Corium International, Inc.
Form S-1
March 03, 2014

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As filed with the Securities and Exchange Commission on March 3, 2014

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Corium International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**38-3230774**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Corium International, Inc.
235 Constitution Drive
Menlo Park, California 94025
(650) 298-8255

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

Peter D. Staple
Chief Executive Officer
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Menlo Park, California 94025
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box: o

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee

Common Stock, $0.001 par value	$50,000,000	$6,440.00

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended.

(2) Includes additional shares that the underwriters have the right to purchase from the Registrant.

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

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

SUBJECT TO COMPLETION, DATED MARCH 3, 2014

PRELIMINARY PROSPECTUS

Shares

Corium International, Inc.

Common Stock

We are offering shares of our common stock. This is our initial public offering of our common stock and no public market currently exists for our common stock. We expect the initial public offering price to be between $ and $ per share. We intend to apply to list our common stock on the NASDAQ Global Market under the symbol "CORI."

We are an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public reporting requirements for this prospectus and future filings.

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

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.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discounts and Commissions		
Proceeds to Corium before Expenses		

Delivery of the shares of common stock is expected to be made on or about , 2014. We have granted the underwriters an option for a period of 30 days to purchase an additional shares of our common stock. If the underwriters exercise the option in full, total underwriting discounts and commissions payable by us will be $, and the total proceeds to us before expenses will be $.

Joint Book-Running Managers

Jefferies **Leerink Partners**

Co-Managers

Needham & Company **FBR**

Prospectus dated , 2014

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Neither we nor the underwriters have 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. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

Until , 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit our initial public offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. You should read the entire prospectus carefully before making an investment in our common stock. You should carefully consider, among other things, our financial statements and the related notes and the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

CORIUM INTERNATIONAL, INC.

Overview

We are a commercial stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage our broad experience in transdermal and transmucosal delivery systems. Together with our partners, we have successfully developed six marketed products in the prescription drug and consumer markets, and we are the sole commercial supplier of each of those products for our marketing partners. These marketed products are Clonidine Transdermal Delivery System, or TDS, Fentanyl TDS and four Crest Advanced Seal Whitestrips products. We use our novel transdermal and transmucosal approaches to bring new products to markets with significant opportunities. Our development platforms enable transdermal delivery of large molecules, or biologics, including vaccines, peptides and proteins, as well as small molecules that are otherwise difficult to deliver in a transdermal dosage form. Our pipeline includes three partnered products that are the subject of pending drug marketing applications to the U.S. Food and Drug Administration, or FDA. In addition, we have 12 partner- or self-funded programs at earlier stages.

Since 1999, we have built significant know-how and experience in the development, scale-up and manufacture of complex specialty products and have formed relationships with our partners that include both the development of new product formulations and our manufacture of the resulting products. Our partners include The Procter & Gamble Company, or P&G, Par Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc. and Agile Therapeutics, Inc., as well as several other multinational pharmaceutical companies. We have the capability to develop and manufacture our own product candidates and are one of only a few independent companies that develops and manufactures transdermal products for other parties. We believe our proprietary manufacturing processes, know-how and custom equipment give us a distinct competitive advantage over other pharmaceutical, consumer products and manufacturing companies.

Transdermal drug delivery is the transport of drugs through the skin for absorption into the body. We have developed two proprietary technology platforms, Corplex and MicroCor, that we believe offer significant competitive advantages over existing transdermal approaches. Corplex and MicroCor are designed to be adapted broadly for use in multiple drug categories and indications. We use our Corplex technology to create advanced transdermal and transmucosal systems for small molecules that utilize less of the active ingredient while achieving the same or better therapeutic effect, that can adhere well to either wet or dry surfaces, and that can hold additional ingredients required to aid the diffusion of low-solubility molecules through the skin without losing adhesion. Our MicroCor technology is a biodegradable microstructure system currently in development that enables the painless and convenient delivery of biologics that otherwise must be delivered via injection. Biodegradable microstructures integrate drug molecules and a biocompatible polymer. With slight external pressure, the microstructures penetrate the outer layers of the skin and dissolve to release the drug for local or systemic absorption. MicroCor is designed to expand the market for transdermal delivery of biologics, which cannot currently be delivered by other FDA-approved transdermal technologies.

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In addition to commercialized products, we have a number of products in late stages of development. The most advanced clinical stage product in our pipeline is AG200-15, which is in Phase 3 development by our exclusive marketing partner, Agile. AG200-15 is a combined hormonal contraceptive patch designed to deliver two hormones, ethinyl estradiol and levonorgestrel, through the skin at levels comparable to low-dose oral contraceptives, in an easy-to-use format over seven days. Agile has filed a New Drug Application, or NDA, for approval of this product by the FDA, which is required before marketing a new drug in the United States. The FDA has indicated that Agile's NDA was not sufficient for approval as originally submitted. Agile is preparing to conduct an additional Phase 3 clinical trial based on this guidance and intends to supplement the NDA with the results of the additional Phase 3 clinical trial. Based on market research conducted by Agile, AG200-15 has the potential to reach a peak market share of 9% of hormonal contraceptive prescriptions in the United States. Based upon IMS data, Agile estimates that each percentage point of market share of hormonal contraceptive prescriptions in the United States currently represents approximately $108 million of annual gross sales.

We are developing two additional products utilizing our proprietary technologies that we plan to advance into Phase 2 trials in 2014 and 2015. MicroCor hPTH(1-34) utilizes our MicroCor technology to deliver parathyroid hormone, a peptide for treating osteoporosis that is currently available only in a refrigerated injectable form. Corplex Tamsulosin is a patch being developed to deliver tamsulosin to patients with benign prostatic hyperplasia, or enlarged prostate. Tamsulosin is a drug that relaxes smooth muscle cells in the prostate and bladder neck, thereby decreasing the blockage of urine flow that occurs with an enlarged prostate. It is designed to deliver a controlled dose over several days and to reduce side effects compared to currently marketed products. We are not aware of any FDA-approved transdermal systems for delivering either hPTH(1-34) or tamsulosin.

Transdermal Drug Delivery Industry

Transdermal delivery and transmucosal delivery, or delivery through mucous membranes, offer patients more convenient, non-invasive and comfortable methods of drug delivery. The benefits of transdermal and transmucosal delivery systems over other dosage forms generally include enhancing the efficacy and reducing the side effects of a drug by controlling the rate of delivery and absorption, avoiding the undesirable breakdown of drugs in the liver associated with gastrointestinal absorption, and improving patient compliance and long-term adherence to therapy. According to Datamonitor, the global value of the market for systemic transdermal products, including patches, was approximately $20 billion in 2010 and is expected to grow to approximately $30 billion by 2015. We believe this growth is driven by the increasing availability of transdermal systems for important therapeutic applications and changing disease demographics.

Despite the benefits of current transdermal delivery products, many key challenges prevent broader use and applicability:

Skin Irritation and Adhesion: A number of patches cause skin irritation and sensitization, often brought on by the inclusion of skin-permeating ingredients necessary to overcome the limitations of traditional patch technologies. Some patches also experience adhesion failure resulting from excess moisture or heat while worn by the patient, for example when swimming, bathing or during other normal daily activities.

Safety and Drug Loading: In order to enable effective diffusion of sufficient amounts of drug through the skin, many transdermal delivery systems must incorporate large amounts of drug in the patch. After use, a large residual amount of the drug remains and must be disposed of carefully, especially if the drug is potent or toxic. In some cases, only a small amount of the total drug loaded in a patch is actually delivered into the bloodstream.

Delivery Limitation: The pharmaceutical industry has been unable to formulate certain drugs, especially biologics, for transdermal drug delivery, given the size and complexity of the molecules. These drugs generally are delivered by injection, which causes pain and often requires administration by a medical professional. In addition, these drugs generally must be refrigerated, require biohazard disposal and present the risk of accidental needle sticks. Many small molecules are also difficult to deliver transdermally, especially those that are not soluble in water or are unstable in the presence of air or water.

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One of the greatest opportunities in transdermal drug delivery is the ability to deliver biologics including vaccines, peptides and proteins, without the use of an injection. A number of companies have attempted to develop technologies to address this challenge, but many have experienced commercial and development failures due to the formulation, scale-up and manufacturing complexities. Some of these systems have relied upon large, complex and costly devices, usually with external power sources, which adversely impact their usability and reproducibility.

Our Solution

We are developing and commercializing advanced transdermal drug delivery products that are intended to expand the number and types of drugs that can be delivered transdermally. We believe our technologies can be applied to improve the therapeutic value of many drugs by controlling the levels of drug delivered over a longer period time. They are also designed to eliminate the need for injections of certain drugs and to improve adhesion and skin irritation profiles. Our technologies also allow us to create cost-effective products, especially by eliminating the need for complex devices and refrigeration throughout the supply chain. Our two proprietary platforms, Corplex and MicroCor, separately address some of the primary shortcomings of traditional transdermal drug delivery. We believe our track record within the industry demonstrates our ability to develop commercially successful products.

Corplex Technology

Corplex is a novel technology incorporating combinations of materials that utilize the properties of both traditional pressure-sensitive adhesives, or PSAs, as well as bioadhesives, to enable the transdermal delivery of small molecules. Pressure-sensitive adhesives provide adhesion to dry surfaces, such as skin, and reduced or no adhesion to wet surfaces, while bioadhesives adhere to wet surfaces, including the oral mucosa, with little or no adhesion to dry surfaces. Corplex encompasses combinations and blends of polymers to provide a range of properties that improve adhesion in wet or dry conditions and delivery of active ingredients that may otherwise be difficult to formulate for transdermal delivery. We use our Corplex technology in the Crest Whitestrips line of products and in our clinical stage Corplex Tamsulosin, as well as in other products in development. Additionally, we have one product utilizing Corplex technology for which an Abbreviated New Drug Application, or ANDA, has been filed. An ANDA is a less burdensome application process that allows for an approval by the FDA of a generic drug product by demonstrating bioequivalence to the innovator drug product containing the same active ingredient. Our Corplex transdermal delivery systems provide advanced custom solutions for small molecules and feature the following benefits:

Flexibility: Corplex is adaptable and provides the ability to formulate adhesives to complement a drug's unique properties, enabling new drug dosage forms and delivery options.

Ease-of-Use: Our Corplex systems are designed to improve patient compliance by being easy to use, self-administered and discreet. In addition, Corplex products are suitable for long-term skin contact and are designed to be easily removed with minimal damage to skin and without leaving a residue.

Compatibility: Corplex can incorporate liquid-based components that improve stability and diffusion of the drug without compromising adhesion.

Efficient and Controlled Drug Delivery: Because Corplex enables drugs to diffuse more easily through the skin, we can design Corplex products to require less drug to achieve the desired therapeutic result.

Improved Therapeutic Profile: By achieving a steady dosage level, Corplex systems are designed to minimize side effects that otherwise result from peak concentrations of the drug when delivered with oral or other dosage forms.

We believe the combination of these benefits make Corplex well-suited for the development of a variety of healthcare products that require adhesive properties, including prescription transdermal drug products and personal care, oral care, wound care, medical device and diagnostics products.

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MicroCor Technology

MicroCor is a biodegradable microstructure patch technology that we are developing to enable transdermal delivery of biologics, in a disruptive platform that reduces the need for needles and syringes and enables global distribution of biologics without requiring refrigeration. Because biologics cannot diffuse through the skin due to their size, some mechanism is required to introduce these molecules beyond the outer layer of the skin, or stratum corneum, where they can be absorbed into the body. The further a delivery system penetrates beyond the stratum corneum, the more likely it is to cause pain, bleeding and bruising. By integrating active ingredients directly into arrays of biodegradable microstructures, our MicroCor technology is designed to penetrate only the stratum corneum to release the drug for local or systemic absorption, while eliminating the pain, bleeding and bruising that can be caused by needles and other active delivery devices.

We believe MicroCor will offer the following advantages over other delivery technologies in development for biologics:

Minimal Discomfort: Our MicroCor systems feature an array of microstructures that penetrate the stratum corneum to only a few hundred microns in depth, deep enough for effective delivery without causing pain, bruising or bleeding.

Dose Sparing: MicroCor needles are biodegradable and dissolve in the skin once the system is applied. In our clinical studies to date, we determined that over 90% of the drug contained in a single use of a MicroCor system was delivered into the skin each time the system was administered. We expect our MicroCor systems to reduce drug waste and the costs associated with the excess drug that may be required in less efficient delivery technologies.

Thermally Stable: Our MicroCor systems do not contain moisture, and therefore are designed to be room temperature stable, enabling both stockpiling and worldwide delivery without refrigeration, thereby minimizing drug or product spoilage.

No Biohazard Disposal: Because MicroCor needles completely dissolve in the skin, no sharps remain after use. We believe this feature will allow disposal of the system in a traditional trash receptacle without risk of accidental needle sticks or abuse associated with residual drug left in the delivery system.

Ease-of-Use: MicroCor products are designed to be self-administered, fully-integrated, single-use systems that are worn for only a few minutes. Unlike other delivery systems, MicroCor requires no additional parts, electrical power or complex external enabling devices to effectively deliver the drug or product.

Cost-Effective: In addition to the cost savings associated with dose sparing and thermal stability, MicroCor's fundamental design and our proprietary molding process also minimize costs associated with manufacturing MicroCor systems.

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Our Products and Partners

The following table identifies the products we have developed that are marketed by our partners, products in our advanced pipeline and products currently awaiting FDA approval.

We currently have six marketed products. Clonidine TDS is a treatment for hypertension that we developed as a generic version of the branded drug known as Catapres TTS. Clonidine TDS was launched in 2010 and is marketed by Teva and manufactured by us exclusively for Teva. Fentanyl TDS is a treatment for management of chronic pain, including cancer-related pain, under specified conditions. We developed this product as a generic version of the branded product known as Duragesic. Fentanyl TDS was approved in 2007 and is currently marketed by Par and manufactured by us exclusively for Par. Crest Whitestrips are a series of four products for oral care that we co-developed with P&G. These products utilize our Corplex polymer technology and are sold under the brands Advanced Vivid, Professional Effects, One Hour Express and Flex-Fit. We are the sole supplier of this oral care system for P&G.

There are three products in our advanced pipeline. The Agile AG200-15 product is a combination hormonal contraceptive patch that contains the active ingredients ethinyl estradiol (an estrogen) and levonorgestrel (a progestrin), both of which have an established history of efficacy and safety in currently marketed combination oral contraceptives. AG200-15 is designed to deliver both hormones at levels comparable to low-dose oral contraceptives. By delivering these active ingredients over seven days, this product is designed to promote enhanced compliance by patients with a convenient, easy-to-use format. If approved, the patch will be applied once weekly for three weeks, followed by a week without a patch. Agile designed AG200-15, we performed the process development and manufacturing, and we are currently working with Agile to prepare for an additional Phase 3 clinical trial.

MicroCor hPTH(1-34) is a transdermal system designed to use our MicroCor technology to provide simplified delivery of parathyroid hormone, the active ingredient of Forteo, an injectable product for the treatment of severe osteoporosis. With a simple one-step application process, short wear time and a favorable pharmacokinetic profile, MicroCor hPTH(1-34) represents, if approved, an opportunity to effectively deliver an improved anabolic therapy and increase patient compliance in the osteoporosis market. We believe MicroCor hPTH(1-34) is the only integrated, single step application PTH transdermal product currently in clinical development. We have self-funded this program since inception, and are planning to advance it into Phase 2 clinical trials with proceeds from this offering. We expect to partner with a company active in bone health, women's health or endocrinology to distribute and sell the product, if approved.

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Corplex Tamsulosin is a transdermal patch designed to use our Corplex technology to provide controlled delivery of tamsulosin, the active ingredient in the leading once-daily capsule product for treatment of benign prostatic hyperplasia, or BPH, marketed under the brand name Flomax. By providing a controlled and relatively steady level of drug over an extended time, Corplex Tamsulosin is intended to alleviate the side effects associated with peak blood concentrations of the drug in its current oral formulation and to provide a consistent level of efficacy. Our completed Phase 1 pharmacokinetic study in healthy subjects demonstrated that Corplex Tamsulosin enabled delivery of the drug at blood concentration levels equivalent to the effective levels provided with the oral dosage form, but with an extended and controlled release profile. If successfully commercialized, Corplex Tamsulosin could be the only patch available for tamsulosin. We have self-funded this program since inception, and are planning to advance it into Phase 2 clinical studies with proceeds from this offering in the first half of 2015. We expect to partner this product with a company with marketing experience and capability in the urology field.

Moreover, we have two products currently pending FDA approval. We have developed a three-day generic transdermal product for the prevention of nausea and vomiting associated with motion sickness with Teva, and the ANDA is currently pending with the FDA. We have completed all of the development, scale-up and clinical activities for submission of the ANDA and expect this product to launch in 2014, if approved. In addition, we have developed a three-to-four-day generic transdermal product for treatment of a urologic condition with Teva, and the ANDA is currently pending with the FDA. We have completed all of the required development, scale-up and clinical activities for submission of the ANDA and expect this product to launch in 2015, if approved, pursuant to the terms of a patent settlement agreement between Teva and Actavis.

Our Strategy

We believe our balanced portfolio strategy enables us to capitalize on our proven strengths and technological advantages while diversifying risk and limiting our financial exposure. The key components of our strategy are to:

Expand our existing revenue base by commercializing our advanced pipeline. We intend to work with our existing partners to gain regulatory approval and commercially launch the AG200-15 contraceptive patch with Agile and a motion sickness patch and a urology patch with Teva. We also plan to develop, launch and manufacture new oral care products and certain other new products outside of oral care, through our partnership with P&G.

Advance the development of proprietary products already in development. We plan to advance the development of MicroCor hPTH(1-34) and Corplex Tamsulosin, and selectively work with new partners to advance certain products in our earlier stage pipeline. We intend to focus primarily on products that incorporate FDA-approved drugs, thereby allowing us to take advantage of the 505(b)(2) regulatory pathway.

Enter into co-development and commercialization agreements with new and existing partners for new products. We are actively evaluating potential new product candidates that leverage our proprietary technologies. Additionally, we plan to transition our MicroCor technology feasibility programs with leading pharmaceutical partners into co-development partnerships to develop and commercialize transdermal system-based vaccines and proprietary biologic products.

Expand our MicroCor manufacturing capabilities. We intend to further develop MicroCor manufacturing capabilities to commercial scale, enabling late-stage development, launch and commercial production of multiple new high-margin biologic products.

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Further leverage our core competencies and proprietary technologies. We intend to apply our technologies to create and develop a portfolio of new transdermal products in areas of significant unmet need in particular, chronic, degenerative and progressive conditions affecting the brain and central nervous system, such as Alzheimer's and Parkinson's diseases. We are focusing our self-funded new product efforts on products that we could commercialize with a relatively small specialty sales force.

Risks Related to Our Business

Our ability to implement our business strategy is subject to numerous risks and uncertainties, some of which are inherent in our business of developing, manufacturing and commercializing pharmaceutical products. You should carefully consider all of the information set forth in this prospectus and, in particular, the information under the heading "Risk Factors," prior to making an investment in our common stock. These risks include, among others, the following:

We have limited operating revenues, a history of operational losses and an accumulated deficit of $94.5 million as of December 31, 2013, and we may not achieve or sustain profitability;

We are dependent on the commercial success of our Clonidine TDS, Fentanyl TDS and Crest Whitestrips, and although we are generating revenues from sales of our products, we expect a decline in revenues generated by our Clonidine TDS and Fentanyl TDS products;

We depend on a few partners for a significant amount of our revenues; in fiscal 2013 and the three months ended December 31, 2013, three of our partners accounted for 90% and 94% of our total revenues, respectively;

We have had significant and increasing operating expenses and may require additional funding;

We or our partners may choose not to continue developing or commercialize a product or product candidate at any time during development or after approval, which would reduce or eliminate our potential return on investment for that product or product candidate;

Our near-term product revenue growth heavily relies on the success of the AG200-15 contraceptive patch, which has not yet been approved by the FDA, and for which the FDA has issued a complete response letter identifying certain issues to be addressed before approval can be granted;

We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our drug delivery systems and technologies with sufficient breadth;

We are dependent on numerous third parties in our supply chain for the commercial supply of our products;

Our current and future products will be subject to ongoing and continued regulatory review, which may result in significant expense and limit the commercialization of such products; for example, the FDA has inspected our manufacturing facilities multiple times over the last five years and has issued five Forms 483 that describe deficiencies in our manufacturing and quality systems, and we have made significant investments in addressing these issues;

We may encounter manufacturing failures that could impede or delay commercial production of our products or product candidates, or the preclinical and clinical development or regulatory approval of our product candidates;

We 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; to date we have settled 18 product liability claims, and we currently have one suit pending;

We have been subject to product recalls in the past, including recalls of Fentanyl TDS in 2008 and 2010, and may be subject to additional product recalls in the future;

We face intense competition, in both our delivery systems and products, including from generic drug products;

If we or our partners are unable to achieve and maintain adequate levels of coverage and reimbursement for our products, or any future products we may seek to commercialize, their commercial success may be severely hindered;

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

Our principal stockholder has the ability to control our business, which may be disadvantageous.

Our Corporate Information

We were incorporated in Michigan in 1995 as Corium Corporation and in 1996 as Converting Systems, Inc. In 2002, these companies were merged and re-named Corium International, Inc. and our place of incorporation changed to Delaware. Our principal executive offices are located at 235 Constitution Drive, Menlo Park, CA 94025, and our telephone number is (650) 298-8255. We have research and development operations and corporate offices in Menlo Park, California and pilot-scale and commercial-scale manufacturing facilities in Grand Rapids, Michigan. Our website address is www.coriumgroup.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. We have included our website address in this prospectus solely as an inactive textual reference.

Unless the context indicates otherwise, as used in this prospectus, the terms "Corium," "we," "us" and "our" refer to Corium International, Inc., a Delaware corporation. We registered the trademarks "Corplex" and "MicroCor" in the United States, European Union, Canada, Australia and Japan as well as the Russian Federation and Madrid Protocol. The "Corium" logo and certain product names contained in this prospectus are our common law trademarks. This prospectus also includes references to trade names, trademarks and service marks of other entities, and those trade names, trademarks and service marks are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

Our fiscal year ends on September 30. Throughout this prospectus, references to "fiscal" refer to the years ended September 30.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We refer to the Jumpstart Our Business Startups Act of 2012 in this prospectus as the "JOBS Act" and references to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Conditions and Results of Operations" disclosure;

reduced disclosure about our executive compensation arrangements;

no requirement that we hold non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of some of these reduced burdens, and thus the information we provide stockholders may be different from what you might receive from other public companies in which you hold shares.

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THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after our initial public offering	shares
Option to purchase additional shares of common stock offered by us	shares
Use of proceeds	We expect that our net proceeds from the sale of the common stock that we are offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purpose of this offering is to create a public market for our common stock. We intend to use the net proceeds to us from our initial public offering for Phase 2 clinical trials for MicroCor hPTH(1-34) and Corplex Tamsulosin; scale up of production capability for our MicroCor products; formulation and development of our proprietary Corplex products; advancement of our MicroCor technology; the repurchase of shares of common stock pursuant to the recapitalization described below; and working capital and other general corporate purposes. See "Use of Proceeds."
Risk Factors	See "Risk Factors" beginning on page 13 for a discussion of risks you should consider before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol	"CORI"

The number of shares of common stock to be outstanding after our initial public offering is based on shares of our common stock outstanding as of December 31, 2013. This number assumes (i) the conversion of all outstanding shares of our convertible preferred stock, (ii) the automatic net exercise of certain warrants based on an assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover of this prospectus, and (iii) the recapitalization, as discussed in greater detail below, and excludes:

- 15,454,366 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013, with a weighted-average exercise price of $0.22 per share;
- 4,718,000 shares of common stock issuable upon the exercise of options granted between January 1, 2014 and March 3, 2014, with an exercise price of $0.41 per share;
- 1,543,765 shares of common stock issuable upon the exercise of warrants to purchase convertible preferred stock that were outstanding as of December 31, 2013, with an exercise price of $0.92 per share, that do not expire upon the completion of this offering;
- 82,000 shares of common stock issuable upon the exercise of warrants to purchase common stock that were outstanding as of December 31, 2013, with an exercise price of $0.01 per share, that do not expire upon the completion of this offering;

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shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan that will become effective in connection with this offering;

shares of our common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan that will become effective in connection with this offering; and

542,018 shares of common stock available for future issuance as of March 3, 2014 under our 2012 Equity Incentive Plan, which will be added to the shares reserved for issuance under the 2014 Equity Incentive Plan that will become effective in connection with this offering.

Unless expressly indicated or the context requires otherwise, all information in this prospectus assumes:

a -for- reverse stock split of our outstanding capital stock that was effected on , 2014;

the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 36,034,900 shares of common stock immediately prior to the closing of this offering;

the recapitalization as discussed in greater detail below;

the conversion of warrants to purchase shares of our convertible preferred stock that do not expire at the closing of this offering into warrants to purchase an aggregate of shares of common stock effective immediately prior to the closing of this offering;

the automatic net exercise of warrants to purchase an aggregate of shares of common stock effective immediately prior to the closing of this offering, which is based on an assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover of this prospectus;

no exercise by the underwriters of their right to purchase up to an additional shares of common stock; and

the filing of our restated certificate of incorporation and the effectiveness of our restated bylaws in connection with our initial public offering.

Recapitalization

Prior to the completion of this offering, as of September 30, 2013, we had outstanding certain convertible notes with principal and accrued interest of approximately $18.9 million and a subordinated note with principal and accrued interest of $15.7 million, most of which are held by Essex Woodlands, our largest stockholder. In December 2013, we and Essex Woodlands entered into an agreement that (i) amended the convertible notes to provide that they will automatically convert either into 20,569,231 shares of our common stock immediately prior to the closing of this offering or into 20,569,231 shares of our Series C preferred stock immediately prior to the first closing of a qualified equity financing that occurs prior to the closing of this offering and the convertible notes will be terminated; (ii) amended the subordinated note to provide that it will automatically convert either into 34,210,182 shares of our common stock immediately prior to the closing of this offering or into 34,210,182 a new series of our preferred stock (with identical rights, preferences and privileges as our Series C preferred stock, but with a liquidation preference of one times its original issue price) immediately prior to the first closing of a qualified equity financing that occurs prior to the closing of this offering and the subordinated note will be terminated; and (iii) requires Essex Woodlands to effect the automatic conversion of all outstanding shares of our preferred stock in connection with the completion of this offering.

Simultaneously, we also entered into a repurchase agreement pursuant to which we agreed to repurchase 10,885,884 shares of our common stock for an aggregate repurchase price of $5.2 million from our founders. These repurchases will occur immediately prior to earlier of the consummation of this offering and the first closing of a qualified equity financing.

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SUMMARY FINANCIAL DATA

The following tables summarize our historical financial data. We have derived the summary statement of operations data for fiscal 2012 and 2013 from our audited financial statements and related notes included elsewhere in this prospectus. We derived the summary statements of operations data for the three months ended December 31, 2012 and 2013 and the summary balance sheet data as of December 31, 2013 from our unaudited interim condensed financial statements and related notes included elsewhere in this prospectus. Our unaudited interim condensed financial statements were prepared on the same basis as our audited financial statements and include, in our opinion, all normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The following summary financial data should be read in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Year Ended September 30,		Three Months Ended December 31,	
	2012	2013	2012	2013
	(In thousands, except share and per share data)			
Statement of Operations Data:				
Revenues:				
Product revenues	$ 35,716	$ 38,704	$ 9,972	$ 8,100
Contract research and development revenues	6,838	10,750	2,588	2,064
Other revenues	306	816	64	304
Total revenues	42,860	50,270	12,624	10,468
Costs and operating expenses:				
Cost of product revenues	24,360	24,828	6,233	5,229
Cost of contract research and development revenues	10,244	11,856	3,122	3,537
Research and development expenses	3,966	5,496	1,052	861
General and administrative expenses	4,645	6,525	1,792	1,810
Amortization of intangible assets	512	541	131	130
Gain on disposal and sale and leaseback of equipment	(57)	(177)	(43)	(37)
Total costs and operating expenses	43,670	49,069	12,287	11,530
Income (loss) from operations	(810)	1,201	337	(1,062)
Interest income	4	9	3	2
Interest expense	(5,247)	(7,705)	(1,773)	(2,024)
Change in fair value of preferred stock warrant liability	21	(14)		(43)
Change in fair value of subordinated note embedded derivative liability		(7,367)		1,029
Other income	582			
Loss before income taxes	(5,450)	(13,876)	(1,433)	(2,098)
Income tax benefit (expense)	7	(1)		
Net loss and comprehensive loss	$ (5,443)	$ (13,877)	$ (1,433)	$ (2,098)
Net loss attributable to common stockholders, basic and diluted(1)	$ (5,443)	$ (13,877)	$ (1,433)	$ (2,098)

Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.24)	$ (0.62)	$ (0.06)	$ (0.09)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted(1)	22,227,342	22,452,114	22,341,554	22,521,505
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1):		$		$
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1) :				

(1) See Note 14 to our annual audited financial statements and Note 10 to our unaudited interim condensed financial statements for an explanation of the method used to calculate basic and diluted net loss and pro forma net loss per share attributable to common stockholders and the weighted average number of shares used in the computation of the per share amounts.

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	As of December 31, 2013		
	Actual	Pro Forma(1)	Pro Forma as Adjusted(2)(3)
	(In thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 7,416	$	$
Working capital	5,958		
Total assets	39,484		
Preferred stock warrant liability	603		
Subordinated note embedded derivative liability	6,338		
Deferred contract revenues, current and long-term portions	5,976		
Debt, current and long-term portions	65,903		
Recall liability, current and long-term portions	4,552		
Convertible preferred stock	57,261		
Redeemable common stock	3,224		
Total stockholders' equity (deficit)	(124,620)		

(1) Gives effect to the following items that will occur immediately prior to the closing of this offering: (i) the automatic conversion of all outstanding shares of our convertible preferred stock into common stock, (ii) the related reclassification of the preferred stock warrant liability to additional paid-in capital upon the conversion of the shares of convertible preferred stock underlying the warrants that make up the liability, (iii) the conversion of our outstanding convertible and subordinated notes into 54,779,413 shares of common stock and the related reclassification of the subordinated note embedded derivative liability to additional paid-in capital, (iv) the repurchase of 10,885,884 shares from our founders and the related reclassification of our redeemable common stock to additional paid-in capital and (v) the issuance of shares of common stock upon the automatic net exercise of certain outstanding warrants based on the assumed initial offering price of $ per share, the midpoint of the price range on the cover page this prospectus.

(2) Gives effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale by us of shares of common stock in this offering, at an assumed initial public offering price of $ per share, the midpoint of the price range on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range reflected on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions. Similarly, each increase (decrease) of one million shares in the number of shares offered by us would increase (decrease), cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by approximately $ million, assuming the assumed initial public offering price remains the same and after deducting the underwriting discounts and commissions.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in shares of our common stock. The occurrence of any of the events or developments described in the following risk factors could have a material adverse effect on our business, financial condition, results of operations and prospects. In such an event, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We have limited operating revenues and a history of operational losses and may not achieve or sustain profitability.

We have incurred significant operating and net losses since our inception. For fiscal 2013, we recorded net revenues of $50.3 million and net loss of $13.9 million. For fiscal 2012, we recorded net revenues of $42.9 million and net loss of $5.4 million. In the three months ended December 31, 2013, we recorded net revenues of $10.5 million and net loss of $2.1 million. As of December 31, 2013, we had an accumulated deficit of $94.5 million. We expect to continue to incur net operating losses for at least the next several years as we seek to advance our products through clinical development and regulatory approval, prepare for and, if approved, proceed to further commercialization, and expand our operations. Our ability to generate sufficient revenues from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flow is uncertain, and we may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow. In particular, we expect our operating expenses to continue to increase in the near-term as we expand our operations and transition to operating as a public company, and may not be able to generate sufficient revenues to offset this anticipated increase in expenses.

We are dependent on the commercial success of our Clonidine TDS, Fentanyl TDS and Crest Advance Seal Whitestrips, and although we are generating revenues from sales of our products, we expect a decline in revenues generated by our Clonidine TDS and Fentanyl TDS products.

We anticipate that, in the near term, our ability to become profitable will depend upon the commercial success of the products marketed by our partners. To date, we have generated limited revenues from sales of these products, and in addition, we have incurred liability in association with product recalls of Fentanyl TDS. Our Fentanyl TDS product revenues in fiscal 2013 were $15.6 million. Our Fentanyl TDS marketing partner, Par, has provided us with forecasted demand that indicates we should expect revenues from Fentanyl TDS to decline significantly in fiscal 2014. We are also experiencing increased competition in that market, including a new product that is manufactured by one of two suppliers of the fentanyl active pharmaceutical ingredient, or API. In addition, Fentanyl TDS relies on a reservoir patch design instead of a matrix patch design. Although both reservoir and matrix patches have been subject to safety concerns and recalls in the past, our current competitors, most of whom use a matrix patch, may raise questions about the design and safety of a reservoir patch and the FDA may decide that the current reservoir patch design is a less safe design and may require the use of matrix patch technology instead. This would result in a more substantial decrease in our revenues and harm our operating results. Our product revenues from Clonidine TDS in fiscal 2013 were $13.2 million, significantly higher than historic levels, primarily as a result of Teva's increased market share resulting from a major competitor's diminished ability to supply its product for seven months during the year. We expect our product revenues from Clonidine TDS during fiscal 2014 to be lower than they were during fiscal 2013, and more consistent with the amount of product revenues in fiscal 2012, as this competitor has resumed supply at historic levels.

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In addition to the risks discussed elsewhere in this section, our ability to continue to generate revenues from our commercialized products will depend on a number of factors, including, but not limited to:

- achievement of broad market acceptance and coverage by third-party payors for our products;
- the effectiveness of our partners' efforts in marketing and selling our products;
- our ability to successfully manufacture commercial quantities of our products at acceptable cost levels and in compliance with regulatory requirements;
- our ability to maintain a cost-efficient organization and, to the extent we seek to do so, to partner successfully with additional third parties;
- our ability to expand and maintain intellectual property protection for our products successfully;
- the efficacy and safety of our products; and
- our ability to comply with regulatory requirements, which are subject to change.

Because of the numerous risks and uncertainties associated with our commercialization efforts, including our reliance on our partners for the marketing and distribution of our products, and other factors, we are unable to predict the extent to which we will continue to generate revenues from our products or the timing for when or the extent to which we will become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We depend on a few partners for a significant amount of our revenues, and if we lose any of our significant partners, our business could be harmed.

The majority of our revenues come from only a few partners. For fiscal 2013, three partners, P&G, Teva and Par, individually comprised approximately 23%, 33%, and 33%, respectively, of our total revenues. In the three months ended December 31, 2013, three partners, P&G, Teva and Par, individually comprised approximately 28%, 35%, and 31%, respectively, of our total revenues. We expect that revenues from a limited number of partners will continue to account for a large portion of our revenues in the future. The loss by us of any of these partners or a material reduction in their purchases could harm our business, results of operations, financial condition and prospects. In addition, if any of these partners were to fail to pay us in a timely manner, it could harm our cash flow.

We or our partners may choose not to continue developing or commercialize a product or product candidate at any time during development or after approval, which would reduce or eliminate our potential return on investment for that product or product candidate.

We currently have six products on the market, two of which are drugs approved under Abbreviated New Drug Applications, or ANDAs, and four consumer products. In addition, three drug product candidates that we have developed in partnership with other companies are the subject of pending applications for approval by the FDA and we have four self-funded drug product candidates in early stages of research and development.

At any time, we or our partners may decide to discontinue the development of a marketed product or drug product candidate or not to continue commercializing a marketed product or a drug product candidate for a variety of reasons, including the appearance of new technologies that make our product obsolete, the position of our partner in the market, 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. If one of

our partners terminates a development program or ceases to market an approved or commercial product, we will not receive any future milestone payments or royalties relating to that program or product under our partnership agreement with that party.

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Our near-term product revenue growth heavily relies on the success of the AG200-15 contraceptive patch.

The near-term growth of our product revenues heavily relies on the Agile AG200-15 transdermal contraceptive patch reaching the market in 2016. Our collaboration partner Agile has conducted Phase 3 clinical studies and filed an NDA with the FDA for AG200-15 in April 2012. The FDA issued a "Complete Response Letter" in February 2013, identifying certain issues, including a request for additional clinical data, which must be addressed before approval can be granted. Accordingly, Agile intends to conduct an additional Phase 3 clinical trial, which it expects will not be completed before late 2015. We cannot assure you that Agile will be able to complete an additional clinical trial in a timely manner, or at all, and ultimately obtain regulatory approval for the AG200-15 product, which would limit our near-term growth prospects, and would create uncertainty around the value and usefulness of our AG200-15 manufacturing facility and equipment.

Since 2003, we have devoted substantial resources to the development of the AG200-15 contraceptive patch in collaboration with Agile. The success of the AG200-15 product is a key component of our business growth over the next few years and we have projected we will receive revenues from sales of this product beginning in 2016. The AG200-15 product requires a process step that we have not yet incorporated into commercial production, which involves the laser-etching of label information on each patch. In addition to requiring an additional Phase 3 clinical study, the FDA has requested information relating to this laser-etching process to demonstrate that it does not adversely affect the performance of the patch. If this product is not approved and launched by mid-2016, or at all, we will not realize our anticipated revenue growth for 2016. In addition, one of our three buildings in our manufacturing facility in Grand Rapids, Michigan has been built out for the anticipated commercial production of AG200-15. Although some of the equipment used in that building may be repurposed for other uses with Agile's permission, it would be expensive and time consuming to do so. If AG200-15 is not approved, our business and financial prospects will be significantly harmed.

We are dependent on numerous third parties in our supply chain for the commercial supply of our products, and if we fail to maintain our supply relationships with these third parties, develop new relationships with other third parties or suffer disruptions in supply, we may be unable to continue to commercialize our products or to develop our product candidates.

We rely on a number of third parties for the supply of active ingredients and other raw materials for our products and the clinical supply of our product candidates. Our ability to commercially supply our products and to develop our product candidates depends, in part, on our ability to obtain successfully the APIs used in the products, in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to commercialize our products, or develop any other product candidates or our MicroCor systems.

We also rely on certain third parties as the current sole source of the materials they supply. Although many of these materials are produced in more than one location or are available from another supplier, if any of these materials becomes unavailable to us for any reason, we likely would incur added costs and delays in identifying or qualifying replacement materials and there can be no assurance that replacements would be available to us on acceptable terms, or at all. In certain cases we may be required to get regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely.

If our third-party suppliers fail to deliver the required commercial quantities of sub-components and starting materials, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued commercialization of our products and the development of our product candidates would be impeded, delayed, limited or prevented, which could harm our business, results of operations, financial condition and prospects.

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We face intense competition, in both our delivery systems and products, including from generic drug products, and if our competitors market or develop alternative treatments that are approved more quickly or marketed more effectively than our product candidates or are demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, experience in obtaining regulatory approvals for drug product candidates and other resources than us.

Many pharmaceutical companies are developing transdermal drug delivery systems, including 3M, Johnson & Johnson, Lohmann Therapies Systems, or LTS, Mylan, Hisamitsu, or Noven, and Actavis. In the field of microneedle transdermal systems, other participants include 3M, Zosano, Theraject, Fujifilm and several academic institutions. For more information about the competition we face, see "Business Competition."

We also face competition from third parties in obtaining allotments of fentanyl and other controlled substances under applicable annual quotas of the U.S. Drug Enforcement Administration, or DEA, recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients in clinical trials, and in identifying and acquiring or in-licensing new products and product candidates.

Our competitors may develop products that are more effective, better tolerated, subject to fewer or less severe side effects, more useful, more widely prescribed or accepted, or less costly than ours. For each product we commercialize, sales and marketing efficiency are likely to be significant competitive factors. We do not have internal sales or marketing departments, and there can be no assurance that we can develop or contract out these capabilities in a manner that will be cost-efficient and competitive with the sales and marketing efforts of our competitors, especially since some or all of those competitors could expend greater economic resources than we do and/or employ third-party sales and marketing channels. Such competition can lead to reduced market share for our products and contribute to downward pressure in our pricing, which could harm our business, results of operations, financial condition and prospects.

We 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.

The commercial use of our products and clinical use of our product candidates expose us to the risk of product liability claims. 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, such as the case with Fentanyl TDS and Clonidine TDS, 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 products or our product candidates could result in injury to a patient or even death. We have had 19 past legal proceedings related to Fentanyl TDS. Eighteen of the cases have been settled and dismissed with prejudice, and one case is pending. The complaint for the one pending product liability suit did not state a specified amount of compensatory or exemplary damages. We have insurance coverage up to $10 million dollars with a maximum liability of $50,000 of out-of-pocket expense for this claim. We cannot offer any assurance that we will not face other 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.

Fentanyl TDS is an opioid pain reliever that contains fentanyl, which is a regulated "controlled substance" under the Controlled Substances Act of 1970, or CSA, and could result in harm to patients relating to the potent effects of the opioid drug and its potential for abuse. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury. Product

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liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or 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:

- the inability to commercialize our products or, if approved, our product candidates;
- decreased demand for our products or, if approved, product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $10 million per occurrence and a $10 million annual aggregate coverage limit. 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. If we determine that it is prudent to increase our product liability coverage based on sales of our products, approval of other product candidates, or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of our products and our product candidates. 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, results of operations, financial condition and prospects.

We have been subject to product recalls in the past, and may be subject to additional product recalls in the future that could harm our reputation and could negatively affect our business.

We may be subject to product recalls, withdrawals or seizures if any of the products we formulate, manufacture or sell fail to meet their specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale, or distribution of any of our products. In 2008 and 2010, Actavis voluntarily recalled certain lots of Fentanyl TDS, due to imperfections in our manufacturing processes, including an issue that resulted in some patches that may have released the active ingredient at a faster rate than the rate provided in the product specifications. Any similar recall, withdrawal or seizure in the future, particularly if they involve our own proprietary product candidates, could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our products. In addition, a recall, withdrawal or seizure of any of our products would require significant management attention, would likely result in substantial and unexpected expenditures, and would harm our business, financial condition, and results of operations.

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If we or our partners are unable to achieve and maintain adequate levels of coverage and reimbursement for our products, or any future products we may seek to commercialize, their commercial success may be severely hindered.

For our products that are available only by prescription, successful sales by our partners depend on the availability of adequate coverage and 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. Adequate coverage and 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 our products do not demonstrate superior efficacy profiles, they may not qualify for coverage and reimbursement. 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 products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, 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 products 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 our products or 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, results of operations, financial condition and prospects.

Our partners depend on wholesale pharmaceutical distributors for retail distribution of our products and, if our partners lose any of their significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our partners' sales are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. The loss of any of these wholesale pharmaceutical distributors' accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot assure you that we or our partners can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

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Our results of operations may be adversely affected by demand fluctuations outside our ability to control or influence.

In general, our marketing partners are required to provide us with 12-month rolling forecasts of their demand on a quarterly basis, and are also required to place firm purchase orders with us based on the near-term portion of those forecasts. If wholesaler or market demand for these products is lower than forecasted, our marketing partners or their wholesaler customers may accumulate excess inventory. Additionally, our marketing partners may price our products at levels that result in lost contract sales to their wholesaler customers. If such conditions persist, our marketing partners may sharply reduce subsequent purchase orders for a sustained period of time until such excess inventory is consumed, if ever. Significant and unplanned reductions in our manufacturing orders have occurred in the past and our results of operations were harmed. If such reductions occur again in the future, our revenues will be negatively impacted, we will lose our economies of scale, and our revenues may be insufficient to fully absorb our overhead costs, which could result in larger net losses. Conversely, if our marketing partners promote significantly increased demand, we may not be able to manufacture such unplanned increases in a timely manner, especially following prolonged periods of reduced demand. As we have no control over these factors, including our marketing partners' decisions on pricing, our purchase orders could fluctuate significantly from quarter to quarter, and the results of our operations could fluctuate accordingly.

Our MicroCor technology has not been incorporated into a therapeutic commercial product and is still at a relatively early stage of development.

Our MicroCor technology, utilizing proprietary microneedle arrays, has not been incorporated into a therapeutic commercial product and is still at a relatively early stage of development. We use this technology in several of our therapeutic candidates. Although we have conducted Phase 1 clinical trials for our product candidate MicroCor hPTH(1-34), additional studies are required for this product candidate and there is no guarantee that future clinical trials will prove the technology is effective or does not have harmful side effects. Any failures or setbacks in utilizing our MicroCor technology, including adverse effects resulting from the use of this technology in humans, could have a detrimental impact on our internal product candidate pipeline and our ability to enter into new corporate collaborations regarding this technology, which would harm our business and financial position. As of yet, no microneedle technology has been approved by the FDA for commercial sale.

In addition, our MicroCor 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 MicroCor product candidates. In order to conduct larger or late-stage scale clinical trials for a MicroCor product candidate and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of such 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 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 finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up the manufacture of any of our MicroCor product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting drug products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business.

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If we are not able to establish 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. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, although we have initiated Phase I clinical trials through self-funding, we will need to find a partner or partners for the commercialization of MicroCor hPTH(1-34) if we are to effectively compete in the target primary care market against generic medicines and drug delivery systems.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and experience, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator 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 collaborators. 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 collaborators.

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 revenues.

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

Our recurring losses from operations and negative cash flows from operations 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 financial statements for fiscal 2013 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 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. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

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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 may not be adequate to support our business plan and future growth. As a public company, 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, including the implementation of new enterprise resource management software;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities for our products and product candidates effectively and in a cost-effective manner;
- manage our relationship with our partners related to the commercialization of our products and product candidates;
- manage our clinical trials effectively;
- manage our internal manufacturing operations effectively and in a cost-effective manner while increasing production capabilities for our current product candidates to commercial levels;
- 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. Because we rely on consultants for certain functions of our business, we will need to be able 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 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 commercialize our products, develop 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 and other personnel. We are highly dependent on our management and scientific personnel, including our President and Chief Executive Officer, Peter Staple, our Chief Financial Officer, Robert Breuil, and our Chief Technology Officer and Vice President, Research and Development, Parminder Singh. The loss of the services of any of these individuals could impede, delay or prevent the continuing commercialization of our products and the development of our product candidates 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

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to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. We do not currently have a chief medical officer, and we cannot assure you that, if we require such a position to be filled, we will be able to hire a qualified candidate for this position. 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 may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. 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;
- higher-than-expected 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 key employees 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, results of operations, financial condition and prospects. We have no current plan, commitment or obligation to enter into any transaction described above.

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

Our research and development activities and our manufacturing activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our products and product candidates and other hazardous compounds. We 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 facilities pending use and disposal and we dispose of certain materials directly through incineration. We 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 employees and others, 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 we utilize 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 and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations, or CROs, may engage in fraudulent or other illegal activity. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. 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 and serious harm to our reputation. We have dismissed employees in the past for improper handling and theft of our product components, and although we reported their actions to all relevant authorities, any similar incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. In connection with the consummation of this offering, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. 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 results of operations.

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We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Menlo Park, California, near major earthquake and fire zones. Our manufacturing facilities are in Grand Rapids, Michigan, where other natural disasters or similar events, like blizzards, tornadoes, fires or explosions or large-scale accidents or power outages, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or our Grand Rapids facility, that damaged critical infrastructure, such as enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations at either location, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

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.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. For example, we estimate annual market revenues based on patient prescriptions using an analysis of third-party information and third-party market research data. If this third-party data underestimates or overestimates actual revenues for a given period, adjustments to revenues may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Changes in accounting standards and their interpretations could adversely affect our operating results.

GAAP are subject to interpretation by the Financial Accounting Standards Board, or FASB, the American Institute of Certified Public Accountants, or AICPA, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

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Risks Related to Our Financial Position and Capital Requirements

We have had significant and increasing operating expenses and may require additional funding.

Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for fiscal 2013 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations. We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon and our existing line of credit, 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 financial resources much faster than we currently expect. Further, we may need to raise additional capital following this offering to fund our operations and continue to support our planned research and development and commercialization activities.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the timing and amount of revenues from sales of our approved products and any subsequently approved product candidates that are commercialized;
- the size and cost of our commercial infrastructure;
- the timing of FDA approval of our product candidates, if at all;
- the timing, rate of progress and cost of any future clinical trials and other product development activities for our product candidates that we may develop, in-license or acquire;
- costs associated with marketing, manufacturing and distributing any subsequently approved product candidates;
- costs and timing of completion of any additional outsourced commercial manufacturing supply arrangements that we may establish;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our products and 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 effect of competing technological and market developments;

our ability to acquire or in-license products and product candidates, technologies or businesses;

personnel, facilities and equipment requirements; and

the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be diluted. 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.

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. 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. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

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Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting our obligations.

As of December 31, 2013, the amount of our total indebtedness was approximately $65.9 million, of which we borrowed $36.7 million pursuant to our term loan agreement with Capital Royalty, and the remainder was primarily amounts outstanding under convertible or subordinated notes. As of December 31, 2013, no principal funds remained available to us for borrowing under the Capital Royalty term loan agreement. We are required to make significant payments to Capital Royalty beginning on September 30, 2016, as described in more detail in "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Our outstanding debt and related debt service obligations could have important adverse consequences to us, including:

- heightening our vulnerability to downturns in our business or our industry or the general economy and restricting us from making improvements or acquisitions, or exploring business opportunities;
- requiring a significant portion of our available cash to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our available cash to fund our operations, capital expenditures and future business opportunities;
- limiting our ability to adjust to changing market conditions and placing us at a competitive disadvantage compared to our competitors who have greater capital resources; and
- subjecting us to financial and other restrictive covenants in our debt instruments, the failure with which to comply could result in an event of default under the applicable debt instrument that allows the lender to demand immediate repayment of the related debt.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay product development, sales and marketing, capital and other expenditures, sell assets, seek additional capital or restructure or refinance our indebtedness. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. This risk is increased by the fact that borrowings under our revolving credit facility with Silicon Valley Bank, or our SVB line, bear interest at a variable rates, exposing us to the risk that the amount of cash required to pay interest will increase to the extent that market interest rates increase.

The terms of our bank line of credit and term loan agreement place restrictions on our operating and financial flexibility.

During any such times when credit remains available to us under the SVB line, or we have outstanding borrowings under the term loan agreement with Capital Royalty, we will be required to maintain certain deposits and minimum balances as well as be prohibited from engaging in significant business transactions without the prior consent of Silicon Valley Bank and Capital Royalty, respectively, including a change of control or the acquisition by us of another company, or engaging in new business activities which are substantially different from 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. In addition, in the event of a default under either of these arrangements, our repayment obligations may be accelerated in full. In the event that we do not have sufficient capital to repay the amounts then owed, we may be required to renegotiate such arrangements on terms less favorable to us, pursue strategic alternatives, including sale of our company or our significant assets, or to cease operations. Furthermore, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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

As of September 30, 2013, we had NOLs for federal and state income tax purposes of $63.2 million and $12.0 million, respectively. If not utilized, these NOLs will expire beginning in 2026 and 2017 for federal and state income purposes, respectively. 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 net operating loss carryforwards, or NOLs, 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 NOLs 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 NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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 or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments, and we expect that amounts earned from our collaboration agreements will continue to be an important source of our revenues. Accordingly, our revenues will depend on development funding and the achievement of development and clinical milestones under our existing collaboration arrangements, 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. For example, our product revenues from Clonidine TDS in fiscal 2013 were higher than historic levels, primarily as a result of Teva's increased market share resulting from a major competitor's diminished ability to supply its product for seven months during the year. We expect our product revenues from Clonidine TDS during fiscal 2014 to be significantly lower than they were during fiscal 2013, as this competitor resumed supply at historic levels. 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:

- 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;
- 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;
- future accounting pronouncements or changes in our accounting policies;

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the timing and success or failure of clinical studies 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;

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. 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 results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to risk.

Risks Related to Regulation of our Products and Product Candidates

Our currently marketed products, and any of our product candidates that we or our partners commercialize, will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our or our partners' ability to commercialize such products.

Even after we achieve U.S. regulatory approval for a product, or after we or our partners commercialize an FDA-regulated product that does not require premarket approval (such as our consumer teeth whitening products), we will be subject to continued regulatory review and compliance obligations. For example, with respect to our drug products, 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 drug product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, 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 the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, requirements and with Good Clinical Practice, or GCP, and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product 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 the case of Fentanyl TDS and any of our product candidates containing controlled substances, we will also be subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, including the Quality System Regulation, or QSR, requirements for medical device components of our products or similar requirements, if applicable. 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.

For instance, in connection with the recall of selected lots of fentanyl patches we manufactured for Actavis in 2008, the FDA inspected our manufacturing facilities and issued a Form 483 describing certain

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deficiencies in our manufacturing and quality systems. We submitted a response to the Form 483, and held a regulatory meeting with the FDA District Office in October 2008 to review actions we took relating to such observations, and resumed manufacture of Fentanyl TDS in September 2008 with first commercial shipments beginning December 2008.

The FDA conducted another inspection of our production facility in March 2009 as part of a general assignment by the FDA's Center for Drug Evaluation and Research to inspect the producers of liquid reservoir transdermal patches. Transdermal fentanyl products, including reservoir-format patches, have been the subject of significant regulatory scrutiny. Following this inspection, the FDA issued a Form 483 with nine observations. We submitted a response to these observations and the FDA subsequently closed out the inspection and issued us an Establishment Inspection Report, or EIR.

In response to a fentanyl product recall in October 2010 by our partner Actavis, the FDA inspected our facility and issued a Form 483 with three observations. The FDA again inspected our production facility in November 2011. Following the inspection, the FDA issued a Form 483 with nine observations. We submitted a reply to these observations and the FDA subsequently closed out the inspection and issued us an EIR. The FDA has subsequently inspected our facilities two times, most recently in January and February 2013, when it issued a Form 483 identifying three observations, and that inspection has been closed out with the issuance of an EIR in March 2013.

If we, our products or product candidates or the manufacturing facilities for our products or 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;
- 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 fines or other civil or criminal penalties;
- suspend any ongoing clinical trials;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- 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 to initiate a product recall.

In addition, our or our partners' product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

The FDA's regulations, policies or guidance 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

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United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products, which would adversely affect our ability to generate revenues and achieve or maintain profitability.

Some of our products or product candidates contain controlled substances, the making, use, sale, importation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies.

Fentanyl TDS and certain of our other drug product candidates contain active ingredients which are classified as controlled substances, which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Controlled substances are regulated under the Controlled Substances Act of 1970, or CSA, and the regulations of the Drug Enforcement Administration, or DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Fentanyl TDS is regulated by the DEA as a Schedule II controlled substance.

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. Adverse scheduling could impair the commercial attractiveness of such product. We or our collaborators must also obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For our products or product candidates containing controlled substances, we and our partners, suppliers, contractors and distributors are required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our products containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our pharmaceutical systems containing controlled substances. In particular, among other things, there is a risk that these regulations may interfere with the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceeding. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances.

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In addition to the level of commercial success of our approved products, our future growth is also dependent on our ability to successfully develop a pipeline of product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval or that any approved products will be successfully commercialized.

Our long-term growth will be limited unless we successfully develop a pipeline of additional product candidates. We do not have internal new drug discovery capabilities, and our primary focus is on developing improved transdermal drug delivery systems by reforumulating FDA approved drugs using our proprietary technologies.

Our near-term growth is dependent on bringing the Agile AG200-15 transdermal contraceptive patch to market in 2016. Our collaboration partner Agile has conducted Phase 3 clinical studies and filed an NDA with the FDA for AG200-15 in April 2012. The FDA issued a Complete Response Letter in February 2013 identifying certain issues, including a request for additional clinical data, which must be addressed before approval can be granted. We cannot assure you that Agile will be able to obtain regulatory approval for the AG200-15 product, which would limit our near-term growth prospects, and would create uncertainty around the value and usefulness of our AG200-15 manufacturing facility and equipment.

We have two other partnered product candidates that are the subject of ANDAs submitted by our partners to the FDA, and three product candidates in clinical development. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries. Obtaining approval of an NDA or ANDA is a lengthy, expensive and uncertain process. The FDA also has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may disagree with the design or implementation of clinical trials;
- the FDA may not deem a product candidate safe and effective for its proposed indication, or may deem a product's safety risks to outweigh its clinical or other benefits;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- the FDA may disagree with our or our partners' interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or ANDA;
- the FDA may require additional pre-clinical studies or clinical trials;
- the FDA may not approve of our manufacturing processes and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Any of our product candidates may fail to achieve their specified endpoints in clinical trials. Furthermore, product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with the design of clinical trials and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we or our partners request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we or our partners believe are necessary or desirable for the successful commercialization of our product candidates.

If we are unable to expand our pipeline and obtain regulatory approval for our product candidates on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would harm our long-term business, results of operations, financial condition and prospects.

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We manufacture our products internally and may encounter manufacturing failures that could impede or delay commercial production of our current products or our product candidates, if approved, or the preclinical and clinical development or regulatory approval of our product candidates.

Any failure in our internal manufacturing operations could cause us to be unable to meet the demand for our products and lose potential revenues, delay the preclinical and clinical development or regulatory approval of our product candidates, and harm our reputation. Our internal manufacturing operations may encounter difficulties involving, among other things, production yields, regulatory compliance, quality control and quality assurance, obtaining DEA quotas which allow us to produce in the quantities needed to execute on our business plan, and shortages of qualified personnel. Our ability to commercially supply our products, and regulatory approval of our product candidates, could be impeded, delayed, limited or denied if the FDA does not maintain the approval of our manufacturing processes and facilities. In addition, we have no experience producing our MicroCor system in commercial quantities. We have experienced product recalls in the past and we may encounter difficulties when we attempt to manufacture commercial quantities of our product candidates in the quantities needed for our preclinical studies or clinical trials. Such difficulties could result in commercial supply shortfalls of our products, delay in the commercial launch of any of our product candidates, if approved, delays in our preclinical studies, clinical trials and regulatory submissions, or the recall or withdrawal of our products from the market.

We must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. In addition, we must obtain and maintain necessary DEA and state registrations, and must establish and maintain processes to assure compliance with DEA and state requirements governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances. We must also apply for and receive a quota for fentanyl for our Fentanyl TDS product. Any failure to comply with these requirements may result in penalties, including fines and civil penalties, suspension of production, suspension or delay in product approvals, product seizure or recall, operating restrictions, criminal prosecutions, withdrawal of product approvals or severe reputational harm, any of which could adversely affect our business. 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 commercialization, preclinical studies and clinical trials, regulatory submissions or approvals of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our approved products.

Clinical drug development for our product candidates is expensive, time consuming, uncertain and susceptible to change, delay or termination.

Clinical drug development for our product candidates is very expensive, time-consuming and difficult to design and implement. Our product candidates are in varying stages of development ranging from pre-clinical feasibility studies to registration. We estimate that clinical trials for these product candidates, if and when initiated, will continue for several years and may take significantly longer than expected to complete. In addition, we, our partners, the FDA, an Institutional Review Board, or IRB, or other regulatory authorities, including state and local agencies, may suspend, delay or terminate our clinical trials at any time, for various reasons, including:

- obtaining IRB approval of each site;
- recruiting suitable patients to participate in a trial;
- lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;

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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;

delays in 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;

delays in obtaining regulatory authorization to commence a study, or "clinical holds" or delays requiring suspension or termination of a study by a regulatory agency, such as the FDA, before or after a study is commenced;

changes in applicable regulatory policies and regulations;

delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations, or CROs, and clinical trial sites;

uncertainty regarding proper dosing;

unfavorable results from ongoing clinical trials and preclinical studies;

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 collaboration partners or their employees, or our CROs 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 controlled substances;

scheduling conflicts with participating clinicians and clinical institutions;

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.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We or our partners 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. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. Even after the completion of Phase 3 clinical studies, we may have to address additional issues raised by the FDA in response to the NDA or ANDA filed by us or our partners, such as the issues with the Agile contraceptive patch. In the event that we or our 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, we may not be able to become profitable, our reputation in the industry and in the investment community could be significantly damaged and our stock price could decrease significantly.

We have in the past relied and expect to continue to rely on third parties to conduct and oversee our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required we may not be able to 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. For example, we contracted with Nucleus Network in Australia to conduct the Phase 1 clinical trials for both our MicroCor hPTH(1-34) and the Corplex Tamsulosin products.

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 good clinical practice regulations and state regulations governing the handling, storage, security and

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recordkeeping for controlled substances. These CROs and 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 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 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 requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP 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 trials complies with GCP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations 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 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 have conducted and may in the future conduct clinical trials for our products or product candidates outside the United States and the FDA 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. For example, our CRO conducted the Phase 1 clinical trials for both our MicroCor hPTH (1-34) and the Corplex Tamsulosin products in Australia. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be conducted in accordance with GCP requirements and the FDA must be able to validate the data from the study through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole 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 (3) the data is considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such 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 will accept data from trials conducted outside of the United States. If the FDA does not accept any 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.

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If the FDA does not conclude that certain of our product candidates satisfy the requirements under Section 505(b)(2)of the Federal Food Drug and Cosmetics 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 and our collaboration partners are developing several proprietary product candidates, for which we and our partners intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing 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, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we or our partners would need to generate in order to obtain FDA approval. If the FDA does not allow us or our partners to pursue the Section 505(b)(2) regulatory pathway as anticipated, we or our partners may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we or our partners 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 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we or our partners 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 or our partners' NDAs for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved 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 or our partners 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.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

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The products that we make and develop 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.

Undesirable side effects caused by product candidates could cause us, or partners, or regulatory authorities to interrupt, 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. 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 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 and prospects significantly.

The labeling for our Fentanyl TDS product, which is common to all fentanyl transdermal products, includes warnings of serious adverse events relating to abuse potential, respiratory depression and death, and risks relating to accidental exposure, drug interactions and exposure to heat.

Agile has conducted two Phase 3 clinical studies of the AG200-15 product. The safety population in these studies included patients who received at least one dose of either AG200-15 or a combination oral contraceptive, or COC. In the combined safety population of Agile's Phase 3 trials, there were a total of 22 serious treatment emergent adverse effects, or SAEs, of which 16 were from the AG200-15 group, three (0.2%) of which were considered to be possibly related to the study drug, consisting of drug overdose with Benadryl, uncontrollable nausea and vomiting, and left subclavian deep vein thrombosis. Agile believes that AG200-15 will have a label consistent with all marketed hormonal contraceptive products, which include class labeling that warns of risks of certain serious conditions, including venous and arterial blood clot events, such as heart attacks, thromboembolism and stroke, as well as liver tumors, gallbladder disease, and hypertension. Regulatory authorities may require the inclusion of additional statements in the AG200-15 label, which may include a "black box" warning or contraindication.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our products, other products with the same or related active ingredients or our, or our partners, product candidates, after obtaining U.S. regulatory approval, a number of potentially significant 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 partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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 revenues and profitability and the future revenues and profitability of our partners. 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 will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to certain individuals enrolled in Medicaid managed care organizations, (ii) established annual fees on manufacturers of certain branded prescription drugs and (iii) 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. 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.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, 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 could be subject to healthcare fraud and abuse and patient privacy 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, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

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- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities that provide coding and billing advice to customers;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal physician sunshine requirements under the Affordable Care Act, which requires 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 made by certain manufacturers to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, all of which govern the conduct of certain electronic healthcare transactions and protect the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made 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 physicians and other 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, amends the intent requirement of the Federal Anti-Kickback Statute and 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 provides 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 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 civil and criminal penalties, damages, fines, the exclusion from participation in federal and state healthcare programs, 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.

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Risks Related to Our Intellectual Property

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

Our success with respect to our drug delivery systems 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 approved products, product candidates or drug delivery systems from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Some of the drugs we use in our products have been approved for many years and therefore our ability to obtain any patent protection relating to the drug ingredients in our products may be limited.

Our patent portfolio related to our transdermal drug delivery systems and technologies 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 products or product candidates.

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 provide us with sufficient protection for our products and 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.

Our MicroCor technology is new, although patents relating to microneedle technology were first filed in the 1990s. Although we believe that this technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering our more recent developments in this technology and we are unsure of the patent protection that we will be successful in obtaining, if any.

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

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

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

If we or our licensors fail to prosecute, maintain and enforce patent protection for our drug delivery technologies, products or product candidates, our ability to develop and commercialize our technologies, products or product candidates could be adversely affected and we might not be able to prevent competitors from making, using and selling competing technologies or products. This failure to properly protect the intellectual property rights relating to our technologies, products or product candidates could have a material adverse effect on our business, financial condition and results of operations. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Furthermore, in connection with our license agreement with P&G, we granted to P&G a broad exclusive license for certain fields of use, excluding prescription drug products and foot care and wound care products, to our Corplex technology and related know-how. P&G may sublicense its rights under that license, including to another manufacturer, at any time, and we do not have any assurance that they will continue to use us as their development partner and manufacturer in the future.

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 proprietary information and invention 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 licensees, partners and suppliers. 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.

If we or our partners 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 and the ability of our partners to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our products and product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our drug delivery systems, technologies, products or product candidates infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, drug delivery systems or their methods of use. Thus, because of the large

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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 products, product candidates, technologies or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our products, 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 products, product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed an 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.

A substantial portion of our partners' products and product candidates are generic versions of pre-existing brand name drugs and we may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our partners' products and/or product candidates and/or proprietary technologies infringe their 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 results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. In addition to facing litigation risks directly, we have agreed to indemnify several of our 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 partners that could require us to pay some of the costs of patent litigation brought against those partners 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.

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 or our partners infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- 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, upfront fees and/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.

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Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we or our partners 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, results of operations, financial condition and prospects.

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 other clients or former employers.

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

Risks Relating to this Offering and an Investment in Our Common Stock

Our principal stockholder has the ability to control our business, which may be disadvantageous to other stockholders.

Following the completion of this offering, after giving effect to the recapitalization described under "Related Party Transactions Recapitalization," Essex Woodlands Health Venture Fund VII, L.P., together with certain of its affiliates, which together we refer to as Essex Woodlands, will collectively beneficially own or control approximately % of the voting power of our outstanding common stock, assuming no exercise of the underwriters' option to purchase additional shares. In addition, Ron Eastman, a Managing Director of Essex Woodlands, is a member of our board of directors. As a result of its ability to control a majority of the voting power of our outstanding common stock, Essex Woodlands has the ability to control all matters requiring approval by our stockholders, including the election and removal of directors, amendments to our certificate of incorporation and bylaws, any proposed merger, consolidation or sale of all or substantially all of our assets and other corporate transactions. Essex Woodlands may have interests that are different from those of other stockholders. Moreover, this concentration of share ownership makes it impossible for other stockholders to replace directors and management without the consent of Essex Woodlands. In addition, this significant concentration of share ownership may adversely affect the price at which prospective buyers are willing to pay for our common stock because investors may perceive disadvantages in owning stock in companies with controlling stockholders.

We will be a "controlled company" within the meaning of the NASDAQ rules and, as a result, will qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions in the future, you will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Upon completion of this offering, Essex Woodlands will continue to control a majority of the voting power of our outstanding common stock. As a result, we will be a "controlled company" within the meaning of the NASDAQ corporate governance requirements. Under these rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements:

- that a majority of the board of directors consists of independent directors;

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that we have a nominating and corporate governance committee that is composed entirely of independent directors; and

that we have a compensation committee that is composed entirely of independent directors.

We do not intend to utilize these exemptions. However, we may use these exemptions in the future, and as a result, we could choose not to have a majority of independent directors on our board of directors, or any of our board committees. If that were the case, you would not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ corporate governance requirements.

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

If you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma as adjusted amount of $ per share, because the initial public offering price of $ is substantially higher than the pro forma as adjusted net book value per share of our outstanding common stock as of December 31, 2013. 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 their shares. There will also be substantial dilution from the issuance of additional shares of common stock in the recapitalization that is occurring concurrently with this offering. In addition, you may also experience additional dilution upon future equity issuances, including upon conversion of any outstanding debt, or the exercise of stock options to purchase common stock granted to our employees, consultants and directors under our stock option and equity incentive plans. See the section entitled "Dilution."

We expect that the price of our common stock will fluctuate substantially.

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 the 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 may not develop upon closing of this offering or, if it does develop, it may not be sustainable. The trading prices of the securities of pharmaceutical companies have been highly volatile. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

the success of, and fluctuations in, the commercial sales of Clonidine TDS, Fentanyl TDS and Crest Whitestrips products or any other products approved for commercialization;

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

the execution of our partnering, manufacturing and other aspects of our business plan;

variations in the level of expenses related to our commercialization activities;

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

the results of our or our partners' preclinical studies and clinical trials;

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

price and volume fluctuations in the overall stock market;

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;

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

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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 SEC and announcements relating to litigation or other disputes, strategic transactions, intellectual property or fentanyl or other controlled substances impacting us or our business;
- 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;
- future sales of our common stock by our officers, directors and significant stockholders;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and
- changes in accounting principles.

In addition, the stock markets, and in particular the NASDAQ Global 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. Inferior 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 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 as early as the fiscal year ending September 30, 2015. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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We are in the process of transferring from our previous financial tracking system to an updated enterprise resource planning system. Our previous system had been in place since our founding and the transition will require new training and extensive changes to our system of our internal financial reporting. There is no guarantee that we will be able to transition smoothly and maintain effective internal controls over the reporting process during this transition.

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.

No active market for our common stock exists or may develop, and you may not be able to resell your common stock at or above the initial public offering price.

Prior to this offering, there has been no public market on which our common stock could be traded. The initial public offering price of our common stock for this offering will be determined through negotiations between us and the representatives of the underwriters, and may not be indicative of the market price of our common stock following this offering. If you purchase shares of our common stock, you may not be able to resell those shares at or above the initial public offering price. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the NASDAQ Global Market or otherwise or how liquid that market might become. An active public market for our common stock may not develop or be sustained after the offering. If an active public market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you, or at all.

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, we will have outstanding shares of common stock, based on the number of shares outstanding as of December 31, 2013, that may be sold after the expiration of lock-up agreements at least 180 days after the date of this prospectus pursuant to Rule 144 or Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, 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 "Underwriting No Sales of Similar Securities."

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.

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Anti-takeover provisions in our charter documents and Delaware law might deter acquisition bids for us that you might consider favorable.

Our restated certificate of incorporation and restated bylaws contain provisions that may make the acquisition of our company more difficult without the approval of our board of directors. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- 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 the 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 or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These anti-takeover provisions and other provisions under Delaware law could discourage, delay or prevent a transaction involving a change in control of our company, even if doing so would benefit our stockholders. 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 cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. 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 (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

Our management will have considerable discretion over the use of proceeds from this offering. We intend to use the net proceeds from this offering to fund:

- Phase 2 clinical trials for MicroCor hPTH(1-34) and Corplex Tamsulosin;

scale up of production capability for our MicroCor products;

formulation and development of our proprietary Corplex products;

advancement of our MicroCor technology;

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- the repurchase of shares of common stock pursuant to the recapitalization described in more detail in "Related Party Transactions Recapitalization;" and

- working capital and general corporate purposes.

In addition, a portion of the net proceeds may also be used to acquire or license products, technologies or businesses. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock. 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 result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

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

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. We are also restricted from paying dividends under the SVB line and the term loan agreement with Capital Royalty. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, if you purchase shares in this offering, realization of a gain on your investment will depend entirely on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

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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 results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "would," "could," "should," "intend," "expect," 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 financial condition, 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 are under no duty to update any of these forward-looking statements after the date of this prospectus or to conform these statements to actual results or revised expectations.

INDUSTRY AND MARKET DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our general expectations, 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 solutions. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe the market position, opportunity and market size information included in this prospectus is reliable and the conclusions contained in the third-party information are reasonable. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and elsewhere in this prospectus. 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 our net proceeds from the sale of shares of common stock in this offering will be approximately $ million, or approximately $ million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of $ per share, which is the midpoint of the price range on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions. Similarly, each increase (decrease) of one million shares in the number of shares offered by us at the assumed initial public offering price would increase (decrease) the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions, by $ million.

The principal purpose of this offering is to create a public market for our common stock. We intend to use the net proceeds to us from this offering as follows:

- approximately $ to $ million for Phase 2 clinical trials for MicroCor hPTH(1-34) and Corplex Tamsulosin;
- approximately $ to $ million for scale up of production capability for our MicroCor products;
- approximately $ to $ million for formulation and development of our proprietary Corplex products;
- approximately $ to $ million for advancement of our MicroCor technology;
- approximately $ million for the repurchase of shares of common stock pursuant to the recapitalization described in more detail in "Related Party Transactions Recapitalization;" and
- any remaining balance for working capital and other general corporate purposes.

We may also use a portion of the net proceeds from this offering to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current plan, commitments or obligations to do so.

Pending other uses, we intend to invest the proceeds in interest-bearing, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government, or hold as cash. We cannot predict whether the proceeds invested will yield a favorable return. Our management will have broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any further determination to pay dividends on our capital stock will be at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant. In addition, the SVB line and the term loan agreement with Capital Royalty restricts our ability to pay dividends.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2013:

- on an actual basis;
- on a pro forma basis to give effect to the following items that will occur immediately prior to the closing of this offering: (i) the automatic conversion of all outstanding shares of our convertible preferred stock into common stock, (ii) the related reclassification of the preferred stock warrant liability to additional paid-in capital upon the conversion of the shares of convertible preferred stock underlying the warrants that make up the liability, (iii) the conversion of our outstanding convertible and subordinated notes into 54,779,413 shares of common stock and the related reclassification of the subordinated note embedded derivative liability to additional paid-in capital, (iv) the repurchase of 10,885,884 shares from our founders and the related reclassification of our redeemable common stock to additional paid-in capital, (v) the issuance of shares of common stock upon the automatic net exercise of certain outstanding warrants, based on the assumed initial offering price of $ per share, the midpoint of the price range on the cover page this prospectus, and (vi) the amendment and restatement of our certificate of incorporation in connection with our initial public offering; and
- on a pro forma as adjusted basis to give effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale by us of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The unaudited pro forma and pro forma as adjusted information below is illustrative only, and cash and cash equivalents, total stockholders' equity and total capitalization following the completion of our initial public offering will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing. You should read this table in conjunction with the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock" and our financial statements and related notes included elsewhere in this prospectus.

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	As of December 31, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
	(In thousands, except share and per share data)		
Cash and cash equivalents	$ 7,416	$	$
Debt, current and long-term portions	65,903		
Recall liability, current and long-term portions	4,552		
Preferred stock warrant liability	603		
Subordinated note embedded derivative liability	6,338		
Convertible preferred stock, par value of $0.001 per share; 65,716,300 shares authorized; 36,034,900 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	57,261		
Redeemable common stock, par value $0.001 per share, 3,514,252 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	3,224		
Stockholders' deficit:			
Preferred stock, par value of $0.001 per share; no shares authorized, issued or outstanding, actual; shares authorized, and no shares issued or outstanding, pro forma and pro forma as adjusted			
Common stock, par value of $0.001 per share; 115,000,000 shares authorized and 22,514,144 shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted; shares issued and outstanding, pro forma; shares issued and outstanding, pro forma as adjusted	19		
Additional paid-in capital	(30,118)		
Accumulated deficit	(94,521)		
Total stockholders' equity (deficit)	(124,620)		
Total capitalization	$ 13,261	$	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions. Similarly, each increase (decrease) of one million shares in the number of shares offered by us would increase (decrease) cash or cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately $ million, assuming the assumed initial public offering price remains the same and after deducting the underwriting discounts and commissions. If the underwriters' option to purchase additional shares is exercised in full, the pro forma as adjusted amount of each of cash, cash equivalents and short-term investments, additional paid-in capital, total stockholders' equity and total capitalization would increase by approximately $ million, after deducting estimated underwriting discounts and commissions, and we would have shares of our common stock issued and outstanding, pro forma as adjusted.

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The table above excludes the following shares:

15,454,366 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013, with a weighted-average exercise price of $0.22 per share;

4,718,000 shares of common stock issuable upon the exercise of options granted between January 1, 2014 and March 3, 2014, with an exercise price of $0.41 per share;

1,543,765 shares of common stock issuable upon the exercise of warrants to purchase convertible preferred stock that were outstanding as of December 31, 2013, with a weighted-average exercise price of $0.92 per share, that do not expire upon the completion of this offering;

82,000 shares of common stock issuable upon the exercise of warrants to purchase common stock that were outstanding as of December 31, 2013, with a weighted-average exercise price of $0.01 per share, that do not expire upon the completion of this offering;

shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan that will become effective in connection with this offering;

shares of our common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan that will become effective in connection with this offering; and

542,018 shares of common stock available for future issuance as of March 3, 2014 under our 2012 Equity Incentive Plan, which will be added to the shares reserved for issuance under the 2014 Equity Incentive Plan that will become effective in connection with this offering.

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DILUTION

If you invest in our common stock, your 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.

Our pro forma net tangible book value as of December 31, 2013 was $ million, or $ per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of December 31, 2013, after giving effect to the following items that will occur immediately prior to the closing of this offering: (i) the automatic conversion of all outstanding shares of our convertible preferred stock into common stock, (ii) the related reclassification of the preferred stock warrant liability to additional paid-in capital upon the conversion of the shares of convertible preferred stock underlying the warrants that make up the liability, (iii) the conversion of our outstanding convertible and subordinated notes into 54,779,413 shares of common stock and the related reclassification of the subordinated note embedded derivative liability to additional paid-in capital, (iv) the repurchase of 10,885,884 shares from our founders and the related reclassification of our redeemable common stock to additional paid-in capital, and (v) the issuance of shares of common stock upon the automatic net exercise of certain outstanding warrants, based on the assumed initial offering price of $ per share, the midpoint of the price range on the cover page this prospectus.

After giving effect to our sale in our initial public offering of shares of common stock at an assumed initial public offering price of the common stock of $ per share, the midpoint of the price range on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2013 would have been $ million, or $ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors purchasing shares in our initial public offering.

The following table illustrates this per share dilution.

Assumed initial offering price per share		$
Pro forma net tangible book value per share as of December 31, 2013	$	
Increase in pro forma net tangible book value per share attributable to investors purchasing shares in our initial public offering		
Pro forma as adjusted net tangible book value per share after our initial public offering		
Dilution in pro forma net tangible book value per share to investors in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) our pro forma as adjusted net tangible book value per share after our initial public offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions payable by us. Each increase of one million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share, and decrease the dilution per share to investors in this offering, by $ per share. Each decrease of one million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value per share, and increase the dilution per share to investors in this offering, by $ per share.

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If the underwriters exercise their option to purchase additional shares in full, the pro forma net tangible book value per share after giving effect to our initial public offering would be $ per share, and the dilution in pro forma net tangible book value per share to investors in our initial public offering would be $ per share.

The following table summarizes, on the pro forma as adjusted basis as described above, as of December 31, 2013, the differences between the number of shares of our common stock purchased from us, the total cash consideration paid and the average price per share paid by our existing stockholders and by our new investors purchasing shares in our initial public offering at the assumed initial public offering price of the common stock of $ per share, the midpoint of the price range on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					
Total		%	$	%	

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) total consideration paid by new investors by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions payable by us.

If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding after our initial public offering.

The above table and discussions are based on shares of our common stock outstanding as of December 31, 2013 on the pro forma as adjusted basis described above, and exclude the following shares:

15,454,366 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013, with a weighted-average exercise price of $0.22 per share;

4,718,000 shares of common stock issuable upon the exercise of options granted between January 1, 2014 and March 3, 2014, with an exercise price of $0.41 per share;

1,543,765 shares of common stock issuable upon the exercise of warrants to purchase convertible preferred stock that were outstanding as of December 31, 2013, with a weighted-average exercise price of $0.92 per share, that do not expire upon the completion of this offering;

82,000 shares of common stock issuable upon the exercise of warrants to purchase common stock that were outstanding as of December 31, 2013, with a weighted-average exercise price of $0.01 per share, that do not expire upon the completion of this offering;

shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan that will become effective in connection with this offering;

shares of our common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan that will become effective in connection with this offering; and

542,018 shares of common stock available for future issuance as of March 3, 2014 under our 2012 Equity Incentive Plan, which will be added to the shares reserved for issuance under the 2014 Equity Incentive Plan that will become effective in connection with this offering.

To the extent that any outstanding options or warrants are exercised, new investors will experience further dilution.

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SELECTED FINANCIAL DATA

The following selected statement of operations data for fiscal 2012 and 2013 and the balance sheet data as of September 30, 2012 and 2013 have been derived from our audited financial statements and related notes included elsewhere in this prospectus. We derived the selected statements of operations data for the three months ended December 31, 2012 and 2013 and the selected balance sheet data as of December 31, 2013 from our unaudited interim condensed financial statements and related notes included elsewhere in this prospectus. Our unaudited interim condensed financial statements were prepared on the same basis as our audited financial statements and include, in our opinion, all normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following selected financial data below in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Year Ended September 30,		Three Months Ended December 31,	
	2012	2013	2012	2013
	(In thousands, except share and per share data)			
Statement of Operations Data:				
Revenues:				
Product revenues	$ 35,716	$ 38,704	$ 9,972	$ 8,100
Contract research and development revenues	6,838	10,750	2,588	2,064
Other revenues	306	816	64	304
Total revenues	42,860	50,270	12,624	10,468
Costs and operating expenses:				
Cost of product revenues	24,360	24,828	6,233	5,229
Cost of contract research and development revenues	10,244	11,856	3,122	3,537
Research and development expenses	3,966	5,496	1,052	861
General and administrative expenses	4,645	6,525	1,792	1,810
Amortization of intangible assets	512	541	131	130
Gain on disposal and sale and leaseback of equipment	(57)	(177)	(43)	(37)
Total costs and operating expenses	43,670	49,069	12,287	11,530
Income (loss) from operations	(810)	1,201	337	(1,602)
Interest income	4	9	3	2
Interest expense	(5,247)	(7,705)	(1,773)	(2,064)
Change in fair value of preferred stock warrant liability	21	(14)		(43)
Change in fair value of subordinated note embedded derivative liability		(7,367)		1,029
Other income	582			
Loss before income taxes	(5,450)	(13,876)	(1,433)	(2,098)
Income tax benefit (expense)	7	(1)		
Net loss and comprehensive loss	$ (5,443)	$ (13,877)	$ (1,433)	$ (2,098)
Net loss attributable to common stockholders, basic and diluted(1)	$ (5,443)	$ (13,877)	$ (1,433)	$ (2,098)

Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.24)	$ (0.62)	$ (0.06)	$ (0.09)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted(1)	22,227,342	22,452,114	22,341,554	22,521,505
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)		$		$
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(2) :				

(1) See Note 14 to our annual audited financial statements and Note 10 to our unaudited interim condensed financial statements for an explanation of the method used to calculate basic and diluted net loss and pro forma net loss per share attributable to common stockholders and the weighted average number of shares used in the computation of the per share amounts.

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	As of September 30, 2012	As of September 30, 2013	As of December 31, 2013
	(In thousands)		
Balance Sheet Data:			
Cash and cash equivalents	$ 12,245	$ 13,581	$ 7,416
Working capital	11,102	8,594	5,958
Total assets	37,202	44,022	39,484
Preferred stock warrant liability	546	560	603
Subordinated note embedded derivative liability		7,367	6,338
Deferred contract revenues, current and long-term portions	5,479	5,800	5,976
Debt, current and long-term portions	54,330	63,685	65,903
Recall liability, current and long-term portions	5,000	4,832	4,552
Convertible preferred stock	57,261	57,261	57,261
Redeemable common stock	3,224	3,224	3,224
Total stockholders' deficit	(106,346)	(119,100)	(124,620)

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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 titled "Selected Financial Data" and the financial statements and related notes thereto included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included elsewhere in this prospectus. Our fiscal year ends September 30. Throughout this discussion and analysis, references to "fiscal" refer to the years ended September 30.

Company Overview

We are a commercial stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage our broad experience in transdermal and transmucosal delivery systems. Together with our partners, we have successfully developed six marketed products in the prescription drug and consumer markets, and we are the sole commercial supplier of each of those products for our marketing partners. These marketed products are Clonidine Transdermal Delivery System, or TDS, Fentanyl TDS and four Crest Advanced Seal Whitestrips products. We use our novel transdermal and transmucosal approaches to bring new products to markets with significant opportunities. Our development platforms enable transdermal delivery of large molecules, or biologics, including vaccines, peptides and proteins, as well as small molecules that are otherwise difficult to deliver in a transdermal dosage form. Our pipeline includes three partnered products that are the subject of pending drug marketing applications to the U.S. Food and Drug Administration, or FDA. In addition, we have 12 partner- or self-funded programs at earlier stages.

Since 1999, we have built significant know-how and experience in the development, scale-up and manufacture of complex specialty products and have formed relationships with our partners that include both the development of new product formulations and our manufacture of the resulting products. All of our current products are distributed, promoted and marketed by our partners. Our partners include The Procter & Gamble Company, or P&G, Par Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc. and Agile Therapeutics, Inc., as well as several other multinational pharmaceutical companies. Most of these entities have substantially greater financial and operating resources than we do, including global operations. We have never had, nor do we currently have, our own sales force or marketing capabilities. We do not control the market prices that our marketing partners set for our products and, consequently, we do not control the market shares or rates of adoption for our products.

Our partnership with P&G began in 2005 with the development of Crest Whitestrips, which P&G commercially launched in 2009. P&G currently sells Whitestrips throughout North America. Our total revenues from P&G were $11.8 million in fiscal 2013 and $3.0 million for the three months ended December 31, 2013.

Our partnership with Teva began in 2004, with Teva's predecessor, Barr Laboratories. Together with Barr, we developed Clonidine TDS, which Teva commercially launched in 2010. Teva currently sells Clonidine TDS throughout North America. Our total revenues from Teva were $16.7 million in fiscal 2013 and $3.7 million for the three months ended December 31, 2013.

Our partnership with Par is the result of an FTC-mandated divestiture of the product from Actavis, Inc. in connection with the merger with Watson Pharmaceuticals. We began the development of Fentanyl TDS with Abrika LLLP in May 2002, and Abrika was subsequently acquired by Actavis in 2007. Actavis commercially launched Fentanyl TDS in 2007. Par currently sells Fentanyl TDS throughout the United States. Our total revenues from Par were $16.6 million in fiscal 2013 and $3.2 million for the three months ended December 31, 2013.

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In addition to commercialized products, we have a number of products in late stages of development. The most advanced clinical stage product in our pipeline is AG200-15, which is in Phase 3 development by our partner Agile. AG200-15 is a combined hormonal contraceptive patch designed to deliver two hormones, ethinyl estradiol and levonorgestrel, at levels comparable to low-dose oral contraceptives, through the skin in an easy-to-use format over seven days. Agile has filed a New Drug Application, or NDA, for approval of this product by the FDA, which is required before marketing a new drug in the United States. The FDA has indicated that Agile's NDA was not sufficient for approval as originally submitted. Agile is preparing to conduct an additional Phase 3 clinical trial based on this guidance and intends to supplement the NDA with the results of the additional Phase 3 clinical trial. Based on market research conducted by Agile, AG200-15 has the potential to reach a peak market share of 9% of hormonal contraceptive prescriptions in the United States. Based upon IMS data, Agile estimates that each percentage point of market share of hormonal contraceptive prescriptions in the United States currently represents approximately $108 million of annual gross sales.

We are developing two additional products utilizing our proprietary technologies that we plan to advance into Phase 2 trials in 2014 and 2015. MicroCor hPTH(1-34) utilizes our MicroCor technology to deliver parathyroid hormone, a peptide for treating osteoporosis that is currently available only in a refrigerated injectable form. Corplex Tamsulosin is a patch we are developing to deliver tamsulosin to patients with benign prostatic hyperplasia, or enlarged prostate. It is designed to deliver a controlled dose over several days and to reduce side effects compared to currently marketed products. We are not aware of any FDA-approved transdermal systems for delivering either hPTH(1-34) or tamsulosin.

We have not been profitable since fiscal 2005 and, as of December 31, 2013, had an accumulated deficit of $94.5 million. We incurred net losses of $5.4 million and $13.9 million in the fiscal years 2012 and 2013, respectively, and $2.1 million for the three months ended December 31, 2013. We expect to continue to incur net operating losses for at least the next several years as we advance our products through clinical development, seek regulatory approval, prepare for and, if approved, proceed to further commercialization, expand our operations and facilities, and grow in new and existing markets, territories, and industries. 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. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, or financial condition.

Components of Statements of Operations

Revenues

During fiscal 2012 and 2013 and the three months ended December 31, 2013, we recognized revenues in three categories: product revenues, contract research and development revenues, and other revenues.

Product revenues represented 83% and 77% of our total revenues during fiscal 2012 and 2013, respectively, and 77% of our total revenues during the three months ended December 31, 2013. Product revenues consist of product sales, royalties and profit sharing from products that have been commercialized and are sold by our partners. Clonidine TDS, Fentanyl TDS and Crest Whitestrips make up the significant majority of our product revenues. Our product revenues from Clonidine TDS in fiscal 2013 were higher than historic levels, primarily as a result of Teva's increased market share resulting from a major competitor's diminished ability to supply its product for seven months during the year. We expect our product revenues from Clonidine TDS during fiscal 2014 to be lower than they were during fiscal 2013, and more consistent with the amount of product revenues in fiscal 2012, as this competitor has resumed supply at historic levels. Based on forecasted demand provided to us from our Fentanyl TDS marketing partner, Par, we expect our product revenues from Fentanyl TDS to continue to decline significantly in fiscal 2014.

We also generate contract research and development revenues from agreements for the research, development and commercialization of our products. The terms of the agreements include nonrefundable

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upfront payments, partial or complete reimbursement of research and development costs and milestone payments. Contract research and development revenues are primarily derived from our development activities related to AG200-15, Crest Whitestrips and a product currently in the late stages of development. In fiscal 2013, we received a total of $4.3 million in contract research and development revenues from Agile, $3.5 million from Teva, $2.0 million from P&G and an aggregate of $0.9 million from our other collaboration partners. These amounts represented 40%, 33%, 19% and 8%, respectively, of our total contract research and development revenues for fiscal 2013. For the three months ended December 31, 2013, we received a total of $0.1 million in contract research and development revenues from Agile, $0.8 million from Teva, $0.7 million from P&G and an aggregate of $0.5 million from our other collaboration partners, which amounts represented 6%, 37%, 32% and 25%, respectively, of our total contract research and development revenues for the three months ended December 31, 2013. We believe contract research and development revenues will continue to grow as we further develop existing products and as we continue to add new products with partners.

Other revenues consists primarily of income derived from our arrangements with our partners, whereby a portion of the revenues received under these agreements is treated for accounting purposes as rental income from embedded leases associated with these relationships. Other revenues have not been and are not expected to be a significant portion of our revenues.

Cost of Product Revenues

The primary components of our cost of product revenues are materials, personnel costs, depreciation, facilities costs, other overhead costs, and infrastructure expenses associated with the manufacturing of our products. Our manufacturing overhead costs are significant, and are currently allocated among our products at rates consistent with current unit production volumes. As the number of units we manufacture rises, our overhead costs should rise less rapidly due to efficiencies of scale, resulting in lower cost to produce these higher product volumes. Conversely, if total unit volumes fall, as we expect to be the case in fiscal 2014, the costs of product revenues, measured as a percentage of product revenues, will rise as we lose economies of scale.

Cost of Contract Research and Development Revenues

We incur expenses related to our contract research and development revenues from our partner agreements. These expenses consist primarily of personnel costs, materials and supplies passed through to our partners, and overhead costs. We expense all contract research and development costs, including costs to be subsequently reimbursed under development contracts, in the periods in which they are incurred. Our costs of contract research and development will fluctuate depending on the timing and stage of our various partner arrangements. In certain cases, contract research and development costs exceed contract research and development revenues for those agreements, and will not be profitable. We enter into certain research and development arrangements that we do not expect to be profitable because we expect that the long-term benefits of those arrangements outweigh the short-term costs. Furthermore, we recently, and expect to continue to, enter into other research and development arrangements in which we will be sharing the costs of development with our partner resulting in our costs exceeding our revenues on these projects.

Research and Development Expenses

Research and development expenses include costs incurred to develop our transdermal drug delivery products. These costs consist of personnel costs, materials and supplies, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. We expense all research and development expenses in the periods in which they are incurred. We expect our research and development expenses will increase in absolute dollars in future periods as we continue to invest in research and development activities related to further clinical development of MicroCor hPTH(1-34) for Osteoporosis and Corplex Tamsulosin for BPH and other future development projects.

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General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including stock-based compensation, for employees in our administration, finance, business development, human resources and information technology functions. Other expenses include professional fees for accounting and legal services and costs of consultants and other outside services. We expect that our general and administrative expenses will increase with the growth in our revenues and the continued development of our product pipeline, and will increase significantly as we begin to operate as a public company after the completion of this offering.

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalents balances.

Interest Expense

Interest expense primarily consists of the interest charges associated with our convertible notes, subordinated note, term loan agreement, and capital lease obligations, some of which are paid periodically in cash and others of which accrue without cash payments until maturity. For further discussion see " Liquidity and Capital Resources Description of Certain Indebtedness."

Change in Fair Value of Preferred Stock Warrant Liability

Certain outstanding convertible preferred stock warrants are classified as liabilities on our balance sheets at fair value as we determined them to be derivative instruments because they contain antidilution provisions that protect the holders from certain future equity issuances at prices below the original issue price of the underlying security. We remeasure the convertible preferred stock warrants to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the statements of operations and comprehensive loss. We will continue to adjust the liability for changes in fair value until the earliest of the exercise or expiration of the warrant, conversion of underlying convertible preferred stock into common stock and the removal of the antidilution protection.

Change in Fair Value of Subordinated Note Embedded Derivative Liability

Our outstanding subordinated note contains a provision that provides for the payment of an additional 100% principal payment to the holder upon a sale of our company or substantially all of our assets. This provision is considered an embedded derivative which is remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the statements of operations and comprehensive loss. We will continue to adjust the liability for changes in fair value until the earlier of settlement or termination of this provision or the underlying subordinated note.

Other Income

Other income consists primarily of a gain recognized from the settlement of the costs associated with the product recalls with one of our partnered products. See Note 12 to our annual audited financial statements and Note 9 to our unaudited interim condensed financial statements included elsewhere in this prospectus for more information about this settlement.

Income Tax Benefit (Expense)

Our income tax benefit (expense) has not been historically significant to our business as we have primarily incurred losses from 2006 through fiscal 2013. As of September 30, 2013, we had federal and state net operating loss carryforwards of $63.2 million and $12.0 million, respectively, for which we have provided a full valuation allowance (as it is not more likely than not that we will realize the benefit of such net operating losses). The federal net operating loss carryforwards expire at various dates beginning in 2026 and the state net operating loss carryforwards expire at various dates beginning in 2017.

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Results of Operations

The following table sets forth each of our costs and operating expenses as a percentage of our total revenues:

	Year Ended September 30,		Three Months Ended December 31,	
	2012	2013	2012	2013
Percentage of Revenues				
Total revenues	100%	100%	100%	100%
Costs and operating expenses:				
Cost of product revenues	57	49	49	50
Cost of contract research and development revenues	24	24	25	34
Research and development expenses	9	11	8	8
General and administrative expenses	11	13	14	17
Amortization of intangible assets	1	1	1	1
Gain on disposal and sale and leaseback of equipment	*	*	*	*
Total costs and operating expenses	102%	98%	97%	110%

*

Less than 0.5% of revenues

Comparison of the Three Months Ended December 31, 2012 and 2013

Revenues

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Revenues:				
Product revenues	$ 9,972	$ 8,100	$ (1,872)	(19)%
Contract research and development revenues	2,588	2,064	(524)	(20)
Other revenues	64	304	240	375
Total revenues	$ 12,624	$ 10,468	$ (2,156)	(17)%

Product revenues decreased $1.9 million, or 19%, for the three months ended December 31, 2013 compared to the same period in 2012. The decrease was primarily driven by a decrease of $1.0 million in product revenues from sales of Fentanyl TDS during the three months ended December 31, 2013 as the weakening in demand which began in the latter half of fiscal 2013 continued. The decrease was also impacted by a $0.5 million decrease in Clonidine TDS sales during the three months ended December 31, 2013 resulting from lower production levels for the quarter on this product. We also experienced a $0.3 million decrease in product revenues of Crest Whitestrips, related to reduced product demand during the three months ended December 31, 2013. We expect our product revenues from Fentanyl TDS to continue to decline throughout fiscal 2014, based on information provided by Par. In addition, we expect our product revenues from Clonidine TDS during fiscal 2014 to be lower than they were during fiscal 2013, as a major competitor that had a diminished ability to supply its product for seven months during fiscal 2013 resumed supply.

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Contract research and development revenues decreased $0.5 million, or 20%, for the three months ended December 31, 2013 compared to the same period in 2012. The decrease was primarily driven by a $1.2 million reduction in revenues related to AG200-15, as commercial-scale equipment and facilities neared completion, and was partially offset by a $0.6 million increase related to Crest Whitestrips.

Cost of Product Revenues

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Cost of product revenues	$ 6,233	$ 5,229	$ (1,004)	(16)%

Cost of product revenues decreased $1.0 million, or 16%, for the three months ended December 31, 2013 compared to the same period in 2012, primarily as a result of lower product revenues. While product revenues decreased 19%, cost of product revenues decreased 16%. This difference was primarily due to the smaller decreases for the three months ended December 31, 2013 of product revenues from products with lower production costs, as well as those with a profit-sharing component.

Cost of Contract Research and Development Revenues

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Cost of contract research and development revenues	$ 3,122	$ 3,537	$ 415	13%

Cost of contract research and development revenues increased $0.4 million, or 13%, for the three months ended December 31, 2013 compared to the same period in 2012, primarily as a result of an increase in the number of projects in development, which, in turn, resulted in higher direct and indirect labor costs for the three months ended December 31, 2013 compared to the same period in 2012. While contract research and development revenues decreased 20% for the three months ended December 31, 2013 compared to the same period in 2012, cost of contract research and development revenues increased 13%. Increased cost of contract research and development revenues are primarily a result of increased costs associated with programs that involve partner reimbursement from milestones to be received in subsequent quarters. The differences in contract research and development revenues versus contract research and development costs are a function of the specific project activities undertaken in any given period, especially the proportion of those expenses that are reimbursements for pass-through expenses. In addition, revenue recognition policies may restrict the recognition of certain revenues, while costs continue to be incurred in full. As a result of these revenue timing and expense composition differences, any or all of our contract research and development projects may not be profitable in certain periods, but may be profitable in others.

Research and Development Expenses

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Research and development expenses	$ 1,052	$ 861	$ (191)	(18)%

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Research and development expenses decreased $0.2 million, or 18%, for the three months ended December 31, 2013 compared to the same period in 2012, primarily as a result of decreased research and development spending on Corplex Tamsulosin project and MicroCor technology.

General and Administrative Expenses

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
General and administrative expenses	$ 1,792	$ 1,810	$ 18	1%

General and administrative expenses remained relatively constant during the three months ended December 31, 2013 compared to the same period in 2012.

Interest Expense

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Interest expense	$(1,773)	$(2,064)	$(291)	16%

Interest expense increased $0.3 million, or 16%, for the three months ended December 31, 2013 compared to the same period in 2012, primarily due to increased borrowing under our term loan agreement with Capital Royalty. We drew down an additional $6.0 million under this agreement in December 2012.

Change in Fair Value of Subordinated Note Embedded Derivative Liability

	Three Months Ended December 31,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Change in fair value of subordinated note embedded derivative liability	$	$(1,029)	$(1,029)	nm

We recorded a change in fair value of subordinated note embedded derivative liability of $7.4 million in fiscal 2013 due to the increased probability of a qualifying transaction that would trigger payment of an additional amount equal to the outstanding principal under the subordinated note.

We determined that the fair value of the subordinated note embedded derivative feature had decreased by $1.0 million during the three months ended December 31, 2013, primarily due to the increased likelihood of an initial public offering which would thereby decrease the likelihood of a qualifying transaction that would trigger payment of the additional amount which results in reducing the value of the embedded derivative feature. Accordingly, we recorded a net decrease in fair value of subordinated note embedded derivative liability of $1.0 million for the three months ended December 31, 2013.

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Comparison of Fiscal 2012 and 2013

Revenues

	Year Ended September 30,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Revenues:				
Product revenues	$ 35,716	$ 38,704	$ 2,988	8%
Contract research and development revenues	6,838	10,750	3,912	57
Other revenues	306	816	510	167
Total revenues	$ 42,860	$ 50,270	$ 7,410	17%

Product revenues increased $3.0 million, or 8%, in fiscal 2013 compared to fiscal 2012 primarily as a result of a $2.8 million increase in product revenues of Crest Whitestrips as P&G continues to expand the customer base for this product and a $2.7 million increase in product revenues of Clonidine TDS, primarily as a result of Teva's increased market share resulting from a major competitor's diminished ability to supply its product for seven months during the year. These increases were partially offset by a $1.3 million decrease in product revenues from sales to one of our partners on a consumer product, with whom we terminated our relationship during fiscal 2013, and a $1.3 million decrease in product revenues from sales of Fentanyl TDS during fiscal 2013, primarily in the fourth quarter, as we began experiencing a weakening in demand.

Contract research and development revenues increased $3.9 million, or 57%, in fiscal 2013 compared to fiscal 2012, generally as a result of the increased number of products in development and increased pass-through costs of third-party vendors, such as materials and supplies. More specifically, the increase was primarily the result of a $2.5 million increase in these revenues related to our motion sickness patch, $1.3 million increase in these revenues related to AG200-15 and a $1.1 million increase in these revenues related to Crest Whitestrips and beauty products. These increases were partially offset by a $0.5 million decrease in contract research and development revenues from a partnered development program which was temporarily placed on hold during fiscal 2013. Our partner restarted the development of this product in the fourth quarter of fiscal 2013.

Cost of Product Revenues

	Year Ended September 30,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Cost of product revenues	$ 24,360	$ 24,828	$ 468	2%

Cost of product revenues increased $0.5 million, or 2%, in fiscal 2013 compared to fiscal 2012 primarily as a result of a $0.2 million increase in direct and indirect overhead costs and a $0.2 million increase in materials costs associated with the increase in product revenues. While product revenues increased 8% from fiscal 2012 to fiscal 2013, cost of product revenues increased only 2%. This difference was primarily due to the increase in fiscal 2013 of product revenues from products with lower production costs, as well as those with a profit-sharing component, thereby resulting in a lower comparative increase in costs for the

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same period. In addition, as our unit volumes increased in fiscal 2013, we were able to better leverage our fixed production costs.

Cost of Contract Research and Development Revenues

	Year Ended September 30,		2012 to 2013	
			$	%
	2012	2013	Change	Change
	(Dollars in thousands)			
Cost of contract research and development revenues	$ 10,244	$ 11,856	$ 1,612	16%

Cost of contract research and development revenues increased $1.6 million, or 16%, in fiscal 2013 compared to fiscal 2012 primarily due to a $1.7 million increase in materials, supplies and ancillary equipment costs that we incurred and passed through, generally at our cost, to our partners as revenues in fiscal 2013 related to certain agreements. While contract research and development revenues increased 57% from fiscal 2012 to fiscal 2013, cost of contract research and development revenues increased only 16%.

In fiscal 2012, our various MicroCor contract feasibility projects resulted in a decrease in contract research and development revenues of $0.7 million in fiscal 2013 compared to fiscal 2012 and a decrease of $1.6 million in the costs of these projects in fiscal 2013 compared to fiscal 2012. In addition, our contract research and development revenues increased $2.5 million and $1.1 million for the Teva motion sickness TDS and the P&G Whitestrips projects in fiscal 2013 compared to fiscal 2012, respectively, while the costs of these projects increased $1.9 million and $0.7 million, respectively, in fiscal 2013 compared to fiscal 2012.

Research and Development Expenses

	Year Ended September 30,		2012 to 2013	
			$	%
	2012	2013	Change	Change
	(Dollars in thousands)			
Research and development expenses	$ 3,966	$ 5,496	$ 1,530	39%

Research and development expenses increased $1.5 million, or 39%, in fiscal 2013 compared to fiscal 2012 primarily due to continued expanded research and development activities related to our MicroCor technology, which were $2.4 million and $5.3 million in fiscal 2012 and fiscal 2013, respectively. This increase was primarily due to a $1.1 million increase in personnel costs and a $0.8 million increase in overhead costs. These increases were partially offset by a $0.4 million decrease in out-of-pocket costs associated with specific projects.

General and Administrative Expenses

	Year Ended September 30,		2012 to 2013	
			$	%
	2012	2013	Change	Change
	(Dollars in thousands)			
General and administrative expenses	$ 4,645	$ 6,525	$ 1,880	40%

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General and administrative expenses increased $1.9 million, or 40%, in fiscal 2013 compared to fiscal 2012 primarily due to a $1.9 million increase in salaries, benefits and bonuses as we began implementing an employee bonus plan and hiring additional personnel in preparation for being a public reporting company, along with a $0.5 million increase in directors' fees, travel costs, and outside consulting and other services costs. These increases were offset by a decrease of $0.5 million in product liability costs associated with Fentanyl TDS.

Interest Expense

	Year Ended September 30,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Interest expense	$ (5,247)	$ (7,705)	$ (2,458)	47%

Interest expense increased $2.5 million, or 47%, in fiscal 2013 compared to fiscal 2012 primarily due to increased borrowing under our term loan agreement with Capital Royalty. We drew down $29.0 million and $6.0 million under this agreement in August 2012 and December 2012, respectively.

Change in Fair Value of Subordinated Note Embedded Derivative Liability

	Year Ended September 30,		2012 to 2013	
	2012	2013	$ Change	% Change
	(Dollars in thousands)			
Change in fair value of subordinated note embedded derivative liability	$	$ (7,367)	$ (7,367)	nm

We recorded a change in fair value of subordinated note embedded derivative liability of $7.4 million in fiscal 2013 due to the increased probability of a qualifying transaction that would trigger payment of an additional amount equal to the outstanding principal under the subordinated note.

Liquidity and Capital Resources

Since fiscal 2006, we have incurred losses from operations. Only recently have we had positive cash flows from our operations. For fiscal 2013, we incurred a net loss of $13.9 million and used $1.0 million of cash from operating activities. For the three months ended December 31, 2013, we incurred a net loss of $2.1 million and used $2.7 million of cash from operating activities. As of December 31, 2013, we had working capital of $6.0 million and an accumulated deficit of $94.5 million. Our principal sources of liquidity as of December 31, 2013 were cash and cash equivalents totaling $7.4 million. We hold our cash and cash equivalents in a variety of interest-earning instruments, including investments backed by U.S. government agencies, corporate debt securities and money market accounts. Since our inception, we have financed our operations primarily with the net proceeds of $27.9 million from the sale of our convertible preferred stock, excluding the $3.6 million of cash received from our acquisition of StrataGent Life Sciences in 2007 and $105.8 million from borrowings under various debt arrangements, including lines of credit.

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Plan of Operations and Future Funding Requirements

Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended September 30, 2013 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional financing to fund our operations. We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon and our existing line of credit, 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 financial resources much faster than we currently expect. Further, we may need to raise additional capital following this offering to fund our operations and continue to support our planned research and development and commercialization activities. The sale of additional equity securities would result in additional dilution to our stockholders and those securities may have rights senior to those of our common stock. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot assure you that financing will be available in the amounts we need or 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 commercialization efforts, 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. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

Description of Certain Indebtedness

Our line of credit with our commercial bank, Silicon Valley Bank, or our SVB line, matures on August 31, 2014. The SVB line provides for borrowings up to $6.0 million and is collateralized by a first security interest in cash, accounts receivable, and inventory, as well as a secondary interest in all of our assets. Advances under the line of credit are based on 80% of our eligible accounts receivable. The SVB line bears interest at the bank's prime rate (an effective rate of 4.25% as of September 30, 2013 and December 31, 2013) and provides for a minimum monthly interest charge of $5,000. The SVB line contains a minimum monthly liquidity covenant of $2.0 million of net cash on deposit with Silicon Valley Bank, with which we were in compliance as of September 30, 2013 and December 31, 2013.

Our $35 million term loan agreement with Capital Royalty requires interest to be paid quarterly at a simple annual rate of 15%, and all outstanding principal be repaid in four equal quarterly payments beginning September 30, 2016 and ending on June 30, 2017. Pursuant to the agreement, we plan to continue deferring cash payment of 3.5% on the outstanding principal from the first 11 quarterly interest payments by converting that portion of the interest otherwise due into additional notes. As of December 31, 2013, the principal amount outstanding under the term loan agreement was $36.7 million. The amounts outstanding under the term loan agreement are collateralized by all of our assets and the agreement provides for a prepayment penalty if we choose to repay principal prior to maturity, or upon other specified events, including a change of control. The agreement provides for financial covenants for quarterly minimum revenues, beginning September 30, 2014 and minimum liquidity of $2.0 million, with which we were in compliance as of September 30, 2013 and December 31, 2013. We refer to the term loan agreement with Capital Royalty and the SVB line collectively as our senior debt.

In June and November 2008, we entered into certain note and warrant purchase agreements pursuant to which we issued to certain investors, including Essex Woodlands, one of our principal stockholders, secured convertible promissory notes with an aggregate principal amount of $20.0 million, $10.0 million of which we repaid in August 2012. The amounts outstanding under the convertible notes are collateralized by a

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security interest in all of our assets, subordinated to the interests of our senior debt. In September 2012, we amended and restated these notes and delivered to the noteholders new amended and restated secured convertible promissory notes with aggregate remaining principal amounts of $10.0 million, which matures on July 1, 2017. We refer to these as our convertible notes. Interest accrues on these convertible notes at a rate of 10% per annum, and pursuant to an intercreditor agreement, we are not permitted to pay interest on these notes until maturity.

In May 2009, we entered into a note purchase agreement pursuant to which we issued to Essex Woodlands a subordinated secured promissory note with an aggregate principal amount of $13.0 million. The amount outstanding under the subordinated note is collateralized by a security interest in all of our assets, subordinated to the interests of our senior debt. In September 2012, we amended and restated this note and delivered to Essex Woodlands a new amended and restated subordinated secured promissory note with the same aggregate principal amount, which matures on July 1, 2017. We refer to this as our subordinated note. Interest accrues at a rate of 5% per annum, and pursuant to an intercreditor agreement, we are not permitted to pay interest on this note until maturity. This subordinated note provides for an additional payment equal to 100% of the principal amount of the note to the holder upon a sale of our company or substantially all of our assets.

The aggregate principal amounts and accrued interest of $19.1 million and $15.9 million under the convertible notes and the subordinated note, as of December 31, 2013, will be converted into shares of our capital stock in connection with the recapitalization described in "Related Party Transactions Recapitalization."

We also have several other credit facilities under which we have borrowed funds, including capital leases for equipment purchases, notes payable with lessors for tenant improvements made to leased facilities, and notes payable used to fund the annual insurance premium for our product liability policies. See Note 6 to our annual audited financial statements and Note 4 to our unaudited interim condensed financial statements included elsewhere in this prospectus for further details.

In connection with certain of our partner arrangements, our partners purchase equipment that we use in the production of their products. This reduces our need for financing and lowers the cost of manufacturing these products for these partners, but also limits our ability to use this equipment for other partners' products.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended September 30,		Three Months Ended December 31,	
	2012	2013	2012	2013
	(In thousands)		(In thousands)	
Cash provided (used) by operating activities	$ 40	$ (982)	$ (2,768)	$ (2,679)
Cash used in investing activities	(2,360)	(7,939)	(3,486)	(1,641)
Cash provided (used) by financing activities	13,992	10,257	6,035	(1,845)

Cash Flows from Operating Activities

Cash used by operating activities for the three months ended December 31, 2013 was $2.7 million and was primarily driven by cash provided by changes in our working capital accounts and our net loss adjusted for non-cash items. The net loss of $2.1 million reflects non-cash charges of $1.0 million related to the change in fair value of the subordinated debt embedded derivative, $0.4 million of property and equipment depreciation, $0.1 million in amortization of intangible assets and $0.1 million in amortization of the debt

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discount and issuance costs. The $0.3 million decrease in net operating assets was primarily due to a $1.4 million increase in accounts receivable and unbilled accounts receivable, a $0.7 million increase in prepaid and other current assets, and a $0.3 million decrease in recall liability. These cash outflows were offset by a $1.3 million increase in accrued expenses and other current liabilities, $0.4 million in decreased inventories, and $0.4 million in non-cash interest associated with our convertible and subordinated notes.

Cash used by operating activities for the three months ended December 31, 2012 was $2.8 million and was primarily driven by cash provided by adjustments in our working capital accounts and our net loss adjusted for non-cash items. The net loss of $1.4 million reflects non-cash charges of $0.5 million of property and equipment depreciation, $0.1 million in amortization of intangible assets, $0.1 million in amortization of the debt discount and issuance costs, and $0.2 million of stock-based compensation. The $2.2 million increase in net operating assets was primarily due to a $2.4 million increase in accounts receivable, a $0.3 million increase in inventories, $0.5 million in decreased accounts payable, and $0.1 million decrease in accrued expenses and other current liabilities. These cash outflows were partially offset by a $0.7 million increase in deferred contract revenue, and $0.4 million in non-cash interest associated with our convertible and subordinated notes.

Cash used by operating activities for fiscal 2013 was $1.0 million and was primarily driven by cash provided by adjustments in our working capital accounts and our net loss adjusted for non-cash items. The net loss of $13.9 million reflects non-cash charges of $7.4 million related to the change in fair value of the subordinated debt embedded derivative, $1.9 million of property and equipment depreciation, $0.5 million in amortization of intangible assets, $0.5 million in amortization of the debt discount and issuance costs, and $0.3 million of stock-based compensation. The $2.3 million increase in net operating assets was primarily due to a $1.7 million increase in non-cash interest associated with our convertible and subordinated notes. These increases were partially offset by a $0.9 million decrease in accounts payable.

Cash provided by operating activities for fiscal 2012 was $40,000 and was primarily driven by cash provided by adjustments in our working capital accounts and our net loss of $5.4 million adjusted for certain non-cash items. The net loss includes non-cash charges of $2.0 million for property and equipment depreciation, $0.5 million in amortization of intangible assets, $1.0 million in amortization of the debt discount and issuance costs, and $3.0 million in non-cash consideration associated with the settlement of our liability to Actavis related to a product recall. The $5.6 million increase in net operating assets was primarily due to a $0.9 million decrease in accounts receivable, a $3.2 million increase in accrued interest payable and a $3.5 million increase in deferred contract revenues, resulting from payments received from partners under development agreements, including $2.8 million from Agile in connection with the buildout of the commercial manufacturing facility, partially offset by a $1.3 million decrease in accounts payable.

Cash Flows from Investing Activities

Cash used in investing activities for the three months ended December 31, 2013 was $1.6 million, consisting primarily of capital expenditures of $1.5 million for equipment and leasehold improvements to support operations and expenditures of $0.1 million relating to acquisition of patents and licensing rights.

Cash used in investing activities for the three months ended December 31, 2012 was $3.5 million, consisting primarily of capital expenditures of $3.4 million for equipment and leasehold improvements to support operations and expenditures of $0.1 million relating to acquisition of patents and licensing rights.

Cash used in investing activities for fiscal 2013 was $7.9 million, consisting primarily of capital expenditures of $7.2 million for equipment and leasehold improvements to support operations and expenditures of $0.7 million relating to acquisition of patents and licensing rights.

Cash used in investing activities for fiscal 2012 was $2.4 million, consisting primarily of capital expenditures of $1.9 million for equipment to support operations and expenditures of $0.5 million relating to acquisition of patents and licensing rights.

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For fiscal 2014, we expect to invest approximately $6.4 million in capital equipment and leasehold improvements.

Cash Flows from Financing Activities

Cash used in financing activities for the three months ended December 31, 2013 was $1.8 million, consisting of repayments of $1.9 million under our SVB line and $0.5 million of repayments of principal of our long-term debt and capital lease obligations. These decreases were partially offset by $0.5 million of drawdowns under our SVB line.

Cash provided by financing activities for the three months ended December 31, 2012 was $6.0 million, consisting of $6.0 million in proceeds from borrowings under our term loan agreement, a $0.6 million tenant improvement loan and a $1.0 million increase from drawdowns under our SVB line. These increases were partially offset by our repayments of $1.1 million under our SVB line and $0.4 million of repayments of principal of our long-term debt and capital lease obligations.

Cash provided by financing activities for fiscal 2013 was $10.3 million, consisting of $7.2 million in proceeds from borrowings, including $6.0 million drawn under our term loan agreement, a $2.3 million increase from proceeds under capital leases and $5.8 million of drawdowns under our SVB line. These increases were partially offset by our repayment of $3.5 million under our SVB line, $1.4 million on principal of our long-term debt and capital lease obligations

Cash provided by financing activities for fiscal 2012 was $14.0 million consisting primarily of $36.5 million in net proceeds from long-term debt financings, including $29.0 million drawn under our term loan agreement, and $24.7 million of drawdowns from our then existing line of credit. These increases were partially offset by our repayment of $26.3 million under our then existing line of credit, $10.0 million of principal on convertible notes and $9.3 million of principal on our long-term debt and capital lease obligations as well as payment of $1.7 million for transaction costs related to our long-term debt. We used a portion of the proceeds from our term loan agreement to repay $10.0 million of our convertible notes and $5.7 million of other long-term debt.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of September 30, 2013:

	Payments Due by Period				
Contractual Obligations:	**Less Than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More Than 5 Years**	**Total**
	(In thousands)				
Total debt obligations	$ 4,330	$ 9,219	$ 49,762	$ 374	$ 63,685
Interest on total debt obligations	7,229	15,028	6,561	64	28,882
Operating lease obligations	974	1,366	1,210	4,276	7,826
Capital lease obligations	1,029	1,580	72		2,681
Total contractual obligations	$ 13,562	$ 27,193	$ 57,605	$ 4,714	$ 103,074

The table above excludes a recall liability of $4.8 million as of September 30, 2013 relating to a settlement reached with Actavis for Fentanyl TDS. See Note 12 to our annual audited financial statements included elsewhere in this prospectus.

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In addition, the table above also excludes any potential payments resulting from the provision in our subordinated debt that provides for the payment of an additional 100% principal payment to the holders upon a sale of our company or a sale of substantially all of our assets and any increase in fair value of the note associated with the modification of the note related to the recapitalization. The table also above excludes payments in kind on the term loan agreement and interest on the subordinated and convertible notes. See Note 6 to our annual audited financial statements included elsewhere in this prospectus.

As of September 30, 2013, we had outstanding commitments to acquire $0.4 million of capital equipment.

Off-Balance Sheet Arrangements

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

Segment Information

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

Quantitative and Qualitative Disclosures about Market Risk

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

Interest Rate Risk

We had cash and cash equivalents and short-term investments of $7.4 million as of December 31, 2013. Our cash and cash equivalents are held in a variety of interest-earning instruments, including investments backed by U.S. government agencies, corporate debt securities and money market accounts. Such interest-earning instruments carry a degree of interest rate risk. To date, fluctuations in interest income have not been significant. We also had total outstanding debt of $65.9 million as of December 31, 2013, of which $2.7 million is due within 12 months. Amounts outstanding under our SVB line carry a variable interest rate. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

The primary objective of our investment activities is to preserve principal while maximizing income without significantly increasing risk. 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. Due to the short-term nature of our investments, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

Critical Accounting Polices and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, costs and expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable. 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. Actual results could differ significantly from our estimates. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving our judgments and estimates.

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Revenue Recognition

We generate revenues from agreements for the development and commercialization of our products. The terms of these agreements may include nonrefundable upfront payments, partial or complete reimbursement of research and development costs, milestone payments, product sales, profit sharing, and royalties. Where applicable multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. This determination is generally based on whether any deliverable has stand-alone value to the customer. This analysis also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific nor third-party evidence is available.

We recognize revenues when the following criteria are met: persuasive evidence of a sales arrangement exists; delivery has occurred; the price is fixed or determinable; and collectability is reasonably assured. During fiscal 2012 and 2013 and for the three months ended December 31, 2012 and 2013, we recognized revenues from the sale of products, related royalties and profit sharing on our partners' sales of our products as well as, from contract research and development activities, and from other revenues.

Product revenues make up a majority of our total revenues during fiscal 2012 and 2013, comprising 83% and 77% of total revenues, respectively. During the three months ended December 31, 2012 and 2013, product revenues comprised 79% and 77% of total revenues, respectively. Product revenues consist of product sales, royalties and profit sharing we receive from our marketing partners.

We generally recognize revenues from product sales as products are shipped and title and risk of loss passes to the marketing partner. We have royalty and profit sharing agreements pursuant to which we earn revenues based on the amount of product sold, on the amount of profits earned by our marketing partners' sales of such products. We generally recognize royalty and profit sharing revenues at the time our marketing partners report product sales to us.

Typically, we have not granted licenses to partners at the beginning of our development arrangements and, thus, there are no delivered items separate from the research and development services provided. As such, upfront payments are recorded as deferred revenues in the balance sheet and are recognized as contract research and development revenues over the estimated period of performance that is consistent with the terms of the research and development obligations contained in the respective agreements.

We generally recognize revenues related to research and development funding received as the related services or activities are performed in accordance with the contract terms. To the extent that agreements specify services are to be performed on a cost-plus basis, revenues are recognized as services are rendered. Such work is generally billed on a monthly basis for time incurred at specified rates in the agreements. To the extent that agreements specify services to be performed on a fixed-price basis, revenues are recognized consistent with the pattern of the work performed. Generally, all of our agreements provide for reimbursement to us of our third-party expenses, and we bill for such reimbursable expenses as revenues as they are incurred.

We use the milestone method for recognizing revenues in agreements with contingent payments. Under the milestone method, a payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved.

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Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, such as property and equipment subject to depreciation and amortization, when events or changes in circumstances indicate that their carrying amount may not be recoverable. Among the factors and circumstances we considered in determining recoverability are: (i) a significant adverse change in the extent to which, or manner in which, a long-lived asset is being used or in its physical condition; (ii) a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset, including an adverse action or assessment by a regulator; (iii) an accumulation of costs significantly in excess of the amount originally expected; and (iv) current-period operating or cash flow loss combined with a history of operating or cash flow losses, or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. We did not record any impairment losses during fiscal 2012 and 2013 or during the three months ended December 31, 2013.

Convertible Preferred Stock Warrants

We account for certain warrants to purchase shares of our convertible preferred stock as liabilities at fair value as we have determined that some of these warrants are derivative instruments because they contain antidilution provisions that protect the holders from certain equity issuances at a price below the original issue price of the underlying security. We remeasure these warrants to fair value at each balance sheet date, and recognize any change in the fair value as a change in the warrant liability in our statements of operations and comprehensive loss. We estimated the fair value of these warrants at the respective balance sheet dates using the Option Pricing Model, or OPM, in fiscal 2012, and the Probability-Weighted Expected Return Model, or PWERM, in fiscal 2013 and as of December 31, 2013. We use a number of assumptions to estimate the fair value including the likelihood of various scenarios, the expected volatility and the fair value of the underlying stock under each scenario.

These assumptions are inherently subjective, and the fair value of these warrants may have differed significantly had we used different assumptions. We will continue to adjust this warrant liability for changes in fair value until the earliest of an exercise or expiration of the warrants, the conversion of underlying convertible preferred stock into common stock, and the removal of the antidilution protection.

Subordinated Note Embedded Derivative Liability

During fiscal 2009, we issued a subordinated note in the aggregate principal amount of $13.0 million. This subordinated note contains a provision that provides for the payment of an additional payment equal to 100% of the principal amount of the note to the holder upon a sale of our company or substantially all of our assets. This provision was determined to be an embedded derivative requiring bifurcation and separate accounting. The embedded derivative liability is remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the statements of operations and comprehensive loss. We will continue to adjust the liability for changes in fair value until the earlier of settlement or termination of this provision or repayment of the underlying subordinated note.

The fair value of the embedded derivative was measured with the PWERM valuation methodology. Under this methodology, fair value is primarily driven by the assessment of the probability and timing of scenarios that could result in the anticipated sale of our company or its significant assets prior to the note's maturity, which would trigger the payment of the additional amount equal to the outstanding principal of the subordinated note. At each balance sheet date from the date of issuance through September 30, 2012, the likelihood of a sale of our company or our significant assets that would trigger such a payment prior to the note's maturity was evaluated to be extremely low. As a result, the fair value of the embedded derivative was immaterial and we did not record a value through fiscal 2012. In fiscal 2013, several factors resulted in significantly increased uncertainty regarding our business, including a significant delay in the planned 2013 launch of the AG200-15 contraceptive patch product. Primarily due to the resulting delay and uncertainty

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of the timing of the launch of this product, we determined that we would experience a significant reduction in our projected cash flows as well as a reduction in the probability that we would have adequate cash flow to finance the planned expansion of our operations and repay or refinance the debt without additional financing. Accordingly, the probability of transactions that would trigger the embedded derivative increased greatly in fiscal 2013. This increased probability caused the estimated fair value of the embedded derivative to increase to $7.4 million. This change in the estimated fair value of $7.4 million was, therefore, recorded to change in fair value of subordinated note embedded derivative in fiscal 2013.

We determined that the fair value of the subordinated note embedded derivative feature had decreased by $1.0 million during the three months ended December 31, 2013, primarily due to the increased likelihood of an initial public offering which would thereby decrease the likelihood of a qualifying transaction that would trigger payment of the additional amount that results in reducing the value of the embedded derivative feature. Accordingly, we recorded a net decrease in fair value of subordinated note embedded derivative liability of $1.0 million for the three months ended December 31, 2013.

As part of the recapitalization described in Note 4 to the unaudited interim condensed financial statements for the three months ended December 31, 2013, in December 2013 the subordinated note was modified to provide that in the event of a qualifying initial public offering or equity financing, the note will automatically convert into 34.2 million shares of common stock or the equivalent amount of preferred stock. As this represents a substantial modification of the debt, it is accounted for as an extinguishment. Accordingly, the book value of the debt prior to the conversion was removed from the financial statements and the fair value of the debt after the modification, including the value of the conversion feature, of $16.5 million was recorded. As the holder of the subordinated debt controls the majority of our equity and can appoint the majority of our board of directors, the modification of the debt is considered a transaction with owners. Accordingly, the difference between the book value of the debt prior to the modification and the fair value of the debt after modification was recorded as a $3.5 million reduction in additional paid in capital.

The fair value of the subordinated note was measured with the PWERM valuation methodology. Under this methodology, the fair value of the note is driven by the cash flows calculated under various scenarios using the estimated probability and timing of each scenario, as determined by our board of directors. The scenarios and the estimated probability and timing used in calculating the fair value of the notes were as follows: (i) 25% to a scenario assuming our liquidation, or a liquidation scenario, (ii) 35% to a scenario assuming an initial public offering, or an IPO scenario, and (iii) 40% to a scenario assuming a sale of our company, or an M&A scenario.

Stock-Based Compensation

Stock-based compensation expense is measured based on the grant-date fair value of the stock-based awards. We estimated the fair value of each employee stock option on the date of grant using the Black-Scholes option-pricing model. We recognize compensation costs for all employee stock-based compensation awards that are expected to vest over the requisite service period of the awards, which is generally the awards' vesting period. These amounts are reduced by an estimated forfeiture rate.

The Black-Scholes option-pricing model requires the use of assumptions, some of which are highly subjective and complex. The assumptions include:

Expected term. The expected term represents the period that our stock-based awards are expected to be outstanding before exercise or cancellation. Through December 31, 2013, our historical share option exercise experience did not provide a reasonable basis upon which to estimate an expected term because of a lack of sufficient data points, and we estimated the expected term by using the simplified method;

Risk-free interest rate. The risk-free interest rate is based on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent term;

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Expected volatility. The expected volatility is derived from the historical stock volatilities of several comparable publicly-traded peers over a period approximately equal to the expected term of the awards because we have limited information on the volatility of our common stock since we have no trading history. When making the selections of the comparable publicly-traded peers to be used in the volatility calculation, we considered the size, operational and economic similarities to our principal business operations; and

Expected dividend yield. The expected dividend yield is based on our current expectations about our anticipated dividend policy, which is that we will not pay dividends for the foreseeable future.

We did not grant any stock options in fiscal 2012. The fair value of each employee stock option granted during fiscal 2013 was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

Expected term (in years)	2.50 - 6.08
Risk-free interest rate	0.70% - 1.38%
Expected volatility	71% - 75%
Expected dividend rate	0%

We recorded stock-based compensation expense of $0.1 million, $0.3 million and $56,000 for fiscal 2012, 2013 and the three months ended December 31, 2013, respectively. We expect to continue to grant stock options and other equity-based awards in the future and, to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase. We did not grant any stock options during the three months ended December 31, 2013.

Significant factors, assumptions and methodologies used in determining the estimated fair value of our common stock

We are also required to estimate the fair value of the common stock underlying our stock-based awards when performing the fair value calculations using the Black-Scholes option-pricing model. Our board of directors, with the assistance of management, determined the fair value of our common stock on each grant 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*. The fair value of our common stock on the date of grant is determined by taking into account several factors, including the following:

contemporaneous valuations performed by unrelated third-party specialists;

indebtedness;

rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;

actual operating and financial performance;

present value of future cash flows;

likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company;

given prevailing market conditions and the nature and history of our business;

illiquidity of stock-based awards involving securities in a private company;

experience of our management team;

market multiples of comparable companies in our industry;

stage of development;

industry information such as market size and growth; and

macroeconomic conditions.

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In determining a fair value for our common stock, we generally considered two valuation approaches to determine the enterprise value of our business: the income approach and the market approach.

The income approach estimates the fair enterprise value of a company based on the present value of the company's future estimated cash flows and the residual value of the company beyond the forecast period. These future cash flows, including the cash flows beyond the forecast period for the residual value, are discounted to their present values using an appropriate discount rate, to reflect the risks inherent in the company achieving these estimated cash flows. The discount rate used in our third-party valuations was based primarily on benchmark venture capital studies of discount rates for other companies in similar stages of development. The income approach was a significant component of all of the valuations noted in this discussion.

The market approach estimates the fair enterprise value of a company by calculating and applying market multiples of comparable publicly traded companies in the biotechnology and pharmaceutical industries or similar lines of business. The market multiples are based on key metrics implied by the enterprise values of our comparable publicly-traded peers and, for our valuations we primarily utilized the last twelve months and projected twelve months revenue multiples from our comparable publicly-traded peers in the market approach. These observed multiples were averaged and then applied to our historical twelve months and projected revenues to arrive at an enterprise value. We deemed multiples of revenues to be the most relevant in our industry as neither we nor many of our peer companies have reached normalized profitability or generated positive historical profit thus making the application of profit based multiples less reliable.

Certain items as of the valuation date, such as the current balance of cash and cash equivalents, net present value of net operating loss carryforwards, or NOLs, and estimated capital expenditures, were added to or deducted from the enterprise value in order to determine the equity value under each of the valuation approaches. The equity values determined by these valuation approaches were then weighted to determine the aggregate equity value of our business.

The resulting equity values were then allocated to the common stock using either OPM or PWERM.

The OPM treats common stock and convertible preferred stock as call options on a business, with exercise prices based on the liquidation preference of the convertible preferred stock. Therefore, the common stock has value only if the funds available for distribution to the common stockholders exceeds the value of the total liquidation preference of the preferred stock at the time of a liquidity event such as a merger, sale or initial public offering, assuming the business has funds available to make a liquidation preference meaningful and collectible by the preferred stockholders. The common stock is modeled to be a call option with a claim on the business at an exercise price equal to the remaining value immediately after the convertible preferred stock is liquidated. The OPM uses the Black-Scholes option-pricing model to value the call option. The OPM is appropriate to use when the range of possible future outcomes is so difficult to predict that lattice or scenario modeling would be highly speculative.

The PWERM involves a forward-looking analysis of the possible future outcomes of a company. This method is particularly useful when discrete future outcomes can be predicted at a high confidence level with a probability distribution. We began using the PWERM as a component of the December 31, 2013 valuation as a result of the increasing likelihood of the occurrence of certain discrete events, including the possibility of an initial public offering and improving market conditions.

September 30, 2012 valuation

We obtained an independent third-party valuation as of September 30, 2012 to assist our board of directors in determining the fair value of our common stock on subsequent grant dates. The September 30, 2012 valuation was prepared on a minority, non-marketable interest basis. The aggregate enterprise value was determined using a combination of the market approach and income approach. In applying the guideline public company method of the market approach, we analyzed the financial performance of our comparable publicly-traded peers. We utilized multiples of the trailing twelve months revenues and research and

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development expenses of our comparable publicly-traded peers as the valuation metric for this approach, and applied such metrics to our forecasted revenues and research and development expenses. Thereafter, the current balance of cash and cash equivalents and net present value of NOLs as of the valuation date were added to the enterprise value, and our debt was then subtracted, in order to determine our equity value under the guideline public company method of the market approach.

Under the income approach, forecasts were prepared for fiscal 2013 through fiscal 2020. The residual value was derived by applying a peer group multiple to the estimated earnings before interest, taxes, depreciation and amortization, or EBITDA, for the fiscal 2020 forecast. The estimated debt-free cash flow forecasts and residual value were then discounted to a present value. Thereafter, the current balance of cash and cash equivalents and net present value of NOLs as of the valuation date were added to the enterprise value, and our debt was then subtracted in order to determine our equity value under the income approach.

The equity values determined under the market and income approaches were each weighted by 50% as our board believed that it was important to balance the inherent strengths and weaknesses of each approach. The aggregate equity value was then allocated to the common stock utilizing an OPM with the following assumptions: a time to a liquidity event of 2.0 years, a risk-free rate of 0.25%, dividend yield of 0%, and volatility of 70% over the time to a liquidity event, which was calculated based on the volatility of the common stock of our comparable publicly-traded peers. We then applied a marketability discount of approximately 38% to the results from the OPM to determine the fair value of the common stock to be $0.22 per share as of September 30, 2012.

December 31, 2013 valuation

We obtained an independent third-party valuation as of December 31, 2013 to assist our board of directors in determining the fair value of our common stock on subsequent grant dates. The December 31, 2013 valuation was prepared on a minority, non-marketable interest basis for three different scenarios an IPO scenario, an M&A scenario, and a liquidation scenario.

The enterprise value for the M&A scenario was determined assuming a sale in 2.25 years and was estimated using a combination of the market approach and the income approach. In applying the guideline public company method of the market approach, we analyzed the financial performance of our comparable publicly listed peers. We utilized multiples of the trailing 12 months revenue and research and development expenses of our comparable publicly listed peers as the valuation metric for this approach and applied such metrics to our own forecasted revenues and research and development expenses. Thereafter, the current balance of cash and cash equivalents and net present value of NOLs as of the valuation date were added to the enterprise value in order to determine our equity value under the guideline public company method of the market approach.

Under the income approach, forecasts were prepared for fiscal 2014 through fiscal 2018. The residual value was derived from an estimated EBITDA multiple derived from the fiscal 2018 forecast. The estimated debt-free cash flow forecasts and residual value were then discounted to a present value. Thereafter, the current balance of cash and cash equivalents and net present value of NOLs as of the valuation date were added to the enterprise value in order to determine our equity value under the income approach.

The equity values determined under the market and income approaches were each weighted by 50% as the board believed at the time that it was important to consider the inherent strengths and weaknesses of each approach for the M&A scenario fair value. The aggregate equity value was then allocated to the common stock utilizing an OPM with the following assumptions: a time to a liquidity event of 2.25 years, a risk-free rate of 0.48%, dividend yield of 0%, and volatility of 70% over the time to a liquidity event, which was calculated based on the volatility of the common stock of our comparable publicly listed peers.

The enterprise value for the liquidation scenario was based on a 25% discount from the enterprise value determined for the M&A scenario assuming a sale in nine months. The enterprise value for the IPO scenario

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is based on expected future equity value assuming the completion of an initial public offering in nine months based on current market conditions and outlook and equity values recognized in similar initial public offerings.

We then utilized the PWERM approach to determine the fair value of our common stock. The per share fair values from the three scenarios were weighted based on our board of directors' estimate of the probability of the potential future outcomes as follows: 25% to the liquidation scenario, 35% to the IPO scenario, and 40% to the M&A scenario. We then applied a marketability discount of approximately 23% to the results from the weighting to determine the fair value of the common stock to be $0.41 per share on a minority, non-marketable basis.

Option grants

The following table summarizes stock awards granted to our employees since October 1, 2012:

Grant date	Number of common shares underlying options granted	Exercise price per common share	Estimated fair value per share of common stock
November 12, 2012	1,342,938	$ 0.22	$ 0.22
December 13, 2012	4,477,968	0.22	0.22
February 20, 2013	1,962,879	0.22	0.22
February 28, 2013	1,734,322	0.22	0.22
April 4, 2013	514,500	0.22	0.22
January 26, 2014	400,000	0.41	0.41
January 27, 2014	4,318,000	0.41	0.41

The estimated fair value per share of the common stock in the table above represents the determination by our board of directors of the estimated fair value of our common stock as of the date of each grant. In establishing this exercise price, at each of these grant dates our board of directors considered input from management, the most recent independent valuation of our common stock, as well as other factors, including:

changes in management, including the addition of a new Vice President of Business Development, in the second quarter of fiscal 2013;

Agile's receipt of a Complete Response Letter from the FDA in February 2013 indicating that its Phase 3 studies would not be sufficient for approval of AG200-15, in the time frame previously anticipated;

the impact of significant ongoing expenses associated with research and development associated with our products under development;

anticipated declines in product revenues from the Clonidine TDS and Fentanyl TDS products in light of various market conditions;

the continued lack of liquidity of our common stock as a private company;

the absence of any capital raising transactions during this period;

the amount and terms of our outstanding indebtedness;

the rights, preferences and privileges of our preferred stock as compared to those of our common stock, including the liquidation preferences of our preferred stock; and

our progress towards an initial public offering, including discussions with investment bankers and an organizational meeting in October 2013. The impact of the progress towards an initial public offering was also noted in the change in valuation methodologies from OPM to PWERM. The change from OPM to PWERM is considered to be significant as such a change will generally increase valuations

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because higher prices tend to be allocated to IPO scenarios than to liquidation scenarios and other scenarios. This is primarily because non-IPO scenarios allocate a large portion of the equity value to the convertible preferred stock to incorporate higher aggregate liquidation preferences. In the IPO scenario, however, the equity value is allocated pro rata among the shares of common stock and each series of convertible preferred stock, which causes the common stock to have a higher relative value per share than it would under a non-IPO scenario.

As a result of the foregoing analyses, our board of directors determined the fair value of our common stock to be at $0.22 per share at each of the grant dates from November 2012 through April 2013 and $0.41 per share at each of the grant dates in January 2014.

We granted options to purchase 1,342,938 shares of our common stock on November 12, 2012. These options were granted pursuant to an option exchange program which allowed for the exchange of all outstanding stock options to acquire common stock granted under our 2002 Stock Option Plan with an exercise price of $0.50 or more per share held by current employees and service providers for new stock options to be granted under our 2012 Equity Incentive Plan at an exercise price per share of $0.22 and a term of five years. Because the cancelled options were all fully vested as of the option exchange date, we recognized an incremental charge in the amount of $0.1 million in fiscal 2013 as a result of the modification.

Income Taxes

We are subject to income taxes in the United States and in the states of California and Michigan, and we use estimates in determining our provision for income taxes. We determine our provision for income taxes under the liability method. Deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and income tax basis of assets and liabilities using statutory rates. This process requires us to project our current tax liability and estimate our deferred tax assets and liabilities, including net operating losses and tax credit carryforwards. In assessing the need for a valuation allowance, we considered our recent operating results, future taxable income projections and feasible tax planning strategies. We have provided a full valuation allowance against our net deferred tax assets at September 30, 2012 and 2013 and at December 31, 2013.

We account for uncertain tax positions recognized in the financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We did not have any recorded liabilities for uncertain tax positions as of September 30, 2012 or 2013 or December 31, 2013.

Newly Adopted Accounting Pronouncements

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

In May 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards, or IFRS. This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level III fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The adoption of this standard on October 1, 2012 did not have an impact on our financial statements.

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In June 2011, the FASB issued ASU No. 2011-05, Presentation of Comprehensive Income, which requires an entity to present total comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements and eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The adoption of this guidance did not have an impact on our financial statements as our net loss and comprehensive loss was the same for all periods presented.

In April 2011, the FASB issued new accounting guidance relating to the accounting for repurchase agreements and other agreements that both entitle and obligate a transferor to repurchase or redeem financial assets before their maturity. The guidance addresses effective control in repurchase agreements and eliminates the requirement for entities to consider whether the transferor (i.e., seller) has the ability to repurchase the financial assets in a repurchase agreement. This new accounting guidance was effective, on a prospective basis, for new transactions or modifications to existing transactions on October 1, 2012. The adoption of this new guidance did not have an impact on our financial statements.

In February 2013, the FASB issued guidance which addresses the presentation of amounts reclassified from accumulated other comprehensive income. This guidance does not change current financial reporting requirements, instead an entity is required to cross-reference to other required disclosures that provide additional detail about amounts reclassified out of accumulated other comprehensive income. In addition, the guidance requires an entity to present significant amounts reclassified out of accumulated other comprehensive income by line item of net income if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. Adoption of this standard is required for periods beginning after December 15, 2012. This new guidance impacts how we report comprehensive income only, and will have no effect on our results of operations, financial position or liquidity upon its required adoption on October 1, 2013.

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BUSINESS

Overview

We are a commercial stage biopharmaceutical company focused on the development, manufacture and commercialization of specialty pharmaceutical products that leverage our broad experience in transdermal and transmucosal delivery systems. Together with our partners, we have successfully developed six marketed products in the prescription drug and consumer markets, and we are the sole commercial supplier of each of those products for our marketing partners. These marketed products are Clonidine Transdermal Delivery System, or TDS, Fentanyl TDS and four Crest Advanced Seal Whitestrips products. We use our novel transdermal and transmucosal approaches to bring new products to markets with significant opportunities. Our development platforms enable transdermal delivery of large molecules, or biologics, including vaccines, peptides and proteins, as well as small molecules that are otherwise difficult to deliver in a transdermal dosage form. Our pipeline includes three partnered products that are the subject of pending drug marketing applications to the U.S. Food and Drug Administration, or FDA. In addition, we have 12 partner- or self-funded programs at earlier stages.

Since 1999, we have built significant know-how and experience in the development, scale-up and manufacture of complex specialty products and have formed relationships with our partners that include both the development of new product formulations and our manufacture of the resulting products. Our partners include The Procter & Gamble Company, or P&G, Par Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc. and Agile Therapeutics, Inc., as well as several other multinational pharmaceutical companies. We have the capability to develop and manufacture our own product candidates and are one of only a few independent companies that develops and manufactures transdermal products for other parties. We believe our proprietary manufacturing processes, know-how and custom equipment give us a distinct competitive advantage over other pharmaceutical, consumer products and manufacturing companies.

Transdermal drug delivery is the transport of drugs through the skin for absorption into the body. We have developed two proprietary technology platforms, Corplex and MicroCor, that we believe offer significant competitive advantages over existing transdermal approaches. Corplex and MicroCor are designed to be adapted broadly for use in multiple drug categories and indications. We use our Corplex technology to create advanced transdermal and transmucosal systems for small molecules that utilize less of the active ingredient while achieving the same or better therapeutic effect, that can adhere well to either wet or dry surfaces, and that can hold additional ingredients required to aid the diffusion of low-solubility molecules through the skin without losing adhesion. Our MicroCor technology is a biodegradable microstructure system currently in development that enables the painless and convenient delivery of biologics that otherwise must be delivered via injection. Biodegradable microstructures integrate drug molecules and a biocompatible polymer. With slight external pressure, the microstructures penetrate the outer layers of the skin and dissolve to release the drug for local or systemic absorption. MicroCor is designed to expand the market for transdermal delivery of biologics, which cannot currently be delivered by other FDA-approved transdermal technologies.

In addition to commercialized products, we have a number of products in late stages of development. The most advanced clinical stage product in our pipeline is AG200-15, which is in Phase 3 development by our partner Agile. AG200-15 is a combination hormonal contraceptive patch designed to deliver two hormones, ethinyl estradiol and levonorgestrel, at levels comparable to low-dose oral contraceptives, through the skin in an easy-to-use format over seven days. Agile has filed a New Drug Application, or NDA, for approval of this product by the FDA, which is required before marketing a new drug in the United States. The FDA has indicated that Agile's NDA was not sufficient for approval as originally submitted. Agile is preparing to conduct an additional Phase 3 clinical trial based on this guidance, and intends to supplement its NDA with the results of the additional Phase 3 clinical trial. Based on market research conducted by Agile, AG200-15 has the potential to reach a peak market share of 9% of hormonal contraceptive prescriptions in the United States. Based upon IMS data, Agile estimates that each percentage point of market share of

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hormonal contraceptive prescriptions in the United States currently represents approximately $108 million of annual gross sales.

Additional therapeutic programs utilizing our proprietary technologies are progressing through our pipeline at earlier stages. We have advanced the following Phase 2-ready, self-funded programs through Phase 1 pharmacokinetic clinical studies:

- A MicroCor transdermal system designed to deliver parathyroid hormone, or hPTH(1-34), a peptide for treating osteoporosis that is currently available only in a refrigerated injectable form; and

- A Corplex transdermal patch designed to deliver tamsulosin for treating patients with benign prostate hyperplasia, or BPH, with a controlled dose over several days to reduce side effects compared to currently marketed products.

We are not aware of any FDA-approved transdermal systems for delivering either hPTH(1-34) or tamsulosin.

The following table identifies the products we have developed that are marketed by our partners, products in our advanced pipeline and products currently awaiting FDA approval.

Transdermal Drug Delivery Industry

Patients have benefited from the use of transdermal delivery systems since the first commercially approved transdermal product, ALZA Corporation's Transderm Scop for the prevention of motion sickness was approved in 1979. To date, we are aware of approximately 20 drugs that have been successfully formulated and approved by the FDA for delivery in transdermal patches, though the market is growing. According to Datamonitor, the global value of the market for systemic transdermal products, including patches, was approximately $20 billion in 2010 and is expected to grow to approximately $30 billion by 2015. We believe this growth is driven by the increasing availability of transdermal systems for important therapeutic applications and changing disease demographics.

Transdermal delivery and transmucosal delivery, or delivery through mucous membranes, offer patients more convenient, non-invasive and comfortable methods of drug delivery. The benefits of transdermal and transmucosal delivery systems over other dosage forms generally include enhancing the efficacy and reducing the side effects of a drug by controlling the rate of delivery and absorption, avoiding the undesirable breakdown of drugs in the liver associated with gastrointestinal absorption, and improving the level of patient compliance and long-term adherence to therapy.

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Despite the benefits of current transdermal delivery products, many key challenges prevent broader use and applicability:

Skin Irritation and Adhesion: A number of patches cause skin irritation and sensitization, often brought on by the inclusion of skin-permeating ingredients necessary to overcome the limitations of traditional patch technologies. Some patches also experience adhesion failure resulting from excess moisture or heat while worn by the patient, for example when swimming, bathing or during other normal daily activities.

Safety and Drug Loading: In order to enable effective diffusion of sufficient amounts of drug through the skin, many transdermal delivery systems must incorporate large amounts of drug in the patch. After use, a large residual amount of the drug remains and must be disposed of carefully, especially if the drug is potent or toxic. In some cases, only a small amount of the total drug loaded in a patch is actually delivered into the bloodstream.

Delivery Limitation: The pharmaceutical industry has been unable to formulate certain drugs, especially biologics, for transdermal drug delivery, given the size and complexity of the molecules. These drugs generally are delivered by injection, which causes pain and often requires administration by a medical professional. In addition, these drugs generally must be refrigerated, require biohazard disposal and present the risk of accidental needle sticks. Many small molecules are also difficult to deliver transdermally, especially those that are not soluble in water or are unstable in the presence of air or water.

One of the greatest opportunities in transdermal drug delivery is the ability to deliver biologics, including vaccines, peptides and proteins without the use of an injection. A number of companies have attempted to develop technologies to address this challenge, but many have experienced commercial and development failures due to the formulation, scale-up and manufacturing complexities. Some of these systems have relied upon large, complex and costly devices, usually with external power sources, which adversely impact their usability and reproducibility.

Our Solution

We are developing and commercializing advanced transdermal drug delivery products that are intended to expand the number and types of drugs that can be delivered transdermally. We believe our technologies can be applied to improve the therapeutic value of many drugs by controlling the levels of drug delivered over a longer period of time. They are also designed to eliminate the need for injections of certain drugs and to improve adhesion and skin irritation profiles. Our technologies also allow us to create cost-effective products, especially by eliminating the need for complex devices and refrigeration throughout the supply chain. Our two proprietary platforms, Corplex and MicroCor, separately address some of the primary shortcomings of traditional transdermal drug delivery. We believe our track record within the industry demonstrates our ability to develop commercially successful products.

Corplex Technology

Corplex is a novel technology incorporating combinations of materials that utilize the properties of both traditional pressure-sensitive adhesives, or PSAs, as well as bioadhesives, to enable the transdermal delivery of small molecules. Corplex encompasses combinations and blends of polymers to provide a range of properties that improve adhesion and delivery of active ingredients that may otherwise be difficult to formulate for transdermal delivery. We use our Corplex technology in the Crest Whitestrips line of products and in our clinical stage Corplex Tamsulosin, as well as in other products in development. Additionally, we have one product utilizing Corplex technology for which an ANDA has been filed. Our Corplex transdermal delivery systems provide advanced custom solutions for small molecules and feature the following benefits:

Flexibility: Corplex is adaptable and provides the ability to formulate adhesives to complement a drug's unique properties, enabling new drug dosage forms and delivery options. As a result, Corplex systems can be formulated in several dosage forms ranging from liquids (sprays, film-forming liquids), to semi-solids (gels, creams and ointments) to solids (powders, particles, dry and wet films, and patches).

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Ease-of-Use: Our Corplex systems are designed to improve patient compliance by being easy to use, self-administered and discreet. In addition, Corplex products are suitable for long-term skin contact and are designed to be easily removed with minimal damage to skin and without leaving a residue. Corplex incorporates unique compositions and blends of polymers to provide a range of hydrophilic to hydrophobic properties, enabling excellent adhesion to both dry and wet surfaces with a variety of wear times, ranging from seconds to up to seven days.

Compatibility: Corplex can incorporate liquid-based components that improve stability and diffusion of the drug without compromising adhesion. As a result, Corplex is compatible with many chemically diverse drugs, including compounds that are highly soluble or highly insoluble in water, as well as a wide range of solubilizing agents and enhancers that enable the delivery of these molecules, thereby expanding the universe of drugs that can be delivered transdermally.

Efficient and Controlled Drug Delivery: Because Corplex enables drugs to diffuse more easily through the skin, we can design Corplex products to require less drug to achieve the desired therapeutic result. Patch sizes can also be smaller than conventional patches, reducing costs and improving the user experience. Additionally, Corplex allows for development of products with drug delivery profiles ranging from immediate release to sustained release or a combination of fast-acting and long-lasting types of release.

Improved Therapeutic Profile: By achieving a steady dosage level, Corplex systems are designed to minimize side effects that otherwise result from peak concentrations of the drug when delivered with oral or other dosage forms. Corplex allows us to minimize the use of ingredients that can cause skin irritation and sensitization, two of the most common side effects of transdermal drug delivery. In our Corplex systems, we use materials that are well established for use in medical products by the FDA.

We believe the combination of these benefits make Corplex well-suited for the development of a variety of healthcare products that require adhesive properties, including prescription transdermal drug products, personal care, oral care, wound care, medical device and diagnostics products.

MicroCor Technology

MicroCor is a biodegradable microstructure patch technology that we are developing to enable transdermal delivery of biologics, in a disruptive platform that reduces the need for needles and syringes and enables global distribution of biologics without requiring refrigeration. Because biologics cannot diffuse through the skin due to their size, some mechanism is required to introduce these molecules beyond the outer layer of the skin, or stratum corneum, where they can be absorbed into the body. The further a delivery system penetrates beyond the stratum corneum, the more likely it is to cause pain, bleeding and bruising. By integrating active ingredients directly into arrays of biodegradable microstructures, our MicroCor technology is designed to penetrate only the stratum corneum to release the drug for local or systemic absorption, while eliminating the pain, bleeding and bruising that can be caused by needles and other active delivery devices.

We believe MicroCor will offer the following advantages over other delivery technologies in development for biologics:

Minimal Discomfort: Our MicroCor systems feature an array of microstructures that penetrate the stratum corneum to only a few hundred microns in depth, deep enough for effective delivery without causing pain, bruising or bleeding.

Dose Sparing: MicroCor needles are biodegradable and dissolve in the skin once the system is applied. In our clinical studies to date, we determined that over 90% of the drug contained in a single use of a MicroCor system was delivered into the skin each time the system was administered. We expect our MicroCor systems to reduce drug waste and the costs associated with the excess drug that may be required in less efficient delivery technologies.

Thermally Stable: Our MicroCor systems do not contain moisture, and therefore are designed to be room temperature stable, enabling both stockpiling and worldwide delivery without refrigeration, thereby minimizing drug or product spoilage.

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No Biohazard Disposal: Because MicroCor needles completely dissolve in the skin, no sharps remain after use. We believe this feature will allow disposal of the system in a traditional trash receptacle without risk of accidental needle sticks or abuse associated with residual drug left in the delivery system.

Ease-of-Use: MicroCor products are designed to be self-administered, fully-integrated, single-use systems that are worn for only a few minutes. Unlike other delivery systems, MicroCor requires no additional parts, electrical power or complex external enabling devices to effectively deliver the drug or product.

Cost-Effective: In addition to the cost savings associated with dose sparing and thermal stability, MicroCor's fundamental design and our proprietary molding process also minimize costs associated with manufacturing MicroCor systems. Our process allows us to reduce waste of active ingredients used in manufacturing, as compared to needle coating processes used by other delivery technologies for large molecules.

The figure below depicts the MicroCor technology:

Our Strategy

We believe our balanced portfolio strategy enables us to capitalize on our proven strengths and technological advantages while diversifying risk and limiting our financial exposure. The key components of our strategy are to:

Expand our existing revenue base by commercializing our advanced pipeline. We intend to work with our existing partners to gain regulatory approval and commercially launch the AG200-15 contraceptive patch with Agile and a motion sickness patch and an urology patch with Teva. We also plan to develop, launch and manufacture new oral care products and certain other new products outside of oral care through our partnership with P&G.

Advance the development of proprietary products already in development. We plan to advance the development of MicroCor hPTH(1-34) and Corplex Tamsulosin, and selectively work with new partners to advance certain products in our earlier stage pipeline. We intend to focus primarily on products that incorporate FDA-approved drugs, thereby allowing us to take advantage of the 505(b)(2) regulatory pathway.

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Enter into co-development and commercialization agreements with new and existing partners for new products. We are actively evaluating potential new product candidates that leverage our proprietary technologies. Additionally, we plan to transition our MicroCor technology feasibility programs with leading pharmaceutical partners into co-development partnerships to develop and commercialize transdermal system-based vaccines and proprietary biologic products.

Expand our MicroCor manufacturing capabilities. We intend to further develop MicroCor manufacturing capabilities to commercial scale, enabling late-stage development, launch and commercial production of multiple new high-margin biologic products.

Further leverage our core competencies and proprietary technologies. We intend to apply our technologies to create and develop a portfolio of new transdermal products in areas of significant unmet need in particular, chronic, degenerative and progressive conditions affecting the brain and central nervous system, such as Alzheimer's and Parkinson's diseases. We are focusing our self-funded new product efforts on products that we could commercialize with a relatively small specialty sales force.

Strategic Relationships

Our partners are critical to our success. We currently have strategic relationships with the following companies, as well as earlier-stage relationships with a number of other companies. This diversified mix of partnerships provides multiple potential sources of revenue growth in the future. In each of fiscal 2012 and 2013, we derived nearly all of our revenues from our partners P&G, Teva, Actavis and Par. In fiscal 2012, we received $7.9 million of our revenues from P&G, $11.4 million from Teva, and $18.1 million from Actavis, or 18%, 26%, and 42%, respectively. In fiscal 2013, we received $11.8 million of our revenues from P&G, $16.7 million from Teva, and $16.6 million from Par, or 23%, 33%, and 33%, respectively. In the three months ended December 31, 2013, we received $3.0 million of our revenues from P&G, $3.7 million from Teva, and $3.2 million from Par, or 28%, 35%, and 31%, respectively.

The Procter & Gamble Company

In June 2005, we entered into a multi-faceted strategic arrangement with P&G, one of the largest consumer products companies in the world. Our relationship includes a worldwide license to P&G for the use of our Corplex technology in products in the general field of consumer products. This field does not include rights in the prescription drug, foot care and wound care fields. P&G paid us fees for the license, plus additional future milestone payments for products that we develop for P&G. In addition, we entered into a long term joint development agreement under which we perform numerous research and development activities for P&G based upon agreed-upon statements of work and budgets. We also have a commercial supply agreement in place, under which we are responsible for the production and supply to P&G of four oral care products. Our supply agreement with P&G was previously extended for a three-year term to the end of 2013 and was amended recently to extend through July 2014. We are in the process of negotiating an additional extension, which we expect to have completed by July 2014. The supply agreement can be expanded to include any additional products that move into commercial supply. We believe that we have unique capabilities and know-how related to the manufacture of Corplex-based Crest Whitestrips, which would be difficult for another party to duplicate.

We have developed and commercialized four oral care products for P&G sold under the brand name Crest Whitestrips. The four products are Advanced Vivid, Professional Effects, One Hour Express and Flex-Fit. We have developed all of these products under the joint development agreement and are currently supplying the product in an intermediate, not final packaging, stage to P&G. In addition, we have other products in development for the oral care business at P&G as well as certain products in development for other businesses at P&G.

In addition to the license and joint development transactions, in 2005 we also acquired P&G's microneedles patent portfolio and know-how. In exchange for the assignment of the patent portfolio of 51 patents and

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patent applications, we issued to P&G 1,266,830 shares of our common stock and granted P&G certain co-sale and board observer rights.

In addition to contract research and development and product revenues, from the inception of our collaborations with P&G, we have received a total of $3.2 million in license fees and $2.0 million in milestone payments from P&G. Pursuant to programs currently underway, we may be eligible for up to $5.0 million in future milestone payments. None of our arrangements with P&G require a royalty to be paid to us.

Teva Pharmaceuticals, USA Inc.

In 2004, we entered into a development, manufacturing and commercialization agreement with Barr Laboratories, Inc. for four generic transdermal drug products. We entered into three separate agreements with Barr, one in 2006 and two in 2007, to develop and commercialize additional ANDA transdermal patch products. In 2008, Teva Pharmaceuticals, Inc. acquired Barr. Following this acquisition and its review of resource allocations and potential conflicts, Teva continued three of these development programs. One of these programs has resulted in an approved product marketed as Clonidine TDS, and the other two, a motion sickness patch and a urology patch, are the subject of pending ANDAs.

Under our agreements with Teva, we are the exclusive suppliers of the products that are the subject of each development program. We receive compensation for developing the product, plus a manufacturing margin, expressed as a margin above costs, and a profit share based on Teva's net profits on the products. Teva has an exclusive license to use certain of our intellectual property to the extent necessary to commercialize, make, use or sell the ANDA product.

The Teva product contracts extend for ten years beyond the respective product launch dates, with provisions for automatic annual renewal thereafter. The contracts may be terminated, with three months notice before the end of a renewal period, or for uncured material breach, bankruptcy, or certain conditions preceding ANDA filing. If Teva were to terminate the agreement, it would be required to obtain FDA approval for an alternate manufacturing site before it could obtain additional supply of the product, a process that generally takes two years or more.

Clonidine TDS was the first product under our partnership with Teva to be approved by the FDA. Teva launched the product in 2010, and currently has the largest share of the clonidine patch market. We also have two additional products partnered with Teva awaiting FDA approval, a motion sickness patch and a urology patch, and are in negotiations to add three additional ANDA products to our portfolio of Teva-partnered products.

In addition to contract research and development revenues and product revenues, from the inception of our collaborations with Teva and its predecessor, we have received no license fees and $0.2 million in milestone payments. Under our current agreements, we are not eligible for additional milestone payments. We receive a profit share equal to a low tens percentage of Teva's net sales of Clonidine TDS, after deducting certain selling-related expenses.

Par Pharmaceutical, Inc.

In 2002, we entered into a product development, collaboration and license agreement and in 2003 we entered into a manufacturing and supply agreement with Abrika LLLP for a generic equivalent of Duragesic, a fentanyl transdermal product marketed by Johnson & Johnson. In 2007, Abrika was acquired by Actavis, Inc. In 2007, the FDA approved and Actavis launched our Fentanyl TDS product. In 2012, Par Pharmaceuticals, or Par, acquired the fentanyl business from Actavis, and Par currently markets Fentanyl TDS as our partner. Under the manufacturing and supply agreement, we are the exclusive supplier of Fentanyl TDS to Par.

Abrika and Actavis paid us for the development of Fentanyl TDS and we also receive a manufacturing margin and a royalty on net sales of the products by Par. The 2002 agreement may be terminated for uncured material breach, bankruptcy, or certain conditions preceding ANDA filing. If Par were to terminate

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the agreement, it would be required to obtain FDA approval for an alternate manufacturing site before it could obtain additional supply of the product, a process that generally takes two years or more.

In addition to contract research and development revenues and product revenues, from the inception of our collaborations with Par and its predecessors, we have received no license fees and $0.5 million in milestone payments from Par. Under our current agreements, we are not eligible for additional milestone payments. We receive a royalty equal to a mid-single digit percentage of Par's net sales of Fentanyl TDS.

Agile Therapeutics, Inc.

In 2006, we entered into a development, license and commercialization agreement with Agile Therapeutics, Inc., a privately-owned company that focuses on development of women's healthcare products. As part of our relationship, we are the exclusive supplier of the AG200-15 combined hormonal contraceptive patch, which was designed by Agile using its formulation technology and is proprietary to Agile. Under our agreement with Agile, we have performed substantial work, funded by Agile, on the process development and scale-up of the manufacturing process for AG200-15, and we have manufactured the product for each of Agile's clinical trials. Our agreement also includes an additional Agile product, AG890, which is a progestin-only contraceptive patch in Phase 2 of clinical development.

In anticipation of the approval and commercial launch of the AG200-15 product, we have worked in partnership with Agile to prepare facilities and equipment at our Grand Rapids manufacturing site for commercial production of the product. The primary production equipment specifically designed for manufacture of this product has been purchased and is owned by Agile and we are responsible for operating and maintaining that equipment.

Our exclusive right to manufacture AG200-15 and AG890 extends until we have commercially produced an agreed-upon quantity of patches, currently projected to occur no earlier than five years following commercial launch of AG200-15. The contract may be terminated for uncured material breach. Following the end of the exclusivity period, if Agile were to seek a second source of supply, Agile would be required to obtain FDA approval for an additional manufacturing site, a process that generally takes two years or more, and make substantial investments in new facilities and equipment.

In addition to contract research and development revenues, from the inception of our collaborations with Agile, we have received no license fees and $3.5 million in milestone payments from Agile. We are not currently eligible for any future milestone payments, and the terms of our supply agreement do not entitle us to receive a royalty.

Products and Pipeline

We have six commercial products and three products awaiting FDA approval, and we are developing three additional undisclosed prescription drug products with partners. We have seven ongoing feasibility agreements with four major pharmaceutical companies involving our MicroCor technology, and are currently in active discussions with four other companies for additional feasibility projects.

Marketed Products:

In fiscal 2013, we received a total of $38.6 million in product revenues from our three marketed products: $13.2 million from Clonidine TDS, $15.6 million from Fentanyl TDS, and $9.8 million from Crest Whitestrips, representing 34%, 40% and 25% of total product revenues, respectively.

Clonidine TDS is a treatment for hypertension that we developed under an ANDA as a generic version of the branded drug known as Catapres TTS. Clonidine TDS was launched in 2010 and is marketed by Teva and manufactured by us exclusively for Teva. According to Symphony Health Solutions, an independent market research firm, the U.S. generic clonidine patch market was approximately $230 million in 2012, supplied primarily by two companies.

Fentanyl TDS, is a treatment for management of chronic pain, including cancer-related pain, under specified conditions. We developed this product for approval under an ANDA as a generic version of the

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branded product known as Duragesic. Our Fentanyl TDS was approved in 2007 and is currently marketed by Par and manufactured by us exclusively for Par. According to Symphony Health Solutions, the U.S. generic fentanyl patch market was greater than $1 billion in 2012 supplied by seven companies.

Crest Whitestrips are a series of four products for oral care that we co-developed with P&G as part of a broad relationship relating to consumer products. These products utilize our Corplex polymer technology and are sold under the brands Advanced Vivid, Professional Effects, One Hour Express and Flex-Fit. We are the sole supplier of the oral care system marketed as Crest Whitestrips for P&G. The market for teeth whitening products was approximately $580 million in 2012, of which P&G has the majority market share.

Advanced Pipeline Products:

AG200-15 is a combination hormonal contraceptive patch that contains the active ingredients ethinyl estradiol (an estrogen) and levonorgestrel (a progestin), both of which have an established history of efficacy and safety in currently marketed combination contraceptives. AG200-15 is designed to deliver both hormones at levels comparable to low-dose oral contraceptives. By delivering these active ingredients over seven days, this product is designed to promote enhanced compliance by patients with a convenient, easy-to-use format. The patch is applied once weekly for three weeks, followed by a week without a patch. The product, which was designed by Agile and for which we have done process development and manufacturing, will, if approved, be packaged with three patches per carton to provide a cycle (month) of therapy.

The current U.S. market for combination hormonal contraceptive products is approximately $4.2 billion. Historically, the growth of prescriptions in this market has been driven by the introduction of new branded products, and approximately half of the total market sales are represented by only eight branded products. This market includes oral dosage forms as well as other non-oral products, such as a vaginal ring and a transdermal system. An earlier-generation transdermal contraceptive product known as Ortho Evra, launched in 2002 by Johnson & Johnson, was the most successful product launch in the history of the U.S. contraceptive market, and rapidly gained annual sales levels of nearly $400 million by 2004. However, sales of that product declined rapidly following the emergence of safety concerns that were associated with the relatively high levels of estrogen delivered by Ortho Evra. Based on the market experience of other non-oral dosage forms, including the Ortho Evra product, we believe there is a continuing demand for an innovative transdermal contraceptive patch that can provide convenience in a low-dose transdermal format.

Agile has conducted multiple clinical studies of AG200-15, including pharmacokinetic studies and Phase 3 efficacy and safety studies. In a pharmacokinetic study comparing AG200-15 to an oral contraceptive, Agile demonstrated that AG200-15 delivers a dose that results in estrogen exposure similar to low-dose oral contraceptives. Although Agile did not conduct a head-to-head study with Ortho Evra, this level of estrogen exposure is about one-half the estimated daily dose described in pharmacokinetic studies of Ortho Evra, the first FDA-approved transdermal contraceptive.

Agile also conducted two Phase 3 studies, involving approximately 1,900 patients, to evaluate the safety and efficacy of AG200-15. Each of these studies included an active comparator arm with an oral contraceptive. The results of these studies demonstrated that the AG200-15 product was well-tolerated, with levels of adverse events comparable to those of oral contraceptives. In these studies, the product had a favorable adhesion profile, and subjects had a higher rate of compliance when using the patch compared with the group using oral contraceptives.

In the Phase 3 trials the primary measure of efficacy was the Pearl Index, a measure of the rate of unintended pregnancies experienced by women in the study. The Pearl Index levels for both the AG200-15 patch and oral contraceptive control arms in the Agile Phase 3 studies were higher than those in studies conducted on products previously approved by the FDA. The results for both the patch and oral contraceptive control arms in the Agile Phase 3 studies may have been affected by the inclusion of relatively high proportions of first-time contraceptive users and other population groups that have, in historical clinical studies, tended to have higher rates of pregnancies than the general population.

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In February 2013, Agile received a Complete Response Letter from the FDA, indicating that the results from the completed Phase 3 studies would not be sufficient for approval, and proposing that Agile conduct an additional Phase 3 study. Among the concerns expressed in the letter were the Pearl Index values seen in the studies. Specifically, the FDA indicated the Pearl Index values in the studies (in both the subjects using the AG200-15 patch and the control arm using oral contraceptives) were higher than seen in clinical trials used for registration of other approved hormonal contraceptives. Agile believes that the results for both the patch and oral contraceptive control arms in the Phase 3 trials were affected, in part, by the study population, which differed in composition from the population enrolled in trials of previously approved combination hormonal contraceptive, or CHC. Agile believes it enrolled a disproportionately high number of new users and minorities in both arms of its study, as compared to other CHC clinical trials. Notably, there were higher incidences of non-compliance and loss to follow-up in new users compared with experienced users in the Agile study. These factors may have contributed to the high rates of noncompliance in Agile's trials, which often correlates with a higher contraceptive failure rate. The FDA recommended that Agile conduct an additional Phase 3 trial with a simplified clinical trial design. The Complete Response Letter also requested improvements in the study conduct, including site monitoring and data collection procedures, and additional information on inprocess controls relating to the patch, a drug master file that was referenced in the NDA, and product release specifications.

Agile has met with the FDA and received further guidance on requirements for its application. Based on these discussions, Agile plans to initiate an additional study in the first half of 2014, which it anticipates completing by the end of 2015. This study will be designed to address key issues that arose in the previous studies, including enhanced patient enrollment criteria and processes, and close monitoring of compliance with the study protocol. Based on FDA guidance toward a simplified study design, Agile plans to design and conduct the new clinical study to be a single-arm, non-comparative trial, without an oral contraceptive comparator, expected to cover up to 13 ovulation cycles per subject. The time for selection and training of study sites, and for selection, enrollment and training of subjects will be extended and monitored by study coordinators, and various technologies will be employed to provide reminders and collect information on a real-time basis. To manage the study, Agile recently hired a new chief medical officer, and it plans to retain a new clinical research organization that is experienced in contraceptive clinical studies. There can be no assurance that this additional study will be successful in demonstrating efficacy and safety of the product. However, assuming successful completion of this additional study, Agile would plan to submit a supplement to its NDA in early 2016. Assuming a six-month review by the FDA, approval would occur late in 2016. Our marketing partner intends to launch the product as soon as possible following FDA approval.

We are working with Agile to prepare for the additional Phase 3 study, including the manufacture of product for use in the study. We have also completed a substantial build-out of our facilities in Grand Rapids, Michigan, and have installed over $10.0 million of equipment purchased by Agile to accommodate the commercial production of AG200-15 if it is approved and launched.

In fiscal 2013, we received a total of $4.3 million in contract research and development revenues from Agile, representing 40% of our total contract research and development revenues.

MicroCor hPTH(1-34) is a transdermal system designed to use our MicroCor technology to provide simplified delivery of parathyroid hormone, the active ingredient of Forteo, an injectable product marketed by Eli Lilly and Company for the treatment of severe osteoporosis. hPTH(1-34) is a shortened version of the naturally occurring parathyroid hormone that promotes bone growth. Forteo achieves annual worldwide sales of greater than $1 billion despite significant patient compliance and convenience challenges, including daily subcutaneous injection and refrigerated storage. According to Datamonitor, the compliance rate of patients being treated with injectable osteoporosis treatment is approximately 50%. With a simple one-step application process, short wear time and a favorable pharmacokinetic profile, MicroCor hPTH(1-34) represents, if approved, an opportunity to effectively deliver an improved anabolic therapy and increase patient compliance in the osteoporosis market.

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The global osteoporosis market represents a significant opportunity, with growing revenues that are estimated to reach greater than $5.2 billion in the seven major market countries by 2021 according to Datamonitor. This growth is driven by both general population aging and the anticipated launches of several premium priced market entrants in the coming years. Current treatment is focused on the use of bisphosphonates as the first-line approach. However, these agents provide only anti-resorptive activity and are associated with significant gastrointestinal side effects and other adverse outcomes. Treatment with PTH is the only treatment approach that promotes bone growth currently available for the treatment of osteoporosis.

We have completed a Phase 1 safety and pharmacokinetic study of MicroCor hPTH(1-34) in healthy women. In this study, MicroCor hPTH(1-34) was shown to be safe and well tolerated with comparable drug exposure to that achieved with the commercially available subcutaneous injections. The product achieved rapid systemic delivery of hPTH with a short wear time of five minutes. On the basis of these results, we are planning further clinical development of MicroCor hPTH(1-34) under a 505(b)(2) regulatory pathway that leverages existing hPTH safety and efficacy data from the approved dosage form of parathyroid hormone. We anticipate that the clinical plan will consist of a Phase 2a pharmacokinetic study, which we plan to commence in the second half of 2014. This will be followed by a six-month Phase 2b efficacy/safety and dose finding study in osteoporosis patients and a one-year Phase 3 trial, each measuring change in bone mineral density as a primary endpoint.

MicroCor hPTH(1-34) has demonstrated a favorable safety profile in multiple nonclinical biocompatibility and microbial studies. The product has also demonstrated favorable room temperature stability. We believe MicroCor hPTH(1-34) is the only integrated, single step application PTH transdermal product currently in clinical development, and is well-positioned for this growing market. We have self-funded this program since inception, and are planning to advance it into Phase 2 clinical trials with proceeds from this offering. We expect to partner with a company active in bone health, women's health or endocrinology to distribute and sell the product, if approved.

We have in place pilot facilities for manufacture of MicroCor products for early clinical testing. We also have extensive experience with process development and commercial scale-up for transdermal products. In preparation for Phase 3 clinical trials of MicroCor hPTH(1-34), we have developed an aseptic manufacturing plan for large scale manufacturing and we have designed the manufacturing process for MicroCor systems to be streamlined, robust and cost effective.

Corplex Tamsulosin is a transdermal patch designed to use our Corplex technology to provide controlled delivery of tamsulosin, the active ingredient in the leading once-daily capsule product for treatment of benign prostatic hyperplasia, or BPH, marketed under the brand name Flomax. Tamsulosin is a drug that relaxes smooth muscle cells in the prostate and bladder neck, thereby decreasing the blockage of urine flow that occurs with an enlarged prostate. The oral dosage form of tamsulosin was first launched in 1993 and, according to Datamonitor, worldwide sales in 2012 neared $550 million. By providing a controlled and relatively steady level of drug over an extended time, Corplex Tamsulosin is intended to alleviate the side effects associated with peak blood concentrations of the drug in its current oral formulation and to provide a consistent level of efficacy. Several companies have attempted to formulate tamsulosin into a patch, but have not succeeded due to the low solubility properties of this drug. Our completed Phase 1 pharmacokinetic study in healthy subjects demonstrated that Corplex Tamsulosin enabled delivery of the drug at blood concentration levels equivalent to the effective levels provided with the oral dosage form, but with an extended and controlled release profile. If successfully commercialized, Corplex Tamsulosin could be the only patch available for tamsulosin.

We expect Corplex Tamsulosin to offer the following potential advantages over the oral tamsulosin product:

Enhanced safety and efficacy: Corplex Tamsulosin is designed to provide a relatively steady dosage over multiple days. Studies have shown that a steady 24-hour pharmacokinetic profile for tamsulosin is associated with better control of nocturia, or frequent night time urination, and reduced cardiovascular side effects.

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Enhanced convenience and compliance: Patients may apply Corplex Tamsulosin once or twice weekly instead of a once daily oral dose. In addition, oral dosage forms must be taken approximately 30 minutes following the same meal every day because of the effects of food on tamsulosin's pharmacokinetics.

Ease of use: We believe the predominantly elderly and growing BPH population would benefit from a transdermal system because many older patients have difficulty swallowing oral dosage forms.

We have completed a Phase 1 safety and pharmacokinetic study of Corplex Tamsulosin in healthy men. In this study, Corplex Tamsulosin demonstrated a favorable safety profile, was well-tolerated and the drug exposure of the once-weekly patch was comparable to daily oral Flomax capsules. Planning is underway for further clinical development under a 505(b)(2) regulatory pathway that leverages existing tamsulosin safety and efficacy data of the marketed product. We anticipate that the clinical plan will consist of a one month Phase 2 efficacy/safety and dose finding study in patients and a three month (with open label extension of six to nine months) Phase 3 trial in patients, using an American Urology Association symptom score or International Prostrate Symptom Score as the primary end point.

We have self-funded this program since inception, and are planning to advance it into Phase 2 with proceeds from this offering in the first half of 2015. We expect to partner this product with a company with marketing experience and capability in the urology field.

Products Awaiting Approval:

Motion Sickness Patch. We have developed a generic transdermal product for the prevention of nausea and vomiting associated with motion sickness. We developed a three-day patch for Teva under an ANDA, and Teva is currently awaiting FDA approval. We have completed all of the development, scale-up and clinical activities and expect this product to launch in 2014, if approved.

In fiscal 2013, we received a total of $2.9 million in contract research and development revenues from Teva for this product, representing 27% of our total contract research and development revenues.

Urology Patch. We have developed a generic transdermal product for treatment of a urologic condition. We developed a three-to-four-day patch for Teva under an ANDA, and Teva is currently awaiting FDA approval. We have completed all of the required development, scale-up and clinical activities and expect this product, if approved, to launch in 2015, pursuant to the terms of a patent settlement agreement between Teva and Actavis.

In fiscal 2013, we received a total of $0.7 million in contract research and development revenues from Teva for this product, representing 6% of our total contract research and development revenues.

Development Pipeline Products:

Alzheimer's Disease (Donepezil and Memantine)

Alzheimer's disease, the leading cause of dementia, is characterized by the progressive loss of memory, thinking and ability to perform activities of daily living, such as bathing, feeding and self-care, as well as significant behavioral disturbances such as agitation, aggression, delusions and hallucinations. According to industry sources, Alzheimer's disease currently affects approximately 5.3 million people in the United States, including as many as 13% of people aged 65 and older and approximately 50% of those 85 and older. Total annual expenditures on caring for patients with Alzheimer's disease in the United States alone exceeds $200 billion.

According to Datamonitor, the worldwide market for Alzheimer's disease therapies currently exceeds $3.9 billion, with the largest selling products being the cholinesterase inhibitor, Aricept, and the NMDA-receptor antagonist, Namenda. By 2015, both of these branded Alzheimer's drugs will lose patent protection in the United States and Europe.

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We have initiated development work on advanced transdermal patches for the treatment of Alzheimer's disease incorporating proven and approved molecules, one of which is the active ingredient in Aricept, under a 505(b)(2) regulatory pathway, which we believe will allow for reduced nonclinical and clinical study cost and time. The products are designed to decrease the side effects of the current therapies, such as nausea, which may improve patient adherence and compliance.

Parkinson's Disease (Ropinerole and Pramipexole)

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. Approximately one million people in the United States and from four to six million people worldwide suffer from this disease, which is commonly treated with dopamine replacement therapies such as levodopa and dopamine agonists, which are molecules that mimic the action of dopamine. According to PharmaCircle, an industry database, the current Parkinson's disease market is approximately $3.0 billion globally.

We are developing advanced therapies incorporating proven and approved molecules under a 505(b)(2) regulatory pathway, which we believe will allow for reduced nonclinical and clinical study cost and time. Because Parkinson's patients have trouble swallowing pills, we believe a transdermal or film product would address an unmet need recognized by patients and physicians alike.

MicroCor Feasibility Programs include seven partner-funded feasibility programs that we have completed or are currently in progress. Additional programs are in the planning process. In the programs performed to date, we have collaborated with leading biopharmaceutical companies to formulate their proprietary active molecules in our MicroCor technology and demonstrate delivery of the drug in animal models. The active molecules in these studies have been primarily large biologic molecules, including vaccines, peptides, proteins and monoclonal antibodies. After completing a number of these programs successfully, we are now advancing certain programs into later stages of development, including new vaccine and therapeutic applications.

Future Pipeline Programs include three additional undisclosed ANDAs that have been partnered with two pharmaceutical companies. Two of the products are in development and we expect the ANDAs to be filed in 2015, while the third product is entering clinical trials in the first quarter of 2014. We also are developing skin care and cosmetics products utilizing our Corplex and MicroCor technologies for our partners.

In fiscal 2013, we received an aggregate total of $2.8 million in contract research and development revenues from our collaboration partners for these programs, representing 26% of our total contract research and development revenues.

Research and Development

Our research and development operations are located in a 25,000 square foot laboratory and office facility in Menlo Park, California that is configured for transdermal and transmucosal systems development. We conduct proprietary drug delivery research utilizing our extensive experience in polymer blending, formulations and system engineering to produce innovative products with high drug delivery efficiency. Our research and development team has full early product development capabilities, including:

- Formulation, system design and engineering;
- Analytical method development and validations;
- Prototyping and pilot manufacturing;
- Early stage quality assurance and quality control;
- Nonclinical and early stage clinical development; and
- Regulatory affairs.

In addition, our Menlo Park site operates a pilot facility capable of making products in accordance with cGMP requirements for anticipated Phase 1 and Phase 2 clinical studies.

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Our Menlo Park research and development team includes 37 scientists and engineers, some of whom were original inventors of transdermal patches. We perform the formulation system design, analytical method development and prototyping for all of our transdermal products. Our research and development team works in collaboration with the process scale-up team in our manufacturing operations early in the product development cycle. This early coordination helps assure streamlined technology transfer success in the final scale-up and commercial manufacture of each product, leading to more robust development programs and greater manufacturing efficiencies.

Manufacturing

Our commercial manufacturing facilities are located in Grand Rapids, Michigan in three buildings comprising approximately 200,000 square feet. We have a full range of development and manufacturing capabilities, from complete process development and scale-up services to commercial manufacture. We have made significant investments in our manufacturing technology that allow us to automate many of our processes and maximize the productivity of our labor force. We employ multiple manufacturing techniques, including solvent cast and extrusion manufacturing processes that minimize the thickness of our patches and reduce the costs of our products. Solvent-casting is well-suited for manufacturing films containing heat-sensitive molecules because the temperatures required to remove the solvents are relatively low compared to those needed for a hot-melt extrusion process. Hot-melt extrusion is not suitable for ingredients that could be thermally degraded in the process, but is environmentally friendly, cost effective and more flexible than solvent cast-only processes.

Our manufacturing platform includes:

- Process development through commercial product manufacture, including final finishing and cartoning;
- Multiple-use equipment providing flexibility for small volume jobs to dedicated equipment for large volume production;
- High accuracy coating for pressure sensitive adhesives, acrylics and polyisobutylene, or PIB;
- Automated solvent casting and extrusion capabilities, including both twin screw and mixer extrusion;
- Automated high-speed, high-accuracy die cutting, and integrated die cutting and pouching;
- Physical testing and analytical method capabilities;
- The licensing required to handle scheduled drugs and compounds requiring special handling;
- The ability to manufacture drug and device combination products with high accuracy assembly for multiple and complex components; and
- Manufacturing capabilities for proprietary MicroCor biodegradable microstructures, including specialty coating, curing, drying and assembly processes.

Our facilities are FDA and DEA registered, and ISO9001 and ISO13485 certified. Our manufacturing facilities in Grand Rapids are licensed to manufacture OTC products, consumer products, prescription transdermal, dermal and mucosal products, as well as wound care products. Our Grand Rapids facilities also have the capacity to produce well over 100 million patches annually and can be expanded as our needs grow. A number of our equipment lines have been fully funded by our partners to support the development of partnered products. In these cases, the partners retain title to those equipment lines, while we retain responsibility to maintain and operate them. Our operations include on-site quality control laboratories and testing procedures, quality assurance systems, and internal audit procedures for our processes and equipment.

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Intellectual Property

Our success depends on our ability to obtain patents and protect our trade secrets and know-how. We must be able to operate without infringing on any other company's intellectual property and we must prevent others from infringing our intellectual property. Our strategy is to protect our intellectual property by filing both U.S. and international patents related to our proprietary technologies, products, inventions and improvements that are important to our business. As of January 31, 2014, we held 38 U.S. issued patents and 147 foreign issued patents (which include granted European patents rights that have been validated in various EU member states) and 28 U.S. pending patents and 60 foreign pending patents relating to our Corplex and MicroCor technologies and products. Of the issued U.S. patents, 21 relate to composition of matter and 17 relate to use or process. Of the pending U.S. patents, 25 relate to composition of matter and 3 relate to use or process. Our foreign patents generally include both composition of matter and use or process claims. Our issued U.S. patents and patent applications will expire between 2019 and 2034. Some of the issued patents and pending patent applications, if issued may also be eligible for patent term adjustment and patent term restoration, thereby extending their patent terms.

Proprietary rights for our products in development and our potential products will be protected from use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. Patents owned by us (or licensed by us) may not protect us from competition in the future and our pending patent applications may not result in patent rights being issued. In addition, the laws of certain foreign countries may not protect our intellectual property rights to the same extent as they do under U.S. law.

The patent positions of pharmaceutical, drug delivery and biotechnology companies are complex and enforcement cannot be predicted with certainty. Our patents or patent applications, if issued, may be challenged or invalidated and the rights granted may not provide proprietary protection or competitive advantages over our competitors with similar technologies. Our competitors may also develop similar technologies to ours, or in fact duplicate our technologies. Because the regulatory timeline is quite long and expensive to develop the types of products that we develop, it is possible that before any of our products are commercialized, any related patent may expire or exist for only a short period of time following commercialization. This could negatively impact our ability to protect our future products and consequently our operating results and financial position.

Our products in developments may be covered by third party patents or other intellectual property rights, in which case we would need to obtain a license to continue to develop and/or market these products. Such licenses may not be available on acceptable terms and such licenses may not be attainable, which could delay product launches if we are required to design around a patent. Litigation may be necessary to defend against or assert claims of infringement enforce patents, protect trade secrets or know-how or to determine validity in order to freely sell a product in the marketplace. In addition, interference, derivation, post-grant oppositions or other proceedings may be necessary to determine rights to inventions in our patents. Litigation could incur substantial financial costs and may have a material adverse effect on our business, financial condition or results of operations.

In certain circumstances, we rely on trade secrets to protect our technology. Trade secrets are difficult to protect. Generally we protect our proprietary processes and manufacturing this way and we secure confidentiality agreements from all of our employees, contractors, consultants and advisors. We cannot assure that the agreements will not be breached or that we will be able to remedy such a breach or that our trade secrets will not become known in the public domain and be discovered by our competitors. Disputes may also arise with respect to know-how and inventions created by our employees, contractors and consultants. See the section entitled "Risk Factors Risks Related to Our Intellectual Property."

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Regulatory

Food and Drug Administration. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical, and consumer cosmetic products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products. Many of our products are combination drug-device products that are regulated as drugs by the FDA, with consultations from the device center in the FDA. Others, such as consumer teeth whitening products, are regulated by the FDA as cosmetics. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA Regulation of Drugs. The process required by the FDA under the new drug provisions of the Federal Food, Drug, and Cosmetic Act, or the FFDC Act, before our investigational drugs may be marketed in the U.S. generally involves the following:

- Completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- Submission of an Investigational New Drug application, or IND, which must become effective before clinical trials may begin;
- Performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational drug for each proposed indication in accordance with the FDA's current good clinical practice, or GCP, requirements;
- Submission to the FDA of a New Drug Application, or NDA, after completion of all pivotal clinical trials;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the drug will be produced to assess compliance with current good manufacturing practice, or cGMP, regulations, or, for our medical device components, the Quality System Regulation, or QSR; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

Preclinical tests include laboratory evaluation of the investigational drug, its chemistry, formulation and stability, as well as animal studies to assess its potential safety and efficacy. For human clinical trials to be conducted in the United States, we must generally submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we may begin human clinical trials. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. Further, an independent Institutional Review Board, or IRB, at each medical center proposing to conduct the clinical trials must review and approve any clinical study as well as the related informed consent forms and authorization forms that permit us to use individually identifiable health information of study participants.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objective of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. The IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trial results to public registries.

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The foregoing discussion of clinical trials applies to clinical trials conducted under an IND. In some instances, we may conduct clinical trials outside of the United States, which may require different or additional regulatory submissions depending on the country in which the trial is conducted.

Human clinical trials are typically conducted in three sequential phases which may overlap or be combined:

Phase 1: Includes the initial introduction of an investigational drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. Phase 1 studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During these studies, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. These studies include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase 2: Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug.

Phase 3: When Phase 2 clinical trials suggest effectiveness of a drug, Phase 3 clinical trials are undertaken to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 clinical trials of our investigational drugs within any specific time period, if at all. Furthermore, the FDA or the IRB or the sponsor may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Sponsors of clinical trials may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. During the clinical development of products, sponsors may meet and consult with the FDA in an effort to ensure that the design of their studies will likely provide data both sufficient and relevant for later regulatory approval; however, no assurance of approvability can be given by the FDA.

The results of product development, preclinical studies and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product. Submission of an NDA requires the payment of a substantial user fee to the FDA, and although the agency has defined user fee goals that govern the length of an NDA's review time, we cannot assure that the FDA will make a review decision in any particular timeframe. After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its active pharmaceutical ingredient, or API, will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete but the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an one or more additional clinical trials, as FDA has required of our partner Agile, and/or other requirements related to clinical trials, preclinical studies or manufacturing, any of which may be expensive and require considerable time to complete. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

After approving a drug, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if safety problems occur after the product reaches the market. Requirements for additional Phase 4 studies (post approval marketing studies) to confirm safety and effectiveness in a broader commercial use population may be imposed as a condition of marketing approval. In addition, the FDA requires surveillance programs to monitor approved products which have been commercialized, and the

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agency has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our pharmaceutical systems under development on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Evolving safety concerns can result in the imposition of new requirements for expensive and time consuming tests. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Any pharmaceutical systems that we may develop and obtain approval for would also be subject to adverse findings of the active drug ingredients being marketed in different dosage forms and formulations. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our pharmaceutical systems abroad will require similar regulatory approvals and is subject to similar risks. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action. Our partners are the NDA and ANDA holders and therefore communicate with FDA with respect to the applications.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including cGMP requirements, and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic announced and unannounced inspections by the FDA and state agencies for compliance with cGMP regulations, which impose procedural and documentation requirements upon us and our third party manufacturers. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements.

Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. For example, in 2008 and 2010 we conducted recalls of our fentanyl products and were inspected by the FDA. These inspections led to the issuance of FDA Forms 483 identifying inspectional observations. The most recent FDA inspection of our facility was a Pre-Approval Inspection for NDA 20407 and ANDA 90526 (transdermal patches). The FDA issued a three-observation 483, which we addressed as part of our ongoing obligations under the FDA's quality system regulation.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses, and federal and state authorities are also

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actively litigating against sponsors who promote their drugs for unapproved uses under various fraud and abuse and false claims act statutes. We and our pharmaceutical systems are also subject to a variety of state laws and regulations in those states or localities where our pharmaceutical systems are or will be marketed. Any applicable state or local regulations may constrain our ability to market our pharmaceutical systems in those states or localities. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our drug product candidates. Moreover, increased attention to the containment of health care costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The FDA also has the authority to require a risk evaluation and mitigation strategy (REMS) to ensure the safe use of the drug. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007, or FDAAA, when necessary to ensure that the benefits of a drug outweigh the risks.In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy at 18 months, three years, and seven years after the strategy's approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks.

On July 9, 2012, the FDA approved a REMS for extended-release and long-acting opioid medications. Several of our currently marketed drug products and investigational drugs, including fentanyl and buprenorphine, are subject to the REMS. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of drugs subject to the REMS requirement, which could negatively impact the commercial benefits to us and our partners from the sale of these drug products and, if approved, drug product candidates. Our partners, as the holders of the marketing applications for the affected drugs, are responsible for compliance with the opioid REMS requirements.

Hatch-Waxman Act. Section 505 of the FFDC Act describes three types of NDAs that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and effectiveness. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, created two additional marketing pathways under Sections 505(b)(2) and 505(j) of the FFDC Act. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness but 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. This regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously

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approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to (i.e., performs in the same manner as) the innovator drug. The generic version generally must deliver approximately the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30 month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA may obtain five years of exclusivity upon approval of a new drug containing a new chemical entity, or NCE, that has not been previously approved by the FDA. The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDA for drugs that include the innovation that required the new clinical data.

We expect that some of our drug candidates will utilize the section 505(b)(2) regulatory pathway. Even though several of our drug products utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish safety and effectiveness of those active ingredients in the formulation and dosage forms that we are developing. We also have several partnered products that are approved pursuant to ANDAs or will be filed under the ANDA pathway. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

The Drug Enforcement Administration. Certain of our products, including our fentanyl patch, are regulated as a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the Drug Enforcement Administration, or DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients such as fentanyl and buprenorphine, are listed by the DEA as Schedule II and Schedule III respectively under the CSA. Consequently, their manufacture, research, shipment, storage,

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sale and use are subject to a high degree of oversight and regulation. For example, all Schedule II drug prescriptions must be signed by a physician, generally physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances we can obtain for clinical trials and commercial distribution is limited by the DEA in accordance with a quota system and our quota may not be sufficient to complete clinical trials or meet commercial demand. The DEA establishes annually an aggregate quota for how much fentanyl may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of fentanyl that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce or procure any Schedule II substance, including fentanyl for use in manufacturing our fentanyl products. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings. Individual states also regulate controlled substances, and we and our partners will be subject to state regulation on distribution of these products.

There is a risk that DEA regulations may interfere with the supply of the drugs used in our clinical trials and sold commercially, and, thus on our ability to produce and distribute our products in the volume needed to meet clinical and commercial demand.

FDA Regulation of Consumer Cosmetic Products. Consumer teeth whitening products are regulated by the FDA as cosmetics. The processing, formulation, safety, manufacturing, packaging, labeling, advertising and distribution of these products are subject to regulation by one or more federal agencies, including the FDA and the Federal Trade Commission, or FTC, and by various agencies of the states and localities in which these products are sold. Cosmetic products and their ingredients do not require premarket approval prior to sale, but are subject to specific labeling regulations. While the FDA has not promulgated specific cGMPs for the manufacture of cosmetics, the FDA has provided guidelines for cosmetic manufacturers to follow to ensure that their products are neither misbranded or adulterated.

The FTC exercises jurisdiction over the advertising of cosmetics. In recent years, the FTC has instituted numerous enforcement actions against companies for failure to have adequate substantiation for claims

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made in advertising or for the use of false or misleading advertising claims. We are also subject to regulation under various state, local, and international laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising, and distribution of cosmetics.

Other Healthcare Laws. Although we do not directly market or promote any of our products, we and our partners are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws may include, without limitation: (a) federal and state laws relating to the Medicare and Medicaid programs and any other federal healthcare program; (b) federal and state laws relating to healthcare fraud and abuse, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the federal False Claims Act (31 U.S.C. §§ 3729 et seq.), the False Statements Statute, (42 U.S.C. § 1320a-7b(a)), the Exclusion Laws (42 U.S.C. § 1320a-7), the federal Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the Anti-Inducement Statute (42 U.S.C. § 1320a-7a(a)(5)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a) and criminal laws relating to healthcare fraud and abuse, including but not limited to 18 U.S.C. Section 286 and 287, and the Health Insurance Portability and Accountability Act of 1996, or HIPAA (Pub.L. 104-191); (c) state laws relating to Medicaid or any other state healthcare or health insurance programs; (d) federal or state laws relating to billing or claims for reimbursement submitted to any third party payor, employer or similar entity, or patient; (e) any other federal or state laws relating to fraudulent, abusive or unlawful practices connected in any way with the provision or marketing of healthcare items or services, including laws relating to the billing or submitting of claims for reimbursement for any items or services reimbursable under any state, federal or other governmental healthcare or health insurance program or any private payor; and (f) federal and state laws relating to health information privacy and security, including HIPAA, and any rules or regulations promulgated thereunder, the Health Information Technology for Economic and Clinical Health Act, or HITECH, enacted as part of the American Recovery and Reinvestment Act of 2009 and any regulations promulgated thereunder. If our operations or our partners' operations and practices are found to be in violation of any of such laws or any other governmental regulations that apply to us or our partners, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Coverage and Reimbursement. Sales of our products marketed by our partners will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for certain medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued 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. Decreases in third-party reimbursement for our products or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have a material adverse effect on our sales, results of operations and financial condition. In addition, state and federal healthcare reform measures have been and 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 or additional pricing pressures.

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Marketing and Sales

Due to the nature of our partnerships and our current business relationships, we currently do not have or require an in-house commercial sales force or marketing function. We have a business development program that generates new business opportunities with pharmaceutical and biopharma companies, including delivering their proprietary drugs in transdermal systems to improve their therapeutic profile, extending the brand life of drugs by offering new dosage formats, and co-developing products that we have initiated. Historically, we have partnered with pharmaceutical companies to market and sell each of the products that we develop and manufacture. In most cases, we work together with our partners to decide which products to develop. However, in some instances we selectively develop products on our own prior to partnering with another company. In the future, we may build our own commercial sales and marketing capability in certain niche markets in order to capture more of the economic value of the products that we may develop. We may also enter into co-promotion agreements for certain of our products with our partners. We will continue to pursue strategic alliances with partners who have significant marketing and distribution presence and expertise.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from other companies in numerous industries, including pharmaceuticals and drug delivery. We believe the key competitive factors that will affect the commercial success of our products and the development of our product candidates include onset of action, bioavailability, efficacy, compliance, cost, convenience of dosing, safety and tolerability profile.

Companies focused on delivering small molecules transdermally include 3M, Johnson & Johnson, Lohmann Therapies Systems, or LTS, Mylan, Hisamitsu, or Noven, and Actavis. Companies operating in the microneedle transdermal field include 3M, Zosano, Theraject and Fujifilm. Several academic institutions are also conducting research in the microneedle field. In addition to microneedle technologies, there are other methods of transdermal delivery under development for biologics, including heat ablation, laser, ultrasound and radio frequency. Companies developing and manufacturing transdermal systems for biologics include Becton Dickinson, Vyteris, and Zogenix. Some of these companies may be addressing the same therapeutic areas or indications as we are.

Our current products compete, and products in development will compete, in highly competitive markets against both transdermal products and products addressing similar patient and customer needs through other delivery forms. Clonidine TDS, Fentanyl TDS and our future ANDA products will have competition from other generic pharmaceutical companies, including Mylan and Actavis, both of which have their own transdermal manufacturing capability. Other manufacturers of fentanyl patches use a different technology than ours, and although fentanyl patches made with either technology have experienced manufacturing challenges, competitors may claim their technology is superior. The Crest Whitestrips products compete with teeth whitening products marketed by various private labels such as those at Walgreens and CVS.

Many of our existing and potential competitors have substantially greater financial, research and development, and human resources than we do, may succeed in obtaining patent protection before us, and have greater experience than we do commercializing products and developing product candidates, including obtaining FDA and other regulatory approvals for product candidates. Consequently, our competitors are applying significant resources and experience to the problems of drug delivery and transdermal drug delivery in particular. We cannot assure you that our transdermal delivery systems will compete effectively against existing and future transdermal or other delivery systems.

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Employees

As of January 31, 2014 we had 243 employees, including 29 in research and development, 196 in operations and 18 in general and administrative roles. From time to time, we also employ independent contractors to support our research and development and our administrative organizations. We also hire temporary employees when needed in our manufacturing and quality groups. None of our employees are represented by a collective bargaining unit, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

Legal Proceedings

Historically, there has been litigation surrounding the Fentanyl TDS product that we manufacture for Par, in which we are named as a co-defendant with Actavis. We have had 19 past legal proceedings related to this product. The settlement amounts were shared equally with our partner and were not material. Eighteen of the cases have been dismissed with prejudice, and one case is pending. On August 3, 2012, a wrongful death lawsuit was filed against us in the U.S. District Court for the Northern District of Texas, *Boudreaux vs. Corium International, Inc., et al.* Plaintiffs have alleged a family member died in connection with the use of Fentanyl TDS. The amount of the damages has not been specified. For this pending suit, we have insurance coverage up to $10 million with a maximum liability of $50,000 of out-of-pocket expense. We do not believe that the case has merit and plan to defend against this claim.

Facilities

Our principal executive offices and research and development operations are located in Menlo Park, California, in a 25,000 square foot building which houses full product research and development capabilities, including proprietary drug delivery research in novel polymer blending and formulations; system design and engineering; prototyping and pilot manufacturing; analytical, quality assurance and quality control; early nonclinical and clinical development; and regulatory capabilities for clinical development and pilot scale manufacture. We have been in our current Menlo Park location for seven years and the term of our current Menlo Park lease has been extended to December 2014. We are also evaluating opportunities for facility expansion.

Our manufacturing facilities are located in Grand Rapids, Michigan in three buildings comprising approximately 200,000 square feet. We manufacture all of our current commercial products at these facilities. We also perform process development, prototyping, pilot and commercial manufacturing and quality control in our labs in Grand Rapids. We are qualified for prescription transdermal, dermal, mucosal and wound care products as well as OTC products. The facility is FDA and DEA registered and ISO9001 and ISO13485 certified.

We lease two of our three existing buildings in Grand Rapids on a long term basis. One building is dedicated exclusively to shipping and receiving, inventory and warehousing, but the space has been improved for multipurpose use. Our warehouse lease will expire in 2015. The other two buildings house all commercial manufacturing as well as administrative offices. We also own a four acre lot across the street from the commercial manufacturing operations for planned future expansion.

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MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our executive officers and directors as of December 31, 2013:

Name	Age	Position(s)
Peter D. Staple	62	President, Chief Executive Officer and Director
Robert S. Breuil	52	Chief Financial Officer
Parminder Singh	50	Chief Technology Officer and Vice President, Research and Development
David Greenwood[1]	62	Director, Executive Chairman
Bhaskar Chaudhuri[1][3]	59	Director
Gary W. Cleary	71	Director
Ronald Eastman[2][3]	61	Director
Phyllis Gardner	63	Director
John W. Kozarich	64	Director
Robert W. Thomas[1][2]	52	Director
Daniel G. Welch[2][3]	56	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Governance Committee.

Executive Officers

Peter D. Staple. Mr. Staple has served as our President, Chief Executive Officer and a director on our board since March 2008. He previously served as Chief Executive Officer of BioSeek, Inc., a drug discovery company applying predictive human biology, from 2002 to 2007 and was a director at BioSeek from 2002 to 2008. Prior to BioSeek, starting in 1994, he had various positions at ALZA Corporation, an early leader in the field of oral and transdermal drug delivery, from 1994 to 2001, most recently as Executive Vice President, Chief Administrative Officer and General Counsel, until ALZA's merger with Johnson & Johnson, or J&J, in 2001. Prior to joining ALZA, Mr. Staple served in senior positions at Cetus and Chiron Corporations, each a biotechnology company. Prior to entering the biotechnology industry, Mr. Staple practiced corporate and securities law with Heller Ehrman LLP, a law firm. Mr. Staple serves as chairman of the board of directors of Depomed, Inc. He holds B.A. and J.D. degrees from Stanford University. Our board believes that Mr. Staple's experience in the biotechnology and drug delivery businesses and management expertise qualify him to serve as a member of the board.

Robert S. Breuil. Mr. Breuil joined Corium in September 2012. Prior to that, he served as the Chief Financial Officer of Codexis, Inc., a developer of biocatalysts for the pharmaceutical and fine chemical production industries, from 2006 to September 2009. From 2002 to 2005, Mr. Breuil was the Chief Financial Officer of Aerogen, Inc., a specialty pharmaceutical company focusing on the field of aerosolized drug delivery, which was acquired by Nektar Therapeutics in October 2005. Prior to Aerogen, Mr. Breuil worked at ALZA, where he held numerous positions including Director of Corporate Planning and Analysis and Controller. In 2001, ALZA was acquired by J&J and Mr. Breuil stayed on as Controller until joining Aerogen in 2002. Before his industry experience, he served for eight years as a naval officer and aviator. Mr. Breuil received a B.S. from the United States Naval Academy and an M.B.A. from the Stanford Graduate School of Business.

Parminder Singh, Ph.D. Dr. Singh joined Corium in 2002. Prior to working at Corium, Dr. Singh held research and development and senior management positions at Novartis International AG, an international

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pharmaceutical company, Ciba-Geigy AG, a pharmaceutical company that merged into Novartis and Vyteris, Inc., a specialty pharmaceutical company developing and producing transdermal systems. Dr. Singh holds a B.Pharm and an M.Pharm from Punjab University in India. He received his Ph.D. in Pharmaceutics from the University of Queensland, Australia and completed his post-doctorate fellowship at the University of California, San Francisco. He is a member of the American Association of Pharmaceutical Scientists and the Controlled Release Society.

Directors

David L. Greenwood. Mr. Greenwood has served on our board of directors since December 2010, and as our Executive Chairman since June 2012. Beginning in July 2013, Mr. Greenwood became a full time employee of our company, with primary responsibility in strategic positioning and financing. He is the former President, Chief Executive Officer, Chief Financial Officer and Director of Geron where he worked from 1995 until December 2011. He was previously on the board of directors of Geron's wholly-owned subsidiary, Geron Bio-Med Limited, Geron's majority-owned subsidiary, TA Therapeutics, Ltd., ViaGen, Inc., and Clone International. He also served on the Board of Regents for Pacific Lutheran University. From 1979 until joining Geron, Mr. Greenwood held various positions with J.P. Morgan & Co. Incorporated, an international banking firm. Mr. Greenwood holds a B.A. from Pacific Lutheran University and a M.B.A. from Harvard Business School. Our board believes that Mr. Greenwood's financial and business expertise in the biotech industry qualify him to serve as a member of the board.

Bhaskar Chaudhuri, Ph.D. Dr. Chaudhuri has served on our board of directors since February 2010. He has been an operating partner of Frazier Healthcare since July 2011. He served as President of Valeant Pharmaceuticals International, or Valeant, a pharmaceutical company with a diverse range of products, from January 2009 to September 2010. Prior to Valeant, Dr. Chaudhuri served for seven years as Chief Executive Officer and President of Dow Pharmaceutical Sciences, Inc., a dermatology company specializing in the development of topical products that was acquired by Valeant. Before joining Dow, he served as General Manager of the Dermatology Division of Mylan Laboratories, and as Executive Vice President of Scientific Affairs at Bertek Pharmaceuticals, a subsidiary of Mylan, where he was responsible for research and development activities as well as certain of the company's manufacturing operations. Prior to this, he served as Vice President of Research and Development at Penederm, Inc., a skin-products and drug delivery company. He sits on the board of directors at IGI Laboratories, Inc. and Silvergate Pharmaceuticals, Inc. Dr. Chaudhuri holds a B.Pharm and an M.Pharm from Jadavpur University in India and a Pharm.D from the University of Louisiana. Our board believes that Dr. Chaudhuri's industry management experience gives him extensive product development and commercialization knowledge which qualifies him to serve as a member of the board.

Gary W. Cleary, Ph.D. Dr. Cleary has served on our board of directors since 2002. Dr. Cleary is a co-founder and Scientific Advisor of Corium. During his career, he held research and management positions at the FDA, ALZA, Key Pharmaceuticals, Genentech, Inc., and Cygnus, Inc., a company that developed the Ortho-Evra Patch and self-monitoring devices for glucose measurements. Dr. Cleary founded Cygnus in 1985 and served as its President, Chairman and Scientific Advisor. Early in his career, Dr. Cleary served for three years in the U.S. Public Health Service. Dr. Cleary is a Fellow of the American Association of Pharmaceutical Scientists and the American Institute of Medical and Biomedical Engineering and past president of the Controlled Release Society. Dr. Cleary is currently a member of Rutgers University's Biomedical Engineering Advisory Board, and the Pharmaceutical Advisory Boards of the University of California, San Francisco, the University of Pacific and Appian Labs, LLC. Dr. Cleary earned a Pharm.D. degree from the University of California, San Francisco, an M.B.A. in health sciences from the University of Miami, and a Ph.D. in pharmaceutics from Rutgers University. Our board believes that Dr. Cleary's deep institutional knowledge of Corium and our technologies and his scientific expertise qualify him to serve as a member of the board.

Ronald Eastman. Mr. Eastman has served on our board of directors since 2007. Mr. Eastman joined Essex Woodlands Health Ventures, or Essex Woodlands, in October 2006, as a managing director. Prior to joining

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Essex Woodlands, Mr. Eastman was Chief Executive Officer at Rinat Neuroscience, a private biotech company spun out of Genentech in late 2001. Rinat was acquired by Pfizer in 2006. From 1996 to 1999 he was Chief Executive Officer at Geron Corporation, or Geron, a biotech company in the fields of regenerative medicine and cancer. From 1999 to 2002, Mr. Eastman had a leadership position with HCORP, a hospital-based, interactive patient services company, which was acquired by a competitor in 2001. He began his career at American Cyanamid Company, which was acquired by American Home Products (now Pfizer), where he held jobs with increasing responsibility. He currently serves as Chairman of the board of directors at Elusys Therapeutics, and several other private companies. Mr. Eastman served on the board of directors at The Buck Institute, the largest non-profit research institute in the United States studying diseases of aging. Mr. Eastman holds a B.A. from Williams College and an M.B.A. from Columbia University. Our board believes that Mr. Eastman's experience in the biotech industry and management expertise qualify him to serve as a member of the board.

Phyllis Gardner, M.D. Dr. Gardner has served on our board of directors since 2007. Dr. Gardner is currently a Professor of Medicine at Stanford University, where she has held several positions since she began there in 1984, including Senior Associate Dean for Education and Student Affairs. She has also been an adjunct partner at Essex Woodlands since 1999. From 1994 to 1996, she took a leave of absence to work at ALZA as a Principal Scientist, Vice President of Research and as Head of ALZA Technology Institute. She has received numerous national awards and honors and serves on the board of directors of Revance Therapeutics, Dr. Gardner holds a B.S. from the University of Illinois and an M.D. from Harvard Medical School. She trained in internal medicine at Massachusetts General Hospital, followed by a Chief Residency at Stanford University Medical Center. She completed research fellowships at the College of Physicians and Surgeons at Columbia University and University College, London, U.K. Our board believes that Dr. Gardner's expertise in medicine, pharmacology and drug delivery systems qualify her to serve as a member of the board.

John W. Kozarich, Ph.D. Dr. Kozarich has served on our board of directors since 2007. He has been the President, Chief Science Officer and chairman of the board of directors of ActivX Biosciences, Inc., a company specializing in drug delivery technology, since February 2001. Dr. Kozarich previously served as a Vice President at Merck Research Laboratories, from 1992 to 2001 where he was responsible for programs including antimicrobial drug discovery, enzymology, 5a-reductase biology, lipid biochemistry, nuclear receptors, ion channels and structural biology. Previously, Dr. Kozarich held faculty positions at the University of Maryland, College Park, and Yale University School of Medicine. He also served as Vice President, Research and Development at Alkermes, a biotechnology company that develops products based on sophisticated drug delivery technologies. He is the chairman of the board of directors of Ligand Pharmaceuticals, Inc., the Chief Pharmaceutical Advisor to KinDex Therapeutics, Inc., and the Chief Scientific Advisor for Kyorin Pharmaceutical Co. Dr. Kozarich has also served on numerous government and academic committees. Dr. Kozarich received a B.S. in chemistry from Boston College and a Ph.D. in biological chemistry from the Massachusetts Institute of Technology, where he was a National Science Foundation pre-doctoral Fellow. He was a National Institutes of Health post-doctoral Fellow at Harvard University. Our board believes that Dr. Kozarich's experience in biomedical research and leadership experience in the pharmaceutical industry qualify him to serve as a member of the board.

Robert W. Thomas. Mr. Thomas has served on our board of directors since 2007, and from 2007 to 2008 served as our Chief Executive Officer. Since March 2013, he has been a partner at Aphelion Capital, LLC, a venture capital firm focused on medical technology. From 1998 until 2006, he served as the President, Chief Executive Officer and member of the board directors of Fox Hollow Technologies, Inc. a medical device company specializing in the design, development and manufacture of devices for the treatment of peripheral artery disease, and prior to serving as President and Chief Executive Officer, Mr. Thomas was Vice President of Operations for Fox Hollow. From 1997 through 1998, Mr. Thomas was Vice President of Operations for the women's health company, Conceptus Inc., and prior to that was the founder of Thomas Medical, Inc., a private medical device company that was ultimately sold to GE Healthcare. Mr. Thomas also was a manager and director of operations at Access Devices, where he worked from 1984 to 1990,

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which was acquired by Baxter Healthcare. From 2006 until its acquisition by Stryker in 2011, Mr. Thomas served as a member of the board of directors of Concentric Medical, Inc. From 2009 until January 2013, Mr. Thomas served as a member of the board of directors of CV Ingenuity Corp. and Mr. Thomas currently serves as a member of the board of directors for TriVascular, Inc. Mr. Thomas received a B.A. from Ursinus College. Our board believes that Dr. Thomas' extensive industry management and operations background experience qualify him to serve as a member of the board.

Daniel G. Welch. Mr. Welch has served on our board of directors since 2007. Mr. Welch serves as Chairman, Chief Executive Officer and President of InterMune Inc., a biotech company focused on research, development, and commercialization of therapies for pulmonology and fibrotic diseases, and as a member of the board of directors of InterMune, where he has worked since 2003. Before joining InterMune, Mr. Welch served as a consultant to Warburg Pincus LLC, a global private equity investment firm. From 2002 to 2003, Mr. Welch served as chairman and chief executive officer of Triangle Pharmaceuticals, Inc., a pharmaceutical company. From 2000 to 2002, Mr. Welch served as president of the pharmaceutical division of Elan Corporation, plc. From 1987 to 2000, Mr. Welch served in various senior management roles at Sanofi (now Sanofi-Aventis) and its predecessor companies Sanofi and Sterling Winthrop. From 1980 to 1987, Mr. Welch was with American Critical Care, a division of American Hospital Supply. Mr. Welch has served on the board of directors of Hyperion Therapeutics, Inc. since August 2012 and on the board of directors of Seattle Genetics since 2006, Mr. Welch holds a B.B.A. from the University of Miami and an M.B.A. from the University of North Carolina. Our board believes that Mr. Welch's deep understanding of operational and financial aspects of pharmaceutical companies qualify him to serve as a member of the board.

Appointment of Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

Board Composition

Our board of directors may establish the authorized number of directors from time to time by resolution. Our board of directors currently consists of nine members. Our current certificate of incorporation and a voting agreement among certain investors provide for up to six directors to be designated by holders of our preferred stock. Mr. Eastman, Dr. Gardner and Mr. Welch are the board designees of holders of our preferred stock and the remaining seats reserved for designees of holders of the preferred stock are vacant.

The voting agreement and the provisions of our certificate of incorporation by which Mr. Eastman, Dr. Gardner and Mr. Welch were elected will terminate in connection with our initial public offering and there will be no contractual obligations regarding the election of our directors. Each of our current directors will continue to serve until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

Because Mr. Eastman and his affiliates beneficially own more than a majority of our outstanding voting power, we are eligible to be a "controlled company" under the corporate governance rules of the NASDAQ Global Market. A company that avails itself of the controlled company exemption is not required to have a majority of its board of directors to be independent, nor is it required to have a compensation committee, a nominating and corporate governance committee or an independent nominating function, among other stock exchange listing requirements for companies that are not controlled companies. We have no current plans to avail ourselves of this exemption, and plan to comply with the stock exchange listing requirements for companies that are not controlled companies, but we could elect in the future to avail ourselves of this exemption.

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Classified Board

Our restated certificate of incorporation and restated bylaws that will be in effect upon the completion of this offering provide for a classified board of directors consisting of three classes of directors, each serving staggered three-year terms. Our directors will be divided among the three classes as follows:

Class I directors, whose initial term will expire at the annual meeting of stockholders to be held in 2015, will consist of and ;

Class II directors, whose initial term will expire at the annual meeting of stockholders to be held in 2016, will consist of and ; and

Class III directors, whose initial term will expire at the annual meeting of stockholders to be held in 2017, will consist of and .

Directors in a particular class will be elected for three-year terms at the annual meeting of stockholders in the year in which their terms expire. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Each director's term continues until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

Our restated certificate of incorporation and restated bylaws that will be in effect upon the completion of this offering authorize only our board of directors to fill vacancies on our board of directors. Any additional directorships resulting from an increase in the authorized number of directors would be distributed among the three classes so that, as nearly as possible, each class would consist of one-third of the authorized number of directors.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See "Description of Capital Stock Anti-Takeover Provisions Restated Certificate of Incorporation and Restated Bylaw Provisions."

Director Independence

Our common stock will be listed on the NASDAQ Global Market. The listing rules of this stock exchange generally require that a majority of the members of a listed company's board of directors be independent within specified periods following the closing of an initial public offering. Our board of directors has determined that none of our non-employee directors has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the NASDAQ Global Market.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 within the one year transition period provided by Rule 10A-3 and the current NASDAQ rules.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and governance committee. Each of these committees will have the composition and responsibilities described below as of the closing of our initial public offering. Members serve on these committees until their resignations or until otherwise determined by our board of directors.

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Audit Committee

Our audit committee is comprised of Dr. Chaudhuri, Mr. Thomas and Mr. Greenwood. Mr. Greenwood is the chairman of our audit committee. Dr. Chaudhuri and Mr. Thomas each meet the requirements for independence under the current NASDAQ and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Mr. Greenwood is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to submit anonymously concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- reviewing material related party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee is comprised of Mr. Eastman, Mr. Thomas and Mr. Welch. Mr. Welch is the chairman of our compensation committee. Each member of this committee meets the requirements for independence under the current NASDAQ and SEC rules and regulations and is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1984, as amended, or the Code. Our compensation committee is responsible for, among other things:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- reviewing and approving, or recommending that our board of directors approve, the terms of any compensatory agreements with our executive officers;
- administering our stock and equity incentive plans;

reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans; and

reviewing our overall compensation philosophy.

Nominating and Governance Committee

Our nominating and governance committee is comprised of Dr. Chaudhuri, Mr. Eastman and Mr. Welch. Dr. Chaudhuri is the chairman of our nominating and governance committee. Each member of the nominating and governance committee meets the requirements for independence under the current NASDAQ rules and regulations. Our nominating and governance committee is responsible for, among other things:

identifying and recommending candidates for membership on our board of directors;

developing, reviewing and recommending our corporate governance guidelines and policies;

reviewing proposed waivers of the code of conduct for directors and executive officers; and

assisting our board of directors on corporate governance matters.

We have made our committee charters available on our website at www.coriumgroup.com.

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Compensation Committee Interlocks and Insider Participation

None of our executive officers has served as a member of the board of directors, or as a member of the compensation or similar committee, of any entity that has one or more executive officers who served on our board of directors or compensation committee during fiscal 2013.

Code of Business Ethics and Conduct

In connection with our initial public offering, our board of directors will adopt a code of business ethics and conduct that will apply to all of our employees, officers and directors. The full text of our code of business conduct will be posted on the Investor Relations section of our website. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We intend to disclose future amendments to certain provisions of our code of business conduct, or waivers of these provisions, on our website or in public filings.

Director Compensation

The following table presents the total compensation earned in fiscal 2013 for each member of our board of directors, except for our CEO, Mr. Staple, who receives no additional compensation for his service as a director. Other than as described in the table below, none of our directors, except Mr. Staple, received fees or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) or any equity or non-equity awards in fiscal 2013. Mr. Staple's compensation is described below in the section titled "Executive Compensation."

Director Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)	All Other Compensation ($)	Total ($)
Bhaskar Chaudhuri	15,000	55,619		70,619
Gary W. Cleary			35,315(3)	35,315
Ronald Eastman				
Phyllis Gardner	11,500			11,500
David Greenwood	109,063	223,607	62,361(4)	395,031
John Kozarich	13,500	6,955(5)		20,455
Robert W. Thomas	19,000			19,000
Daniel G. Welch	16,000			16,000

(1) The amounts reported in the Option Awards column represent the grant date fair market value of the stock options granted under the 2012 Equity Incentive Plan during fiscal 2013 as computed in accordance with ASC 718. The assumptions used in calculating the dollar amount recognized for financial statement reporting purposes of the equity awards reported in this column are set forth in note 11 to our financial statements included in this prospectus. Note that the amounts reported in the column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the directors from the stock options.

(2) As of September 30, 2013, Mr. Greenwood held options to purchase up to 1,388,862 shares of common stock, Mr. Thomas held options to purchase up to 359,650 shares of common stock and Dr. Chaudhuri, Dr. Gardner, Dr. Kozarich and Mr. Welch each held options to purchase up to 345,460 shares of common stock.

(3) Represents compensation paid to Dr. Cleary for services as an employee. Dr. Cleary received no compensation for services as a director.

(4) Represents compensation paid to Mr. Greenwood for services as an employee.

(5) Includes the fair value of an option to purchase shares of common stock that was issued in an option exchange in November 2012.

In January 2014, we granted stock options to most of our directors in order to bring their total equity grants to competitive levels. These option grants, other than those made to Mr. Greenwood, vest monthly over a three-year period following the grant date of January 26, 2014. Mr. Greenwood's option to purchase 325,000 shares of common stock vests monthly over a four-year period following the date of grant of January 27, 2014. Mr. Greenwood's option to purchase 250,000 shares of common stock vests monthly

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over a four-year period following the effective date of our initial public offering. All of these option grants have an exercise price of $0.41 per share and were granted in the following amounts:

Name	Number of Shares Underlying Option Grants
Bhaskar Chaudhuri	80,000
Phyllis Gardner	80,000
David Greenwood	575,000
John Kozarich	80,000
Robert W. Thomas	80,000
Daniel G. Welch	80,000

Our board of directors adopted a compensation policy applicable to all of our non-employee directors for cash retainers. This compensation policy provides that each such non-employee director will receive the following compensation for board of director services:

an annual cash retainer for serving on the board of directors of $12,000;

a fee of $1,500 paid for each board meeting attended;

a fee of $500 paid for each committee meeting attended; and

a fee of $500 paid for each telephonic meeting attended.

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EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure set forth information about the compensation provided to our senior executive officers during fiscal 2013. These executive officers, who include our principal executive officer and the two other most highly-compensated executive officers who were serving as executive officers as of September 30, 2013, the end of our last completed fiscal year were:

Peter D. Staple, President, Chief Executive Officer and Director;

Robert S. Breuil, Chief Financial Officer; and

Parminder Singh, Chief Technology Officer and Vice President, Research and Development.

We refer to these individuals in this section as our "Named Executive Officers."

Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to, earned by, and paid to our Named Executive Officers during fiscal 2013.

Name and Principal Position	Salary ($)	Option Awards ($)(1)	Non-equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)	Total ($)
Peter D. Staple *President, Chief Executive Officer and Director*	418,591	319,816		3,619[3]	932,026
Robert S. Breuil *Chief Financial Officer*	343,942	291,600		7,595[4]	663,137
Parminder Singh *Chief Technology Officer and Vice President, Research and Development*	282,140	153,534[5]		2,859[6]	488,533

(1) The amounts reported in the Option Awards column represent the grant date fair market value of the stock options granted to the Named Executive Officers during fiscal 2013 as computed in accordance with ASC 718. The assumptions used in calculating the dollar amount recognized for financial statement reporting purposes of the equity awards reported in this column are set forth in note 11 to our financial statements included in this prospectus. Note that the amounts reported in the column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the Named Executive Officers from the options.

(2) Bonuses to be paid for fiscal 2013 have not yet been determined.

(3) Includes life insurance premiums of $320 and contributions to the officer's 401(k) plan account of $3,299.

(4) Includes pre-employment consulting fees of $7,275 and life insurance premiums of $320.

(5) Includes the fair value of an option to purchase shares of common stock that was issued in an option exchange in November 2012.

(6) Includes life insurance premiums of $320 and contributions to the officer's 401(k) plan account of $2,539.

In January 2014, the compensation committee of our board of directors granted stock options to each of our Named Executive Officers, as well as to a significant number of our other employees. The grants to our Named Executive Officers, in connection with the determination of their total compensation, were intended to strengthen the long-term component of each such officer's compensation, provide further retention incentives for these officers and emphasize incentive-based compensation. The January 2014 option grants

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vest monthly over a four-year period following the grant date of January 27, 2014, have an exercise price of $0.41 per share, and were granted to each of our Named Executive Officers in the following amounts:

Name	Number of Shares Underlying Option Grants
Peter D. Staple	1,280,000
Robert S. Breuil	420,000
Parminder Singh	350,000

Outstanding Equity Awards at Year-End Table

The following table provides information regarding each unexercised stock option held by our Named Executive Officers as of September 30, 2013.

			Option Awards			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Peter D. Staple	08/26/2008	03/26/2008	3,578,600		$ 0.210	08/25/2018
	12/13/2012	12/13/2012	81,164	351,715(1)(2)	$ 0.220	12/12/2022
	12/13/2012	N/A		1,111,089(3)	$ 0.220	12/12/2022
	02/20/2013	02/20/2013	63,128	369,751(2)(4)	$ 0.220	02/19/2023
Robert S. Breuil	12/13/2012	09/04/2012	450,000	1,350,000(1)(2)	$ 0.220	12/12/2022
Parminder Singh	07/21/2004	09/30/2003	30,000		$ 0.234	07/20/2014
	09/30/2004	03/31/2004	30,000		$ 0.234	09/29/2014