition, development and commercialization of product candidates and products that we believe can be successful in the dermatology marketplace.

Overview of the Dermatology Market

Skin is the largest and fastest-growing organ in the human body. There are over 3,000 different skin conditions and diseases, many of which have profound effects on patients' lives. Dermatologists work with patients to find solutions for their skin concerns. These solutions fall broadly into either medical dermatology, which focuses on the treatment of diseases such as psoriasis, atopic dermatitis, hyperhidrosis and acne, or aesthetics, which focuses on improving the patient's appearance, most frequently the signs of aging.

We focus on the medical dermatology market, which addresses many highly prevalent conditions. These conditions can have significant, multidimensional effects on patients' quality of life, including their physical, functional and emotional well-being. For example, psoriasis has been shown to affect a patient's quality of life to an extent similar to that seen in other chronic diseases such as cancer, arthritis, hypertension, heart disease, diabetes and depression. Acne patients have equated their condition as comparable to other serious diseases, such as diabetes, epilepsy, asthma and arthritis. Studies have found hyperhidrosis impedes normal daily activities and can result in occupational, emotional, psychological, social and physical impairment.

According to VisionGain, the medical dermatology market was valued at over \$21 billion in global pharmaceutical sales in 2012. According to the 2010 National Ambulatory Medical Care Survey, there are 56 million annual office visits for medical dermatology conditions in the United States alone. In 2009, there were an estimated 34 million office visits to U.S. dermatologists. Inflammatory skin diseases and acne account for a significant proportion of the market for prescription medical dermatology products. Inflammatory skin diseases, such as psoriasis, an autoimmune disease that can be associated with a wide range of skin symptoms, atopic dermatitis, a disorder involving disruption in the skin's ability to insulate the body from exposure to external substances, and rosacea, a condition characterized by redness and often disfiguration of the central face, collectively represent the largest market in medical dermatology, accounting for over \$9.5 billion in global pharmaceutical sales in 2012. Acne accounted for approximately \$3.7 billion of global pharmaceutical sales in 2012. 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.

In light of the overall lack of innovation in the research and development of new dermatology treatments, the medical dermatology market includes a large number of marginally differentiated products with relatively modest sales. However, there are a number of examples of truly innovative topical, oral and injectable products that have created large markets. These include Elidel and Protopic, topical calcineurin inhibitors for the treatment of atopic dermatitis that achieved aggregate peak sales of over \$500 million in 2004, Accutane, an oral retinoid for the treatment of acne that achieved peak sales of approximately \$760 million in 2000, and Enbrel, Humira and Stelara, injectable biologics that

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achieved aggregate sales of \$4.0 billion in 2012 for the treatment of moderate-to-severe plaque psoriasis.

There were approximately 10,800 dermatologists practicing in the United States in 2012. We believe that dermatologists generally share three characteristics that are relevant to the marketing of dermatology products. First, dermatologists, as a specialty, tend to be particularly focused on the safety of pharmaceutical products because, while skin diseases can have profound effects on patients' quality of life, few are life-threatening. As a result, dermatologists, as well as their patients, often prefer to use topical treatments when possible to limit the risk of systemic side effects. If systemic treatments are required, many dermatologists favor products with well-established safety profiles relative to newer treatments with less safety experience, even if newer treatments may be more effective. Second, dermatologists, who are in relatively short supply in comparison with the demand from patients in the United States, tend to place a high level of emphasis on products that are easy to use because they often manage high volumes of patients. This contributes to their general preference for topical treatments, as well as systemic treatments with well-established safety profiles and limited monitoring requirements. Third, dermatologists tend to engage with sales and medical affairs personnel from the biopharmaceutical industry regarding the scientific evidence supporting dermatology products and the challenges experienced by physicians and patients in the use of these products. Dermatologists often rely on trusted relationships with scientifically competent, customer-focused sales representatives who can provide them with the necessary information to support their use of appropriate treatments.

Our Product Candidates

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

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Cimzia

Cimzia is our late-stage product candidate for the treatment of moderate-to-severe plaque psoriasis. Moderate-to-severe plaque psoriasis is a chronic, inflammatory skin disease characterized by excessive growth of certain skin cells and a wide range of symptoms, including redness, scaling, itching and burning. 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, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease, in multiple countries, including the United States. In 2013, Cimzia generated worldwide sales of over \$800 million, an increase of 27% compared to 2012. In March 2014, we entered into an agreement to collaborate with UCB to develop Cimzia for the treatment of moderate-to-severe plaque psoriasis in the United States, Canada and the European Union and, upon regulatory approval for marketing of the psoriasis indication, to market Cimzia to dermatologists in the United States and Canada.

UCB has conducted two Phase 2 clinical trials, including a 176-patient, randomized, multi-center, double-blind, placebo-controlled trial, that demonstrated significant reductions in the signs and symptoms of moderate-to-severe plaque psoriasis. As the Phase 2 psoriasis clinical trials were conducted in France and Germany, they were not covered by an IND. In June 2014, we and UCB conducted an end-of-Phase 2 meeting with the FDA during which we requested and received feedback from the FDA regarding certain elements of our proposed clinical development plan for Cimzia in psoriasis, including the design and size of Phase 3 clinical trials. UCB filed an IND for the treatment of moderate-to-severe plaque psoriasis with the FDA in September 2014, and we and UCB intend to commence Phase 3 clinical trials in the first half of 2015. 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 plaque psoriasis and market the product to dermatologists in the United States and Canada.

The Moderate-to-Severe Plaque Psoriasis Market

Psoriasis is a chronic, complex, immune-mediated disease that requires long-term treatment. It is commonly considered the most prevalent autoimmune disease in the world. According to Decision Resources, the diagnosed prevalence of psoriasis in the United States was approximately 9.3 million people, or approximately 2.8% of the population, in 2012. In the same year, U.S. sales of psoriasis prescriptions accounted for \$3.6 billion, of which \$2.9 billion were from biologic therapies and \$2.3 billion were from biologic TNF inhibitors alone.

Approximately 80% of psoriasis patients have plaque psoriasis. These patients typically have symmetrically distributed plaques of thickened, inflamed, red skin covered with silvery scales located on portions of the body including the elbows, knees, scalp or back. Approximately 20% of plaque psoriasis patients have moderate-to-severe disease. The National Psoriasis Foundation classifies moderate-to-severe plaque psoriasis as affecting at least 3% of the body surface area, although other factors, such as the location of lesions and their impact on quality of life, are also considered in assessing disease severity.

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Moderate-to-Severe Plaque Psoriasis

The symptoms of psoriasis are not limited to the skin, and evidence increasingly suggests that skin symptoms of psoriasis are a dermal manifestation of a systemic autoimmune disorder. Psoriasis often presents with one or more comorbidities associated with inflammatory etiology, such as joint disease or cardiovascular disease. Psoriatic arthritis, which is psoriasis with concomitant joint disease, develops in up to 40% of psoriasis patients, according to the International Federation of Psoriasis Associations. Recent studies have found that psoriasis is also associated with a significantly increased risk of major adverse cardiovascular events, including heart attack, stroke and cardiovascular mortality. A population-based study conducted from 1987 to 2002 of approximately 18,000 patients concluded that patients with psoriasis requiring systemic or light-based therapy had an average lifespan six years shorter than that of the control population. As a result, there is increasing interest in treating psoriasis with products that can address the systemic manifestations of the disease.

Moderate-to-Severe Plaque Psoriasis Treatments: Options and Limitations

Psoriasis treatments are chosen based on factors including disease severity, comorbidities, patient preference and insurance coverage. Topical treatments, such as steroids, vitamin D derivatives and retinoids, are typically insufficient for patients with moderate-to-severe disease. For decades, moderate-to-severe plaque psoriasis has been treated with traditional light-based or systemic therapies, which are moderately effective and have significant limitations. Light-based therapies are time-consuming and inconvenient and have been associated with accelerated damaging of the skin and increased risk of cancer. Traditional systemic therapies, such as oral and injectable methotrexate, oral cyclosporine and oral acitretin, have well-documented side effects, such as liver and kidney toxicity, increases in blood fats and birth defects, that require intensive monitoring by the prescribing physician.

The treatment of moderate-to-severe plaque psoriasis has been transformed by the introduction of biologic TNF inhibitors over the past decade. 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

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TNF may play a role in comorbidities of psoriasis that are associated with inflammatory etiology, such as rheumatoid arthritis and psoriatic arthritis, 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, such as rheumatoid arthritis and psoriatic arthritis, TNF inhibitors offer improved efficacy over traditional systemic therapies that have more frequent side effects and require more intensive monitoring. Since their launch into the rheumatology market in the late 1990s, TNF inhibitors have grown to become one of the largest-selling product classes in the pharmaceutical industry. According to published sources, U.S. sales of TNF inhibitors were approximately \$14.6 billion in 2012. In the same year, U.S. sales of TNF inhibitors for the treatment of psoriasis were \$2.3 billion, according to Decision Resources.

The TNF inhibitor class has become established as the most frequently used biologic therapy for moderate-to-severe plaque psoriasis. The two self-administered TNF inhibitors approved for marketing in psoriasis are Enbrel and Humira.

Enbrel. Enbrel is a fusion protein comprising a portion of the TNF receptor attached to a non-TNF-binding portion of a naturally occurring molecule called an antibody. It is typically injected by the patient once or twice per week. Launched for psoriasis in 2004, it was the first TNF inhibitor introduced into the dermatology market. While the effect of Enbrel on skin symptoms of psoriasis is relatively modest in comparison to those of other TNF inhibitors, the product continues to enjoy significant market share in light of its well-established safety profile. It has been suggested that the attractive safety profile of Enbrel may be attributable in part to the fact that it is not a complete antibody and, as such, lacks certain biological activities that could potentially lead to toxicity. According to Decision Resources, U.S. sales of Enbrel for the treatment of psoriasis were \$1.1 billion in 2012.

Humira. Humira is an antibody that binds TNF. It is typically injected by the patient every two weeks. Humira is perceived as more effective than Enbrel in treating the skin symptoms of psoriasis, an advantage has been attributed to Humira being a complete, TNF-binding antibody. We believe that Humira has gained market share as dermatologists who are comfortable with the safety profile of TNF inhibitors have sought therapies with improved efficacy. However, it is thought that the efficacy of Humira may be less durable than that of Enbrel because of the increased propensity of Humira to induce an immune response directed against itself within the body, a process known as immunogenicity that causes the therapeutic effect of biologic products to wane over time. According to Decision Resources, U.S. sales of Humira for the treatment of psoriasis were \$1.1 billion in 2012.

The only other TNF inhibitor approved for psoriasis in the United States and Canada is Remicade, which is an intravenously administered TNF-binding antibody. According to Decision Resources, U.S. sales of Remicade for the treatment of psoriasis were approximately \$110 million in 2012.

While most moderate-to-severe plaque psoriasis patients are initially treated with traditional systemic therapies, according to Decision Resources, dermatologists increasingly express a preference to use TNF inhibitors as first-line systemic therapy because of their efficacy, especially in the presence of concomitant psoriatic arthritis, and improved safety profile relative to conventional systemic agents.

Based on the significant therapeutic and commercial success of TNF inhibitors, new systemic therapies for psoriasis have been and are in the process of being developed. Stelara, a biologic product that inhibits two other important inflammatory molecules called interleukin 12 and interleukin 23, was launched in 2009. Notwithstanding its efficacy and convenient administration profile, we believe that Stelara is currently being used primarily as an alternative option for patients who have previously received TNF inhibitors because of its more limited long-term safety data and insurance coverage. According to Decision Resources, U.S. sales of Stelara for the treatment of psoriasis were approximately \$630 million in 2012.

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While these approved biologics have become useful therapeutic options for dermatologists and their psoriasis patients, they suffer from limitations, including the fact that some patients fail to respond, experience reduced response over time or experience side effects. Accordingly, patients treated with TNF inhibitors and other biologics may rotate between different products, including multiple TNF inhibitors. 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.

The Cimzia Solution

Cimzia is a product comprising the TNF-binding portion, or fragment, of an antibody linked to a polymer called polyethylene glycol, or PEG. Attachment of PEG to pharmaceuticals, a process termed pegylation, improves the stability of the pharmaceutical product in the systemic circulation, resulting in more sustained pharmacological activity following administration to the patient. Cimzia is typically injected by the patient every two to four weeks. It is the only pegylated antibody fragment approved for marketing within the TNF inhibitor class.

We believe that Cimzia's molecular structure may offer pharmacological advantages relative to other TNF inhibitors. From an efficacy standpoint, it has been shown in animal studies that Cimzia preferentially accumulates in inflamed tissue to a greater extent than Humira. It is also thought that pegylation may reduce the immunogenicity of Cimzia, which could lead to more durable efficacy. From a safety standpoint, because Cimzia is not a complete antibody, it, like Enbrel, lacks certain biological activities that could potentially lead to toxicity. We believe that these characteristics support a clinical safety and efficacy profile that would be attractive to dermatologists.

Cimzia has demonstrated an attractive efficacy, safety, tolerability and convenience profile across a range of indications, including psoriasis. Based on a cross-study comparison of efficacy data we have compiled from the placebo-controlled Phase 2 clinical trial of Cimzia and published reports regarding the largest pivotal Phase 3 clinical trials conducted with Enbrel and Humira, we believe that Cimzia has an attractive efficacy profile in comparison to these market-leading TNF inhibitors in psoriasis. A comparison of efficacy across these three separate clinical trials on the basis of the most widely accepted efficacy endpoints is shown below.

Cross-study comparison of Cimzia, Enbrel and Humira

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In each of these studies, patients with moderate-to-severe plaque psoriasis received at least 12 weeks of therapy. In the Cimzia Phase 2 clinical trial, 176 patients were randomized to receive either (1) an initial dose of 400 milligrams, or mg, of Cimzia, followed by Cimzia at a dose of 200 mg once every two weeks, or q2w, (2) Cimzia at a dose of 400 mg q2w, or (3) placebo. In the Enbrel Phase 3 clinical trial, 407 patients were randomized to receive either (1) Enbrel at a dose of 50 mg twice weekly, or biw, which is the recommended dose for the first three months of treatment in the U.S. prescribing information, or (2) placebo. In the Humira Phase 3 clinical trial, 1,212 patients were randomized to receive either (1) Humira at an initial dose of 80 mg, followed by Humira at a dose of 40 mg q2w starting one week later, which is the recommended dosing regimen in the U.S. prescribing information, or (2) placebo.

Response rates were reported in terms of the proportion of treated patients who achieved a 75% improvement in the clinical grading scale called the Psoriasis Area and Severity Index, or PASI 75, the endpoint most widely used to measure treatment success in clinical psoriasis trials, and the proportion of patients who achieved clearing or near clearing of psoriasis, as rated by the investigator on a scale called the Physician's Global Assessment, or PGA, 12 weeks following the start of therapy. While there were some differences in the patient populations, particularly in terms of sample size, disease severity, weight and the proportions who had previously used biologic therapies, as well as the PGA scales used to assess efficacy, that make it difficult to draw conclusions from this cross-study comparison, and while this cross-study comparison will not be used to support regulatory filings for Cimzia, we believe that this comparison suggests that Cimzia will have an attractive efficacy profile in comparison to the leading TNF inhibitors in the psoriasis market today. We believe that the efficacy of Cimzia will be particularly attractive to dermatologists as they continue to become more comfortable with the safety profile of the TNF inhibitor class and more interested in improved efficacy.

In addition to efficacy, we believe that Cimzia has other attributes that will be attractive to dermatologists and their patients. Based on accumulated experience in psoriasis and other indications, we believe that the safety profile of Cimzia is consistent with that of other TNF inhibitors. The most frequent adverse events associated with Cimzia are upper respiratory infections, rash and urinary tract infections. As observed with other TNF inhibitors, the most serious adverse reactions are serious infections, heart failure and, possibly, cancer. In addition, we believe that administration every two weeks would be a more convenient dosing regimen for patients than once or twice weekly dosing of Enbrel.

The Market Opportunity

The market for systemic psoriasis therapies is large and growing, and we expect this market growth to continue as dermatologists continue to increase their use of biologic therapies and new products reach the market. We believe that the TNF inhibitor class will continue to represent a significant segment of this market and that Cimzia will be positioned to compete effectively within the market for systemic psoriasis therapies.

According to Decision Resources, U.S. sales of psoriasis prescriptions accounted for \$3.6 billion in 2012. In the same year, U.S. sales of biologic therapies for moderate-to-severe plaque psoriasis were \$2.9 billion, of which \$2.3 billion were from TNF inhibitors. We believe that dermatologists write a significant majority of the prescriptions for biologics in psoriasis. While the same data are not available for sales of TNF inhibitors in psoriasis, data provided by IMS Health National Prescription Audit and National Sales Perspectives indicate that dermatologists accounted for 75% of U.S. sales of Stelara in the first half of 2013, when Stelara was only approved for the treatment of moderate-to-severe plaque psoriasis.

Since the launch of Stelara in 2009 and through 2012, sales of biologic treatments attributable to U.S. dermatologists grew at an average annual rate of 20%. Over the same period, sales of TNF

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inhibitors attributable to U.S. dermatologists grew at an average annual rate of 9%. This indicates that, since the introduction of Stelara, the market for biologics in psoriasis has been expanding beyond that attributable to the continuing growth of the TNF inhibitor class.

We believe that there is a substantial opportunity for continued expansion of the market for biologic psoriasis therapies. Even with the significant recent growth in the market, penetration of biologics into the addressable population of moderate-to-severe plaque psoriasis patients remains relatively low, particularly in comparison to other large biologics markets. In the United States in 2012, according to Decision Resources, only 10.5% of treated moderate-to-severe psoriasis patients received biologics, and 21.7% of treated rheumatoid arthritis patients received biologics. We believe that penetration into the psoriasis patient population may continue to increase as dermatologists become more familiar with available biologic therapies, particularly, the established safety record of TNF inhibitors, and as new biologic products reach the market. Decision Resources projects that U.S. sales of branded, systemic psoriasis therapies will increase from approximately \$3.1 billion in 2012 to \$5.7 billion by 2022.

We believe that the TNF inhibitor class is, and will continue to be, well positioned within the psoriasis market for a number of reasons:

Established Safety Record. Safety is a particularly important product attribute within the dermatology market. The TNF inhibitor product class has now been in commercial use for more than 15 years, including 10 years in psoriasis, and has a well-established track record of safety and efficacy. While TNF inhibitor product labels carry box warnings regarding increased risk of serious infections that may lead to hospitalization or death and a potential association with increased cancer risk, serious infections are uncommon, and the link between TNF inhibitor therapy and cancer risk remains controversial in light of evidence suggesting that the patient populations in which TNF inhibitors are indicated already may have an elevated risk of cancer. We believe that the safety record that has been established by the longstanding commercial use of TNF inhibitors differentiates the TNF inhibitor class relative to Stelara and other potential competing non-TNF inhibitor therapies that are currently under development, for which long-term safety data are more limited.

Attractive Efficacy Profile. The majority of psoriasis patients treated with TNF inhibitors experience significant improvements in their skin symptoms. Importantly, TNF inhibitors are highly effective in treating not only skin symptoms, but also certain systemic manifestations of psoriasis, including the joint disease characteristic of psoriatic arthritis, which develop in a substantial proportion of psoriasis patients. In addition, emerging evidence suggests that TNF inhibitor therapy may reduce the elevated risk of major adverse cardiovascular events in psoriasis patients and may do so more effectively than other therapies. We believe that the overall efficacy profile of TNF inhibitors will be attractive as interest in products that can address both the dermal and systemic manifestations of psoriasis continues to increase. Furthermore, we believe that the efficacy profile of the TNF inhibitor class is differentiated in this regard relative to that of Stelara and other potential competing non-TNF inhibitor therapies that are currently under development, as these newer product classes have demonstrated relatively limited efficacy in joint disease, and their impact on cardiovascular disease risk remains relatively unknown.

Contracting Leverage. We believe that the widespread use of TNF inhibitors across numerous indications has provided relative contracting leverage for this class, resulting in many insurers offering preferred access to TNF inhibitors relative to Stelara. The use of TNF inhibitors to treat several diseases presents an opportunity for manufacturers to contract with insurers for preferred formulary positioning across a target market substantially larger than that of psoriasis alone. We believe that this represents a potential advantage for TNF inhibitors relative to

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Stelara and other potential competing non-TNF inhibitor therapies that target fewer indications and smaller aggregate patient populations.

Accordingly, while there are a number of other systemic products under development for psoriasis by large pharmaceutical companies, including late-stage product candidates representing biologic and oral therapies with alternative mechanisms of action, as well as biosimilar versions of TNF inhibitors, we believe that the branded TNF inhibitor class is well positioned within the psoriasis market because of its longstanding role in the treatment of the disease, its established safety record within the safety-oriented dermatology specialty, its strong efficacy profile in skin symptoms and systemic aspects of the disease and preferred access accorded to products in the class by insurance companies in light of their widespread use across numerous indications. Many of the products and product candidates under late-stage development in psoriasis suffer from one or more potential limitations, such as relatively unproven safety profiles, limited or unproven activity in systemic aspects of the disease, and limited or unproven utility in other indications, that could represent significant disadvantages relative to TNF inhibitors. As a result, we expect the market for TNF inhibitors in psoriasis to remain substantial over the long-term.

In light of its molecular properties and clinical profile, we believe that if successfully developed in psoriasis, Cimzia presents an opportunity to offer dermatologists a product that delivers the strong efficacy of a TNF-binding antibody product such as Humira with the potential safety advantages of a non-antibody product such as Enbrel. We believe that this is a compelling proposition that can be communicated particularly effectively by a dermatology-focused company like ours that is committed to providing the highest level of scientific expertise to dermatologists. In addition, our collaboration with UCB will enable us to utilize the substantial infrastructure UCB has developed to support commercialization of Cimzia in other indications and markets, including established manufacturing and distribution capabilities. We also believe that Cimzia's significant commercial business in other indications will contribute to contracting leverage with insurers that represents a potential advantage relative to competing products with other mechanisms of action that may experience more limited use outside of psoriasis. Within the context of the advantages of the TNF inhibitor class relative to other available and potentially emerging new therapies, we believe that Cimzia, if successfully developed in psoriasis, will be well positioned to compete in the large, growing market for branded, systemic psoriasis therapies.

Clinical Development

Phase 2 Clinical Trials. Clinical development of Cimzia to date has been conducted by UCB. In addition to a number of studies in other indications, UCB has completed two Phase 2 clinical trials evaluating Cimzia in adults with moderate-to-severe 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 a PASI 75 response. 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 mg of Cimzia, followed by Cimzia at a dose of 200 mg 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 of "clear" or "almost clear" on a six-point PGA scale 12 weeks after the start of therapy. Results for these endpoints are presented below.

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Primary Endpoint: PASI 75 at Week 12

*

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 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).

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Primary Endpoint: PGA at Week 12

*

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 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).

At week 12, a PASI 75 response was observed in 6.8% of patients (4/59) who received placebo, 74.6% of patients (44/59) who received Cimzia 200 mg and 82.8% of patients (48/58) who received Cimzia 400 mg. A PGA response was observed in 1.7% of patients (1/59) who received placebo, 52.5% of patients (31/59) who received Cimzia 200 mg and 72.4% of patients (42/58) who received Cimzia 400 mg. Both Cimzia dosing regimens demonstrated meaningful and statistically significant improvements relative to placebo for both co-primary efficacy endpoints.

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. According to the authors who published the results, efficacy observed

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during 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).

According to the authors who published the results of these Phase 2 clinical trials in the British Journal of Dermatology, 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. A summary of treatment-emergent adverse events, or TEAEs, is presented in the following table.

Patients, n (% of patients)	First treatment study				Re-treatment study(a)		
	Placebo (n = 58)	Cimzia 200 mg (n = 60)	Cimzia 400 mg (n = 57)	All (n = 175)	Cimzia 200 mg (n = 34)	Cimzia 400 mg (n = 37)	All (n = 71)
Total AEs, n	133	156	125	414	36	36	72
Any AE	41 (71%)	43 (72%)	40 (70%)	124 (71%)	14 (41%)	18 (49%)	32 (45%)
Led to permanent discontinuation	3 (5%)	2 (3%)	2 (4%)(b)	7 (4%)(b)	0	0	0
Serious AEs	1 (2%)	2 (3%)	3 (5%)(c)	6 (3%)(c)	0	0	0
Infections	0	1 (2%)	2 (4%)	3 (2%)	0	0	0

- (a) The re-treatment study included patients who relapsed after a positive response with Cimzia during an observation period without treatment. No patients who received placebo met the criteria for relapse or were eligible for enrolment in the re-treatment study.
- (b) Does not include one patient who discontinued due to pregnancy.
- (c) Does not include two patients who reported a pregnancy as a serious AE. Treatment-emergent AEs are defined as having an onset date between first study drug administration and up to 12 weeks after last study drug administration.

Adapted from Reich K et al. Br J Dermatol. 2012; 167(1): 180-90.

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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 TEAEs were observed among treatment groups. The most frequently reported TEAEs were nasal congestion, headache and itching. Excluding pregnancies reported as serious adverse events 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 an IND. UCB filed an IND for the treatment of moderate-to-severe plaque psoriasis with the FDA in September 2014, and we and UCB intend to commence Phase 3 clinical trials in the first half of 2015.

Our planned Phase 3 clinical program consists of three randomized, multi-center, blinded Phase 3 clinical trials that will be conducted in multiple countries. In these trials, we plan to enroll a total of approximately 1,000 moderate-to-severe plaque psoriasis patients, including patients who have and patients who have not previously been treated with biologic products, such as TNF inhibitors. The program comprises two clinical trials designed to demonstrate the superiority of treatment with Cimzia relative to placebo, which we call the placebo-controlled Phase 3 clinical trials, and one clinical trial designed to demonstrate the superiority of treatment with Cimzia relative to placebo and relative to treatment with Enbrel, which we call the active-controlled Phase 3 clinical trial. We expect that these trials will be designed as follows:

Placebo-Controlled Phase 3 Clinical Trials. Each of the two placebo-controlled Phase 3 clinical trials will enroll approximately 225 patients. In each trial, patients will be 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 will be 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 will be 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 plaque psoriasis.

Active-Controlled Phase 3 Clinical Trial. The active-controlled Phase 3 clinical trial will enroll approximately 540 patients, who will be randomized to receive one of four regimens for at least

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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 trial, the primary efficacy endpoint will be the proportion of patients achieving a PASI 75 response 12 weeks after the start of treatment. Following the initial 12-week period, patients will be 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 plaque psoriasis.

We and UCB anticipate that marketing applications for Cimzia in moderate-to-severe plaque psoriasis will be based on the data collected through 48 weeks after the start of treatment in each of the three Phase 3 clinical trials, including the results of the primary endpoints at either 12 or 16 weeks and additional results collected during this 48-week period. 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 plaque psoriasis. For the purpose of seeking FDA approval of Cimzia for the treatment of moderate-to-severe plaque psoriasis, we intend to use the results of the initial 16-week treatment period in the placebo-controlled Phase 3 clinical trials to establish efficacy. In addition, we intend to submit the results obtained from weeks 16 through 48 of the active-controlled Phase 3 clinical trial in order to support dosing recommendations for long-term use.

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 plaque psoriasis and market the product to dermatologists in the United States and Canada.

DRM04

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 activation of sweat glands following topical administration. The products currently approved for the treatment of hyperhidrosis suffer from limitations such as moderate efficacy, significant side effects or cumbersome or invasive administration regimens. We believe that, if approved, DRM04 would be a convenient, effective and well-tolerated topical prescription therapy for this disease. In light of the limitations of available hyperhidrosis therapies, we believe that the introduction of such a product could expand the hyperhidrosis market by further penetrating the segment of patients who seek treatment from physicians and encouraging more patients to seek treatment.

Two randomized, double-blind, vehicle-controlled Phase 2 clinical trials, including a 198-patient, multi-center Phase 2b clinical trial and a 38-patient Phase 2a clinical trial, have demonstrated significant reductions in the signs and symptoms of primary axillary, or underarm, hyperhidrosis in patients treated 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. In addition, we are currently conducting a Phase 2b clinical trial in patients with primary axillary hyperhidrosis in which we are comparing DRM04 to the topical formulation of the reference agent. We have conducted the two Phase 2b clinical trials under an IND that was originally filed by Stiefel and that we reactivated in November 2013. We expect data from our ongoing Phase 2b clinical trial in the

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first half of 2015. If successful, we intend to commence a Phase 3 clinical program, which would include one or more Phase 3 clinical trials, in the second half of 2015.

The Hyperhidrosis Market

Hyperhidrosis is a condition of excessive 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, is localized and characteristically symmetric. It 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.

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. While these topical antiperspirants generate over 500,000 prescriptions annually in the United States, 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, as well as encourage more patients to seek treatment.

Current Hyperhidrosis Treatments: Options and Limitations

Current treatment options for hyperhidrosis generally fall into one of three categories:

self-administered, topical antiperspirants containing metal salts that block the release of sweat to the skin surface by clogging the opening of the duct;

injectable, systemic, surgical and other treatments that block activation of the sweat glands; or

surgical and other procedures intended to destroy or remove sweat glands.

Use of these treatments is determined by factors that include affected area and severity of disease.

For decades, topical antiperspirants containing metal salts have been the most widely-used treatment option for hyperhidrosis. OTC antiperspirants contain low concentrations of metal salts and are generally well-tolerated but limited in efficacy. Prescription antiperspirants containing higher concentrations of metal salts are typically recommended as the treatment of choice when OTC antiperspirants are not effective. However, these prescription antiperspirants are only moderately more effective, and their tolerability is limited by skin irritation associated with increased metal salt concentrations, which react with water to form irritating hydrochloric acid.

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Therapeutic options for patients who are unsatisfied with topical antiperspirants are largely limited to more cumbersome or invasive treatment strategies directed to blocking the activation of, destroying or removing the sweat glands. Intradermal injections of botulinum toxin, or Botox, a neurotoxin that blocks the release of acetylcholine, are effective but can be painful and must be administered by a physician, on average through 20 to 30 injections every six to nine months. A microwave device designed to overheat and destroy sweat glands is an alternative option, but treatment can be painful, requires multiple physician visits and is generally not covered by insurance. These treatments are time-consuming and require a significant investment of training and administration time and, in the case of microwave treatment, capital investment by the treating physician, limiting their potential reach to physicians. They are also not approved or well suited for application to the hands or feet. Iontophoresis, which involves soaking the hands or feet in water through which an electrical current is passed, can be performed in a physician's office or at home but requires repeated, time-consuming treatments, is irritating and is not well suited to treatment of the axillae. Patients with severe disease may be treated with surgical techniques that involve removal of sweat glands or destruction of nerves that transmit activating signals to the glands. Surgery is a significant undertaking that can be associated with a number of severe side effects, including increased sweat production in other body areas. As a result of the shortcomings of these treatment options, they are used much less frequently than topical treatments.

Oral anticholinergics, which block the interaction of acetylcholine with cholinergic receptors responsible for sweat gland activation, have demonstrated efficacy in small clinical hyperhidrosis studies. Although they are not currently approved by the FDA for the treatment of hyperhidrosis, they are sometimes used off-label. However, well-known systemic side effects, such as dry mouth, blurred vision, urinary retention and increased heart rate, often limit their use at doses required for efficacy in hyperhidrosis.

As a result of the limitations of available treatments, we believe that there is a significant unmet need for a new, effective, well-tolerated, self-administered, topical hyperhidrosis therapy that can be used across the range of body areas that can be affected by the disease.

The DRM04 Solution

DRM04 is a topical formulation of a novel form of a small-molecule anticholinergic agent that has been approved for systemic administration in other indications. Our initial target indication is the treatment of primary axillary hyperhidrosis. We believe that, if approved, DRM04 would be a convenient, effective and well-tolerated topical prescription therapy for this disease.

DRM04 is designed to block sweat production by inhibiting the interaction between acetylcholine and the cholinergic receptors responsible for sweat gland activation. The concept of inhibiting sweat production by blocking acetylcholine neurotransmission has been clinically validated in studies of Botox and anticholinergics for the treatment of hyperhidrosis. We believe that local, topical administration of DRM04 may offer advantages over oral administration of an anticholinergic by limiting uptake into the systemic circulation and thereby reducing the likelihood and severity of systemic side effects. We believe that it may also offer advantages over the injectable administration of Botox by providing a self-administered, non-invasive, more convenient alternative.

Clinical Development

Our initial target indication for DRM04 is primary axillary hyperhidrosis. Our development strategy involves two parts. First, we have assessed the safety, efficacy and tolerability of a topical formulation of the reference agent. Based on the results of this evaluation, we are currently assessing the profile of DRM04 compared to that of the topical formulation of the reference agent. We intend to develop DRM04 under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or the

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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 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. Our Phase 2 development program includes two completed Phase 2 clinical trials of the topical formulation of the reference agent and one ongoing Phase 2b clinical trial comparing DRM04 to the topical formulation of the reference agent.

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 to seven patients each, two concentrations of the reference agent (2% and 4%) in each of two topical formulations (A and B) were compared with their respective vehicles, which contain no active ingredient. These cohorts are summarized below.

Concentration of reference agent	Formulation A			Formulation B		
	4%	2%	0% (vehicle)	4%	2%	0% (vehicle)

Number of patients enrolled	6	6	7	6	6	7
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Patients were instructed to apply the study product once daily for four weeks using wipes saturated with either the topical formulation of the reference agent or vehicle only. Efficacy was evaluated based on axillary sweat production and disease severity. Assessments were conducted approximately weekly during the four-week treatment period and two weeks after the end of this treatment period. Disease severity was measured using a widely-used patient-reported outcome 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. All 38 patients enrolled in the clinical trial rated the severity of their disease as a three or a four on the 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.

Overall, more patients in the groups treated with the topical formulations of the reference agent than in the vehicle-only groups experienced a reduction in axillary sweating and a reduction in disease severity over the four-week treatment period. Of the 38 patients enrolled in the study, 19 patients received one of the two formulations and 19 patients received the other formulation. Of the 19 who received the formulation selected for further development, which we refer to as Formulation A, all completed at least two weeks of treatment with the exception of one who received vehicle only. This patient withdrew due to an adverse event of dry mouth after one day of treatment with vehicle only and was excluded from the efficacy analysis.

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Presented below are efficacy data for the 18 patients in whom the efficacy of Formulation A was assessed, including 12 who received the reference agent and six who received the vehicle only.

Week	Pre-treatment		Treatment period			Follow-up at two weeks post-treatment
	0	1	2	3	4	6
Number of patients reporting at each time point						
4%	6	6	6	5	5	6
2%	6	6	6	5	5	6
Vehicle	6	6	5	4	5	6
Total	18	18	17	14	15	18
Response rate (% of patients reporting mild or moderate disease severity at each time point)						
			6/6			
4%	0/6 (0%)	5/6 (83%)	(100%)	4/5 (80%)	4/5 (80%)	1/6 (17%)
			6/6	5/5	5/5	
2%	0/6 (0%)	4/6 (67%)	(100%)	(100%)	(100%)	4/6 (67%)
Vehicle	0/6 (0%)	1/6 (17%)	1/5 (20%)	1/4 (25%)	1/5 (20%)	0/6 (0%)

Nine of 12 patients treated with the reference agent reported an improvement in their perception of disease severity, as assessed using the HDSS, from severe to mild or moderate at the first on-treatment assessment, which was conducted approximately one week after the start of therapy. By the second weekly assessment, all 12 severe hyperhidrosis patients treated with the reference agent reported their disease severity as mild or moderate, in comparison with one of six patients who received the vehicle only. In weeks three and four, five out of six patients in each of the 2% and 4% treatment groups reported on their disease severity. Of those patients who reported assessments, patients treated with the reference agent continued to report disease severity as mild or moderate in all reported assessments through the end of the four-week treatment period, except one patient who discontinued treatment after two weeks at the 4% dose who was therefore counted as a non-responder at weeks three and four.

Among the 14 patients treated with Formulation A whose sweat production was measured at the end of the four-week treatment period, sweat production in the nine patients treated with the reference agent was on average 61% lower than at the start of therapy, in comparison with an average 1% increase in sweat production in the five patients who received vehicle only. The effect of the reference agent on sweating and

disease severity appeared to be reversible, as a trend toward a return to levels reported at the start of therapy was observed two weeks following cessation of therapy.

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Adverse events observed across all 38 patients enrolled in the trial are summarized below. The proportions of patients enrolled in each cohort in which selected types of adverse events were reported are shown in parentheses.

Concentration of reference agent	Formulation A			Formulation B		
	4%	2%	0% (vehicle)	4%	2%	0% (vehicle)
Number of patients enrolled	6	6	7	6	6	7
Number of patients reporting any adverse event (% of patients enrolled)	4 (67%)	4 (67%)	5 (71%)	5 (83%)	3 (50%)	4 (57%)
Number of patients reporting any treatment-related adverse event (% of patients enrolled)	2 (33%)	3 (50%)	5 (71%)	3 (50%)	3 (50%)	3 (43%)
Number of treatment-related adverse events	6	4	6	9	4	3

Across all 38 patients enrolled in the trial, the most common TEAEs were dry mouth and upper respiratory tract infection. No serious adverse events were reported. The occurrence of systemic adverse events appeared to be dependent on dose, regardless of the formulation used.

This Phase 2a clinical trial was designed to demonstrate proof-of-concept for the treatment of hyperhidrosis with the topical formulation of the reference agent and was not powered to demonstrate the statistical significance of any of the results. While we believe that the results demonstrated proof-of-concept for the treatment of hyperhidrosis with the topical formulation of the reference agent, the absence of any demonstration of statistical significance increases the possibility that the observations occurred by chance.

Phase 2b Clinical Program. Based on the Phase 2a data, we are conducting a Phase 2b clinical program in patients with primary axillary hyperhidrosis. Our Phase 2b clinical program comprises two Phase 2b clinical trials:

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, which we completed in August 2014; and

Study DRM04-HH02, an ongoing dose-ranging study assessing the safety, efficacy and pharmacokinetics of DRM04, the topical formulation of the reference agent and vehicle only in approximately 100 patients.

Both are randomized, multi-center, double-blind, vehicle-controlled trials in which the topical formulation of the reference agent, DRM04 or vehicle only, as applicable, is administered once daily for four weeks and efficacy is evaluated based on the HDSS and assessments of sweat production. In addition to the HDSS, in Study DRM04-HH02 we are using a patient-reported outcome assessment we have developed that we believe may enable a more specific assessment of disease severity relative to the HDSS.

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. As in the Phase 2a clinical trial, patients were instructed to apply the study product once daily for four weeks using wipes saturated with either the topical formulation of the reference agent 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 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.

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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. 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 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.

Primary Endpoint: HDSS Response Rate at Week Four

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.

At the end of the four-week treatment period, 36.8% to 52.5% of patients in each cohort treated with the reference agent achieved an improvement of at least two points in HDSS score, in comparison with 22.5% of patients who received the vehicle only. Based on these results, patients treated with the reference agent were between 63% and 133% more likely, depending on the concentration of the

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reference agent they received, to achieve an improvement of at least two points in HDSS score than patients who received the vehicle only.

The following chart summarizes the impact of the reference agent on sweat production, assessed as the average absolute change in sweat production from baseline to the end of the four-week treatment period.

Primary Endpoint: Average Absolute Change in Sweat Production at Week Four

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.

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The following table summarizes one of several non-primary efficacy analyses we conducted: the impact of the reference agent on sweat production, assessed as the percent change in sweat production from baseline to the end of the four-week treatment period.

Concentration of reference agent	Vehicle				
	(0%)	1%	2%	3%	4%
N	40	38	40	40	40
Average percent reduction sweat production from baseline	43.2%	54.4%	60.2%	73.4%	71.7%
P-value(a)		0.3378	0.1534	0.0045	0.0055

(a)

P-values reflect comparisons between results observed in each cohort of patients who received the topical formulation of the reference agent relative to the cohort of patients who received the vehicle only. 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.

From baseline to week four, patients in each cohort treated with the reference agent achieved an average reduction in sweat production of 56.6 to 91.4 mg, or 54.4% to 73.4%, in comparison with a reduction of 55.8 mg, or 43.2%, in patients who received the vehicle only.

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 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. In our ongoing Study DRM04-HH02, which is designed to facilitate the development of DRM04 based on data available to characterize the reference agent, we are comparing the topical formulation of the reference agent to DRM04. In this trial, we are randomizing approximately 100 patients with severe primary axillary hyperhidrosis into five cohorts of approximately 20 patients each. Each of the five cohorts is assigned to receive one of the following: a topical formulation containing one of two concentrations of the reference agent, DRM04 containing one of two concentrations of the novel form of the reference agent, or vehicle only. The vehicle in the topical formulation of the reference agent is the same as in DRM04.

Patients are instructed to apply the study product once daily for four weeks using wipes saturated with the topical formulation of the reference agent, DRM04 or vehicle only. We are evaluating efficacy based on axillary sweat production, the HDSS and the patient-reported outcome assessment we have developed that we believe may enable a more specific assessment of disease severity relative to the HDSS. As in Study DRM04-HH01, assessments are to be scheduled approximately weekly during the four-week treatment period and the two-week period after the end of this treatment period. As in the Phase 2a clinical trial and Study DRM04-HH01, we are enrolling patients in Study DRM04-HH02 who,

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prior to the start of treatment, rate the severity of their disease as a three or a four on the HDSS and produce at least 50 mg of sweat in each axilla over a five-minute period.

We began enrolling patients in Study DRM04-HH02 in April 2014 and expect to complete enrollment and obtain the results of this clinical trial in the first half of 2015. Data from all three of our Phase 2 clinical trials will be used to support dose selection for potential Phase 3 clinical trials. We intend to pursue the use of our patient-reported outcome assessment as a measurement of efficacy in our Phase 3 clinical program. Subject to discussions with the FDA, we currently anticipate that the design of potential Phase 3 clinical trials to evaluate the efficacy and safety of DRM04 would be generally similar to the design of Study DRM04-HH02, except that in potential Phase 3 clinical trials, DRM04 would be the only study product evaluated, the dose(s) evaluated would be selected based on the results of our Phase 2 clinical trials and trials would be sized in order to meet patient exposure requirements for regulatory approval.

DRM01

DRM01 is our late-stage product candidate for the treatment of acne. It is a novel, small-molecule prodrug designed to inhibit the production of sebum by delivering a widely-studied lipid synthesis inhibitor to the skin following topical administration. If approved for marketing, DRM01 could add an attractive new mechanism of action to the set of treatment strategies available to dermatologists and their acne patients. We believe that the introduction of such a product 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 2a clinical trial was conducted in Canada, it was not covered by an IND. Based on the results of this trial, we intend to file an IND with the FDA and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015.

The Acne Market

Acne is a common skin disease 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 factors:

excessive production of sebum by sebaceous glands;

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;

colonization of the area in and around the sebaceous gland by bacteria that are nourished by sebum; and

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

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that are comparable to those reported by patients with epilepsy, asthma, diabetes or arthritis. Effective treatment can dramatically improve acne patients' quality of life.

Acne

Acne is one of the most common skin diseases. 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. In 2007, acne represented about one-fourth of U.S. dermatologists' patient volume.

According to VisionGain, acne accounted for approximately \$3.7 billion in global pharmaceutical sales in 2012. In the same year, each of the three major prescription pharmaceutical product classes that are predominantly used to treat acne generated between approximately \$670 million and \$1.9 billion in U.S. sales, according to data provided by Symphony Health Solutions, Pharmaceutical Audit Suite. 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. While the acne market includes a large number of marginally differentiated products with relatively modest sales, which we believe is a result of the lack of innovation in new product development, there are examples of products that have created large markets in acne. These include Accutane, an oral retinoid that achieved peak sales of approximately \$760 million in 2000, and Solodyn, an oral antibiotic that achieved peak sales of approximately \$400 million in 2010. We believe that the introduction of a topical treatment with a new mechanism of action could establish a new product class and expand the acne market.

Current Acne Treatments: Options and Limitations

Acne is commonly treated with topical and oral therapies, often in combination. As for many other skin diseases, dermatologists and their patients often prefer to use topical products that can act locally in the skin while limiting the risk of systemic side effects. As a result, the vast majority of acne patients are treated with topical therapies. For patients with more severe disease, oral treatments are used, usually in combination with topical products. Many patients receive combination therapies comprising two or more topical agents with or without an oral agent.

Acne treatment guidelines published by the Global Alliance to Improve Outcomes in Acne recommend that acne treatment be directed toward as many of the four primary pathogenic factors as possible. Accordingly, patients are often treated with combination regimens that incorporate multiple agents with complementary mechanisms of action targeting different pathogenic factors. 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

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limited by significant, systemic side effects. As a result, we believe that there is an unmet need for a topical treatment that targets excessive sebum production.

For decades, the same four prescription pharmaceutical product classes have been used to treat acne:

Topical retinoids. Topical retinoids target the alterations in skin cells that contribute to clogging of the pores. They are among the most commonly used prescription acne medications. Their limitations include skin irritation and relatively modest efficacy in comparison with systemic therapies. According to data provided by Symphony Health Solutions, Pharmaceutical Audit Suite, U.S. sales of topical retinoid products that are used to treat acne were approximately \$880 million in 2012.

Topical and oral antimicrobials. Antimicrobials target bacterial colonization and inflammation. They are widely used topically and, in more severe disease, orally. While antimicrobials have been shown to be effective, particularly when administered systemically, there is growing interest in limiting the use of antibiotics in acne because of concerns regarding bacterial resistance and the attendant possibility that the efficacy of topical antibiotics in acne may be declining. Despite these concerns, oral antibiotics remain widely used because they tend to be more effective than available topical therapies and safer or better tolerated than other systemic acne treatments. According to data provided by Symphony Health Solutions, Pharmaceutical Audit Suite, U.S. sales of topical and oral antimicrobial products that are used to treat acne were approximately \$1.9 billion, including approximately \$1.3 billion in sales of topical products and approximately \$610 million in sales of oral products, in 2012.

Oral isotretinoin. Oral isotretinoin significantly reduces sebum production. Even in very severe disease, efficacy is dramatic, with nearly all patients achieving partial or complete clearance after one course of therapy and a substantial proportion requiring no further acne treatment. However, oral isotretinoin is associated with significant systemic toxicity, including liver damage and severe birth defects, that largely limit its use to patients with severe disease who comply with the requirements of a complex system intended to restrict distribution of the drug. In spite of this, oral isotretinoin continues to be widely used for severe acne due to the lack of safe products with robust efficacy. According to data provided by Symphony Health Solutions, Pharmaceutical Audit Suite, U.S. sales of oral isotretinoin were approximately \$670 million in 2012.

Oral hormonal therapies. Oral agents that reduce the activity of sex hormones called androgens are also highly effective. These treatments also reduce sebum production, which is stimulated by androgens. They are most often used in the form of contraceptives. Hormonal therapies have well-known, systemic side effects, such as mood disturbance, loss of muscle mass and reduced sexual desire, that are related to their effects on sex hormones. As such, they are not widely used in men or in women not seeking contraception. While oral hormonal therapies are predominantly used for purposes other than acne treatment, approximately 10% of oral contraceptives are primarily used for the treatment of acne, according to VisionGain.

While these available acne treatments are effective in many patients, an unmet need remains for effective therapies that are not associated with antibiotic resistance or treatment-limiting side effects, particularly therapies with novel mechanisms of action. In the context of guidelines recommending that acne therapy be directed to as many of the four primary pathogenic factors as possible, the absence of an available topical treatment that targets excessive sebum production, the systemic side effects associated with oral treatments that target this pathogenic factor and the overall preference for topical products in dermatology, we believe that there is a substantial unmet need and commercial opportunity for a new product class that targets sebum production following topical administration.

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The DRM01 Solution

DRM01 is a novel, small-molecule prodrug designed to inhibit the production of sebum by delivering a well-characterized lipid synthesis inhibitor to the skin following topical administration. A prodrug is a medication designed to be converted to its active form in the body, often in order to enhance delivery of the active form to the site of action by improving the pharmaceutical properties of the molecule administered to the patient. DRM01 is designed to be converted in the body to a lipid synthesis inhibitor that was originally discovered and evaluated in preclinical studies as a potential systemic lipid-lowering treatment and was later found to inhibit sebum production in sebum-producing cells. The lipid synthesis inhibitor targets 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. While systemic administration of the lipid synthesis inhibitor to animals was found to effectively reduce systemic lipid levels and enabled characterization of its preclinical safety profile, the molecule did not reduce sebum production in animals following topical administration. DRM01 is the result of a drug discovery program directed to leveraging the well-characterized nature of the lipid synthesis inhibitor by identifying a prodrug that effectively reduces sebum production when administered topically.

We have completed a 108-patient, randomized, multi-center, double-blind, vehicle-controlled Phase 2a clinical trial that was designed in accordance with published FDA draft guidance regarding the development of acne drugs. In this trial, patients treated with DRM01 achieved significant improvements relative to baseline and relative to patients who received vehicle only in the measures of acne severity that are most widely accepted by clinicians and the FDA as primary endpoints supporting the approval, labeling and use of prescription acne products. We believe that the overall efficacy, safety and tolerability profile observed in our Phase 2a clinical trial of DRM01 compares favorably to the profiles of the leading products in the acne market today, including topical and systemic therapies. This attractive clinical profile is supported by preclinical studies demonstrating that DRM01 inhibits, in a dose-dependent manner, the production of key sebum components in sebum-producing cells and reduces sebaceous gland size in animals.

Clinical Development

We are developing DRM01 in accordance with published FDA draft guidance regarding the development of acne drugs. This draft guidance sets forth the FDA's recommendations regarding the design, conduct and analysis of clinical trials intended to support marketing approval for new acne products. We believe that this published draft guidance streamlines the process of acne drug development by defining the FDA's expectations regarding the design, conduct and analysis of clinical trials. This presents an opportunity to design initial clinical trials that are similar in design to the Phase 3 clinical trials that would be conducted to support regulatory approval if the initial clinical trials are successful, which we believe enhances the predictability of late-stage clinical trial outcomes based on earlier-stage results. In addition, we believe that the principles set forth in the published FDA draft guidance can be used, in the context of guidance obtained from foreign regulatory authorities, to inform the design of a development program that can support marketing approval of a new acne product in jurisdictions outside the United States.

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

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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;

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 of at least two points from baseline on the IGA scale or (2) a reduction of at least two points from baseline on the IGA scale to a final score of zero, representing clear skin, or a score of one, representing almost clear skin.

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.

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.

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Primary Endpoints: Absolute Changes in Lesion Counts at Week 12

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

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The following table summarizes two of several secondary analyses we conducted: the percent reductions in inflammatory and non-inflammatory lesion counts from baseline to the end of the 12-week treatment period.

	Inflammatory lesion count		Non-inflammatory lesion count	
	Vehicle	DRM01	Vehicle	DRM01
N	54	53	54	53
Average percent reduction in lesion count from baseline	45.9%	63.9%	28.8%	48.1%
P-value(a)		0.0006		0.0025

(a)

P-values reflect comparisons between results observed in patients who received DRM01 relative to patients who received the vehicle only. 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. Missing data for one patient in the vehicle cohort for whom no on-treatment efficacy assessment was available are excluded from the patient population observed at the end of the 12-week treatment period.

From baseline to week 12, the number of inflammatory lesions in patients treated with DRM01 was reduced by an average of 19.3, or 63.9%, in comparison with 13.3, or 45.9%, in patients who received the vehicle only. Over the same time period, the number of non-inflammatory lesions in patients treated with DRM01 was reduced by an average of 19.9, or 48.1%, in comparison with 11.2, or 28.8%, in patients who received the vehicle only. 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.

The following chart summarizes the impact of DRM01 on the third primary efficacy endpoint: the proportion of patients who achieved a successful improvement the severity of their disease, as assessed using the IGA.

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Primary Endpoint: IGA Response Rate at Week 12

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.

At the end of the 12-week treatment period, 24.5% of patients (13/53) who received DRM01 achieved a successful improvement in the IGA score, in comparison with 7.3% of patients (4/55) who received the vehicle only. 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.

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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Adverse events observed in this clinical trial are summarized below. The proportion of patients enrolled in each of the two cohorts in which selected types of adverse events were reported are shown in parentheses.

Cohort	DRM01	Vehicle
Number of patients enrolled	53	55
Number of patients reporting any adverse event (% of patients enrolled)	35 (66.0%)	38 (69.1%)
Number of patients reporting any treatment-related adverse event (% of patients enrolled)	12 (22.6%)	8 (14.5%)

The most common adverse events 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 Program. Based on the attractive efficacy, safety and tolerability profile observed in the Phase 2a clinical trial, including significant improvements in the measures of acne severity that are most widely accepted by clinicians and the FDA as primary endpoints supporting the approval, labeling and use of prescription acne products, we intend to file an IND and commence a Phase 2b clinical program, which would include one or more clinical trials, in the first half of 2015. We expect that our Phase 2b clinical program will include a dose-ranging Phase 2b clinical trial comparing multiple DRM01 administration regimens to vehicle only. If the results of these trial(s) are positive, we intend to use them to support dose selection for Phase 3 development. As with our completed Phase 2a clinical trial, we intend to design our Phase 2b clinical program and any Phase 3 clinical trials in accordance with the published FDA draft guidance regarding the development of acne drugs.

The Market Opportunity

According to VisionGain, acne accounted for approximately \$3.7 billion in global pharmaceutical sales in 2012. In the same year, each of the three major prescription pharmaceutical product classes that are predominantly used to treat acne generated between approximately \$670 million and \$1.9 billion in U.S. sales, according to data provided by Symphony Health Solutions, Pharmaceutical Audit Suite. 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 the introduction of a topical treatment with a new mechanism of action could establish a new product class and expand the acne market.

We believe that the profile of DRM01, including its novel mechanism of action and the overall efficacy, safety and tolerability profile observed in our Phase 2a clinical trial, compares favorably to the profiles of the leading products in the acne market today, including topical and systemic therapies. Based on a cross-study comparison of efficacy data we have compiled from the Phase 2a clinical trial of DRM01 and the U.S. prescribing information describing the largest pivotal Phase 3 clinical trials conducted with the leading products in the U.S. market, as measured by annual U.S. sales in 2012, across the four principal prescription pharmaceutical product classes labeled to treat acne with the exception of oral isotretinoin, which is only indicated for severe, recalcitrant, nodular acne, we believe that DRM01 may have an attractive efficacy profile in comparison to these leading products. A comparison of efficacy across these six separate clinical trials on the basis of the measures of acne severity that are most widely accepted by clinicians and the FDA as primary endpoints supporting the approval, labeling and use of prescription acne products is shown below.

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Cross-study comparison of DRM01 and leading acne products in the U.S. market

In each of these studies, acne patients received at least 12 weeks of therapy. In the DRM01 Phase 2a clinical trial, 108 patients were randomized to receive either topical treatment with DRM01 gel twice daily or vehicle gel. In the Aczone Phase 3 clinical trial, 1,525 patients were randomized to receive either topical treatment with Aczone gel twice daily, which is the labeled administration regimen in the United States, or vehicle gel. In the Differin Phase 3 clinical trial, 392 patients were randomized to receive either topical treatment with Differin gel once daily, which is the labeled administration regimen in the United States, or vehicle gel. In the Epiduo Phase 3 clinical trial, 833 patients were randomized to receive either topical treatment with Epiduo gel once daily, which is the labeled administration regimen in the United States, or vehicle gel. In the Solodyn Phase 3 clinical trial, 473 patients were randomized to receive either oral treatment with Solodyn once daily or placebo. In this clinical trial, Solodyn was administered in accordance with the labeled administration regimen in the United States, except that the dose range of 0.76 to 1.5 mg per kilogram of body weight was wider than the labeled dose range of 0.92 to 1.11 mg per kilogram of body weight. In the Yaz Phase 3 clinical trial, 458 patients were randomized to receive either oral treatment with Yaz once daily, which is the labeled administration frequency in the United States, or placebo.

Efficacy data are presented in terms of the average reductions in the numbers of inflammatory and non-inflammatory acne lesions from baseline, expressed as a percentage of the corresponding numbers of lesions present at baseline, as well as the proportions of patients who achieved a successful improvement in the severity of their acne, as rated by the investigator, or PGA success. Data are reported at 12 weeks following the start of therapy except in the case of Yaz, for which data are reported in the U.S. prescribing information at 155 days, or approximately 22 weeks, following the start of therapy. As Solodyn is only approved for the treatment of inflammatory acne, reductions in non-inflammatory lesion counts are not reported in the U.S. prescribing information for this product. While there were some differences in the patient populations, particularly in terms of sample size, disease severity, age and sex, as well as differences in each of the scales and definitions used to assess PGA success, that make it difficult to draw conclusions from this cross-study comparison, and while this cross-study comparison will not be used to support regulatory filings for DRM01, we believe that

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DRM01 may have an attractive efficacy profile in comparison to these leading products in the U.S. acne market today, though without direct comparative efficacy data, we will not be able to make comparative efficacy claims.

In addition to its efficacy, we believe that DRM01 has other attributes that would be attractive to dermatologists and their patients. If the safety and tolerability profile observed in our Phase 2a clinical trial is confirmed in Phase 3 clinical trials, we believe that topical administration of DRM01 would offer physicians an attractive avenue to incorporate targeting of sebum production into acne treatment without the risk of the systemic side effects associated with oral isotretinoin and hormonal therapies, which are currently the only approved pharmaceutical products that effectively inhibit sebum production. In the context of guidelines published by the Global Alliance to Improve Outcomes in Acne recommending that acne treatment be directed toward as many pathogenic factors as possible and the overall preference for topical products in dermatology, we believe that as a topical sebum inhibitor with a mechanism of action that we believe is complementary to all available topical acne treatments, DRM01 would be well-positioned in the acne market.

Early-Stage Development Programs

We are developing one product candidate, DRM02, for the topical treatment of inflammatory skin diseases, and one product candidate, DRM05, for the topical treatment of acne.

DRM02

DRM02 is a novel, topical PDE4 inhibitor under preclinical development for the treatment of inflammatory skin diseases. PDE4 is an enzyme that plays an important role in promoting inflammation. Both systemically and topically administered PDE4 inhibitors have demonstrated efficacy in the treatment of psoriasis and atopic dermatitis in clinical trials. However, systemic treatment has resulted in dose-limiting side effects, including nausea, vomiting and gastric acid production. We believe that a topical PDE4 inhibitor such as DRM02 may offer the advantage of local anti-inflammatory action within the skin, while limiting uptake into the systemic circulation, thereby reducing the risk of systemic side effects observed with oral PDE4 inhibitors.

Preclinical studies have demonstrated that in animal models, DRM02 inhibits the response to a variety of inflammatory stimuli, as well as the production of a range of inflammatory mediators implicated in inflammatory skin diseases. We have completed a Phase 1 clinical trial and a Phase 2a proof-of-concept clinical program exploring the preliminary safety, tolerability and efficacy of DRM02 in patients with inflammatory skin diseases. Initial clinical efficacy data indicate that DRM02 gel was not more effective than vehicle-only gel. We are determining next steps for this product candidate.

DRM05

DRM05 is a novel, topical PDT under preclinical development for the treatment of acne. PDT is an approach to selectively eliminate target tissue by administering a photosensitizing agent to the target tissue, then exposing the tissue to light to activate the photosensitizing agent. PDT is performed in a physician's office and has been approved for the treatment of other skin conditions, such as actinic keratosis. Topical PDT has shown promising efficacy in acne, but has been limited by painful, visible side effects. We believe that there is currently no approved PDT for the treatment of acne.

DRM05 is designed to treat acne by selectively ablating sebaceous glands. We believe that if we are able to selectively target the distribution of our novel photosensitizer to the sebaceous glands and limit distribution to surrounding tissues, DRM05 could be associated with fewer side effects than available topical PDT. Our development program is focused on demonstrating proof-of-concept for DRM05 in animals. If we are successful, we intend to advance DRM05 into clinical development.

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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 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 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, which are all TNF inhibitors, and Stelara, marketed by Janssen.

Other Systemic Treatments. In addition to biologic products, other systemic treatments are prescribed for the treatment of moderate-to-severe plaque psoriasis, including: branded and generic injectable and oral methotrexate products, such as Otrexup, marketed by Antares Pharma, Inc. and LEO Pharma A/S, and generic products marketed by Sandoz Inc., Mylan Inc., Teva Pharmaceutical Industries Ltd. and Hospira, Inc.; branded and generic oral cyclosporine products, such as Neoral, marketed by Novartis AG, Gengraf, marketed by AbbVie, and generic products marketed by Sandoz and IVAX Corporation; and branded and generic oral acitretin products, such as Soriatane, marketed by Stiefel, and generic products marketed by Teva and Prasco, LLC.

Other Treatments. Various light-based treatments are also used to treat moderate-to-severe plaque psoriasis, including various lasers and ultraviolet light-based therapies, such as Oxsoalene-Ultra, marketed by Valeant Pharmaceuticals International. In addition, there are 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 also several pharmaceutical product candidates under development that could potentially be used to treat psoriasis and compete with Cimzia. Products for which applications for marketing in psoriasis are under review by the FDA include Otezla, which is marketed by Celgene Corporation in psoriatic arthritis, and secukinumab, which is being developed by Novartis. In addition, product candidates in Phase 3 clinical trials include Xeljanz, which is marketed in rheumatoid arthritis by Pfizer, ixekizumab from Eli Lilly and Company, brodalumab from Amgen and tildrakizumab from Merck. There are multiple biosimilar versions of TNF inhibitors under development, including late-stage biosimilar versions of Humira from Amgen, Sandoz and Boehringer Ingelheim and other biosimilar versions of TNF inhibitors in development by companies, including Baxter International Inc. and Hospira, Inc.

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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 intradermal injections of Botox, marketed by Allergan, Inc., 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, are also used to destroy nerves that transmit activating signals to sweat glands.

In addition to approved hyperhidrosis treatments, there are also several treatments under development that could potentially be used to treat hyperhidrosis and compete with DRM04, including a laser-based procedure from Cynosure, Inc., an ultrasound device from Ulthera, Inc., topical forms of botulinum toxin A from Revance Therapeutics, Inc. and Anterios, Inc., and topical anticholinergic product candidates from Brickell Biotech, Inc. and GlaxoSmithKline LLC, or GSK.

Acne

If approved for the treatment of acne, we anticipate that DRM01 and DRM05 would compete with other approved prescription acne products, including:

Topical Retinoids. Several topical retinoid products are prescribed for the treatment of acne, including single-agent products such as Differin, marketed by Galderma S.A., Tazorac, marketed by Allergan, Fabior, marketed by Stiefel, and branded and generic tretinoin products, such as Retin-A Micro, marketed by Valeant. In addition to single-agent products, 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 Stiefel.

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 PreCision Dermatology, Inc., and branded and generic benzoyl peroxide, clindamycin phosphate and erythromycin products. In addition to single-agent products, topical antimicrobials are also used in combination products that include a retinoid, as in Ziana and Veltin, or another antimicrobial, as in branded and generic products combining clindamycin phosphate and benzoyl peroxide, such as Acanya, marketed by Medicis. In addition to topical antimicrobial products, oral antibiotics are also prescribed for the treatment of acne, including branded and generic doxycycline and minocycline products, such as Doryx, marketed by Actavis plc, Monodox, marketed by Aqua Pharmaceuticals, LLC, a division of Almirall, S.A., 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 generic contraceptives such as branded and generic combinations of drospirenone and ethinyl estradiol, such as

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Yaz, marketed by Bayer HealthCare AG, and Ocella, marketed by Teva, and branded and generic combinations of norgestimate and ethinyl estradiol, such as Ortho Tri-Cyclen, marketed by Janssen, TriNessa, marketed by Actavis, and Tri-Sprintec, marketed by Teva.

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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.

In addition to prescription acne therapies, a wide range of OTC and device products are used to treat acne, including OTC benzoyl peroxide products and skin cleansers, such as Proactiv, marketed by Guthy-Renker LLC, as well as light-based therapies, such as Blu-U, marketed by Dusa Pharmaceuticals, Inc., a division of Sun Pharmaceutical Industries, Inc.

In addition to commercially available products, there are several product candidates in development that could potentially be used to treat acne and compete with DRM01 or DRM05. Late-stage product candidates include topical antimicrobials in development by Galderma, Valeant and Maruho Co., Ltd., and light-based therapies in development by Photocure ASA, LEO Pharma and KLOX Technologies, Inc. Early-stage product candidates are in development by Androscience Corporation, Valeant, Galderma, Braintree Laboratories, Inc., Novan, Inc., Anterios and Foamix, Ltd.

Inflammatory Skin Diseases

If approved for the treatment for one or more inflammatory skin diseases, we anticipate that DRM02 would compete with other therapies approved for the same or similar indications, as well as potential product candidates for such indications. Currently approved therapies include topical corticosteroids, which are widely available and mostly generic; topical calcineurin inhibitors, antimicrobials, vasoconstrictors, vitamin D derivatives, and retinoids; oral antihistamines, antibiotics and retinoids; and injectable biologics. There are several product candidates in development for the potential treatment of inflammatory skin diseases from competitors including Allergan, Anacor Pharmaceuticals, Inc., Astellas Pharma US, Inc., Bayer, Pfizer, Galderma, GSK, LEO Pharma, McNeil-PPC, Inc., Regeneron Pharmaceuticals, Inc., Sanofi and Valeant.

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 also 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.

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. 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. With respect to the former, our policy is to protect our proprietary position by, among other methods, filing for 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.

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As of September 1, 2014, we own or have an exclusive license to 23 issued U.S. patents and 88 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 37 pending foreign patent applications. Of these patents and patent applications:

There are two issued U.S. patents, one issued Australian patent, five pending U.S. patent applications and four pending foreign applications (one each in Canada, the European Patent Office, Mexico and one under the Patent Cooperation Treaty) relating to DRM04. We own four of the pending U.S. patent applications and one of the pending foreign applications, and have exclusively licensed from Rose U worldwide rights to the two issued U.S. patents, one issued foreign patent, one pending U.S. patent application and three pending foreign patent applications. The issued DRM04 patents contain claims directed to individually packaged wipes for the treatment of hyperhidrosis where the wipes contain a composition comprising DRM04 or other related compounds, and methods of alleviating hyperhidrosis using such compositions. The DRM04 patent applications contain claims directed to compositions comprising DRM04 or other related compounds, individually packaged wipes comprising such compositions, absorbent pads comprising DRM04 pharmaceutical compositions, methods of treating hyperhidrosis with topical administration of DRM04 or other related compounds and methods of synthesis of DRM04. The issued U.S. and foreign patents relating to DRM04 will expire between 2020 and 2029 and the pending U.S. and foreign patent applications relating to DRM04, if issued, will expire between 2028 and 2034.

There are 15 issued foreign patents (one each in Belgium, Denmark, France, Germany, Hong Kong, Ireland, Italy, Luxembourg, Mexico, the Netherlands, New Zealand, Singapore, Spain, Switzerland and the United Kingdom), one pending U.S. patent application and 13 pending foreign patent applications (two in Australia and one each in Brazil, Canada, China, the European Patent Office, Hong Kong, Israel, India, Japan, Russia, Singapore and South Korea) relating to DRM01, all of which we own. The DRM01 patents and patent applications cover the DRM01 compound and other related compounds, pharmaceutical compositions and treatment methods. The issued foreign patents relating to DRM01 will expire in 2030 and the pending U.S. and foreign patent applications relating to DRM01, if issued, will expire in 2030.

In addition, we have patents and patent applications not included in the figures noted above related to Cimzia licensed to us under the UCB agreement, including six issued U.S. patents and two issued Canadian patents. These patents cover the Cimzia TNF inhibitor and related molecules for making them, and will expire between 2014 and 2024. 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.

Altogether, our 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 2014 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.

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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 European Medicines Agency, or 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, purchased \$7.5 million of shares of our Series C convertible preferred stock in August 2014 and concurrently with this offering will purchase from us in a private placement 468,750 shares of our common stock with an aggregate purchase price of \$7.5 million, at the initial public offering 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. Any development costs in excess of this amount 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.

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'

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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 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

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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 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 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

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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 (i) 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 (ii) until such corrective action has taken effect so as to reverse such material decrease, UCB has 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 are required to pay additional amounts totaling up to \$4.6 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.

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 (i) 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 (ii) 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

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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. As of July 25, 2014, the last-to-expire issued patent relating to DRM04 that we license under the license agreement with Rose U expires in 2029.

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.

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.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) in compliance with good clinical practice, or GCP, 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 (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval at each site at which the clinical trial will be conducted.

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An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

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 NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and sponsor under an approved new drug application are also subject to annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also 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 GCP. 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. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

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.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has

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provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then commence a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approval an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third 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.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

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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. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing and are subject to periodic inspection after approval.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form and strength, and that there be no meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Biosimilarity must be shown through analytical studies, animal studies and at least one clinical study, absent a waiver by the Secretary. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. No biosimilar or interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation which are still being evaluated by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (1) one year after first commercial marketing of the first interchangeable biosimilar, (2) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (3) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable

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biosimilar applicant, or (4) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase, the time between IND application and NDA submission, and all of the review phase, the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

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, risk evaluation and mitigation strategies, or 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

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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 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 IRB, 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

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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.

Federal false claims laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate federal false claims laws. Additionally, PPACA amended the federal healthcare program anti-kickback statute such that a violation of that statute can serve as a basis for liability under certain federal false claims laws.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offerer or payor knows or should know is likely to influence the beneficiary to order a reimbursable item or service from a particular supplier, and the healthcare fraud and false statements statutes, which prohibit, among other things, 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 money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

Violations of these federal healthcare fraud and abuse laws are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs.

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.

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

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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 ARRA provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to the U.S. Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any approved product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. If third-party payors do not consider our approved products to be cost-effective compared

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to other available 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 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 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 four CMOs for the manufacturing of our four small-molecule drug substances and three additional CMOs for the manufacturing of our four 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.

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Employees

As of September 1, 2014, we had 25 regular full-time employees, including 17 in research and development. We had one employee located outside of the United States as of September 1, 2014. From time to time, we also retain independent contractors to support our organization. None of our employees is 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.

Facilities

Our corporate headquarters are located in Redwood City, California, where we occupy facilities totaling approximately 14,700 square feet, consisting of approximately 8,500 square feet under lease agreements that expire in November 2014 and approximately 6,200 square feet under a month-to-month lease. We entered into a lease agreement in July 2014 and an amendment in September 2014 for a facility totaling approximately 18,651 square feet in Menlo Park, California. We intend to relocate our corporate headquarters to this facility in the fourth quarter of 2014. The term of the lease commences December 2014 and terminates November 2019, with an option to renew for an additional three-year term. We use our current facilities and intend to use our future facility for our research and development and general and administrative personnel. We believe that our current and future facilities are adequate to meet our needs for the immediate future.

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.

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The following table provides information regarding our executive officers and directors as of September 1, 2014:

Name	Age	Position
Executive Officers:		
Thomas G. Wiggans	62	Chief Executive Officer and Chairman of the Board
Eugene A. Bauer, M.D.	72	Chief Medical Officer and Director
Christopher M. Griffith	38	Vice President, Corporate Development & Strategy
Andrew L. Guggenhime	46	Chief Operating Officer and Chief Financial Officer
Luis C. Peña	52	Executive Vice President, Product Development
Non-Employee Directors:		
David E. Cohen, M.D., M.P.H.(1)(4)	49	Director
Fred B. Craves, Ph.D.(2)(4)	69	Director
Matthew K. Fust(1)(3)	50	Director
Wende S. Hutton(3)	54	Director
Mark D. McDade	59	Director
Jake R. Nunn(4)	44	Director
William R. Ringo(1)(3)	68	Director

- (1) Member of the Audit Committee
- (2) Lead Independent Director
- (3) Member of the Compensation Committee
- (4) Member of the Nominating and Corporate Governance Committee

Executive Officers

Thomas G. 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 Pharmaceuticals, Inc., a biopharmaceutical company, 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, Inc., a biotechnology company, and in August 2008, he became its Chief Executive Officer, and he served in these positions until Peplin's acquisition by LEO Pharma A/S in November 2009. Previously, Mr. Wiggans served as Chief Executive Officer of Connetics Corporation, a biotechnology company, 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 Laboratories, Inc. 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 Chairman of the Biotechnology Institute, a non-profit educational organization, and is 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

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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.

Eugene A. Bauer, M.D. 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 has served on the boards of directors of a number of public and private companies, including the boards of directors of Patient Safety Technologies, Inc. from January 2010 until June 2010 and Vyteris, Inc. from February 2010 until June 2012. From June 2006, Dr. Bauer served as a member of Peplin's board of directors, 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 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, 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 previously served as a member of the boards of directors of Protalex, Inc., Vyteris, Peplin, PetDRx, Inc., Arbor Vita Corp., Patient Safety Technologies, Inc., MediSync Bioservices and Modigene Inc. (now 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 Institute of Medicine of the National Academy of Sciences. 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.

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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.

Luis C. Peña is a co-founder and has served as our Executive Vice President of Product Development since July 2013, after previously serving as 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 Laboratories, 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, Inc., a biotechnology company. 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.

Non-Employee Directors

David