Corium International, Inc.
Form S-1/A
March 24, 2014

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As filed with the Securities and Exchange Commission on March 24, 2014

Registration No. 333-194279

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO

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

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

Please send copies of all communications to:

Cynthia Clarfield Hess **Robert A. Freedman** **Effie Toshav** **Fenwick & West LLP** **801 California Street** **Mountain View, California 94041** **(650) 988-8500**	**Robert S. Breuil** **Chief Financial Officer** **Corium International, Inc.** **235 Constitution Drive** **Menlo Park, California 94025** **(650) 298-8255**	**B. Shayne Kennedy** **Daniel E. Rees** **Latham & Watkins LLP** **650 Town Center Drive, 20th Floor** **Costa Mesa, California 92626** **(714) 540-1234**

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	**Amount to be Registered(1)**	**Proposed Maximum Offering Price Per Unit(2)**	**Proposed Maximum Aggregate Offering**	**Amount of Registration Fee(3)**

			Price(1)(2)	
Common Stock, $0.001 par value	6,325,000	$12.00	$75,900,000	$9,776

(1) Includes 825,000 additional shares that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.

(3) The Registrant previously paid $6,440 of the total registration fee in connection with the prior filing of this Registration Statement. In accordance with Rule 457(a), an additional registration fee of $3,336 is being paid in connection with this amendment to the Registration Statement.

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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SUBJECT TO COMPLETION, DATED MARCH 24, 2014

PRELIMINARY PROSPECTUS

5,500,000 Shares

Corium International, Inc.

Common Stock

We are offering 5,500,000 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 $10.00 and $12.00 per share. We have applied 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[(1)]	$	$
Proceeds to Corium before Expenses	$	$

(1) We refer you to "Underwriting" on page 141 of this prospectus for additional information regarding underwriting compensation.

Certain of our existing equity holders and their affiliated entities, including an equity holder affiliated with one of our directors, have indicated an interest in purchasing up to $8.5 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any of these parties, or any of these parties may determine to purchase more, fewer or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

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 825,000 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 developed two additional generic products that we have partnered with Teva. One is a three-day generic transdermal product for the prevention of nausea and vomiting associated with motion sickness, for which the ANDA is currently pending approval 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 2015, if approved. The second is a three-to-four-day generic transdermal product for treatment of a urologic condition, which was approved in March 2014. Teva is currently reviewing the strategy and potential timing for launch of this product.

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.

- **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.

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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;

- 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.

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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	5,500,000 shares
Common stock to be outstanding after our initial public offering	16,707,765 shares
Option to purchase additional shares of common stock offered by us	825,000 shares
Use of proceeds	We expect that our net proceeds from the sale of the common stock that we are offering will be approximately $53.7 million, assuming an initial public offering price of $11.00 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 11,207,765 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 $11.00 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:

- 1,530,075 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013, with a weighted-average exercise price of $2.18 per share;

- 467,089 shares of common stock issuable upon the exercise of options granted subsequent to January 1, 2014, with an exercise price of $4.14 per share;

- 120,464 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 $9.26 per share, that do not expire upon the completion of this offering;

- 8,118 shares of common stock issuable upon the exercise of a warrant to purchase common stock that was outstanding as of December 31, 2013, with an exercise price of $0.10 per share, that does not expire upon the completion of this offering;

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- 1,000,000 shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan that will become effective in connection with this offering;

- 310,000 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

- 55,867 shares of common stock available for future issuance as of March 21, 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 or gives effect to:

- a 10.1-for-one reverse stock split of our outstanding common stock that was effected on March 21, 2014;

- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 3,567,807 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 120,464 shares of common stock effective immediately prior to the closing of this offering;

- the automatic net exercise of warrants to purchase an aggregate of 1,061,777 shares of common stock effective immediately prior to the closing of this offering, which is based on an assumed initial public offering price of $11.00 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 825,000 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 2,036,555 shares of our common stock immediately prior to the closing of this offering or into shares of our Series C preferred stock convertible into 2,036,555 shares of our common 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 3,387,146 shares of our common stock immediately prior to the closing of this offering or into shares of 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) convertible into 3,387,146 shares of our common stock 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 1,077,809 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)	$	(2.47)	$	(6.24)	$	(0.65)	$	(0.94)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted(1)		2,200,727		2,222,981		2,212,035		2,229,852
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1):			$	(2.40)			$	(0.26)
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1) :				5,790,792				10,143,555

(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	$ 2,191	$ 55,856
Working capital	5,958	1,336	55,001
Total assets	39,484	34,259	87,924
Preferred stock warrant liability	603		
Subordinated note embedded derivative liability	6,338		
Deferred contract revenues, current and long-term portions	5,976	5,976	5,976
Debt, current and long-term portions	65,903	40,021	40,021
Recall liability, current and long-term portions	4,552	4,552	4,552
Convertible preferred stock	57,261		
Redeemable common stock	3,224		
Total stockholders' equity (deficit)	(124,620)	(24,952)	28,713

(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 including $11.6 million of accrued interest into 5,423,701 shares of common stock and the related reclassification of the subordinated note embedded derivative liability to additional paid-in capital, (iv) the repurchase of 1,077,809 shares from our founders and the related reclassification of our redeemable common stock to additional paid-in capital and (v) the issuance of 1,061,777 shares of common stock upon the automatic net exercise of certain outstanding warrants based on the assumed initial offering price of $11.00 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 5,500,000 shares of common stock in this offering, at an assumed initial public offering price of $11.00 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 $11.00 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 $5.1 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 $10.2 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 Advanced 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 late 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;

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 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 one partnered product candidate that is the subject of an ANDA submitted by our partner 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 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 54% 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 $9.68 per share, because the assumed initial public offering price of $11.00, the midpoint of the price range on the cover page of this prospectus, 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;

- 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 11,207,765 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 5,500,000 shares of common stock in this offering will be approximately $53.7 million, or approximately $62.1 million if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of $11.00 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 $11.00 per share would increase (decrease) the net proceeds to us from this offering by $5.1 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 $10.2 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 $15 million to $18 million for Phase 2 clinical trials for MicroCor hPTH(1-34) and Corplex Tamsulosin;
- approximately $15 million to $18 million for scale up of production capability for our MicroCor products;
- approximately $5 million to $7 million for formulation and development of our proprietary Corplex products;
- approximately $2 million to $4 million for advancement of our MicroCor technology;
- approximately $5.2 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 5,423,701 shares of common stock and the related reclassification of the subordinated note embedded derivative liability to additional paid-in capital, (iv) the repurchase of 1,077,809 shares from our founders and the related reclassification of our redeemable common stock to additional paid-in capital, (v) the issuance of 1,061,777 shares of common stock upon the automatic net exercise of certain outstanding warrants, based on the assumed initial offering price of $11.00 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 5,500,000 shares of common stock in this offering at an assumed initial public offering price of $11.00 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	$ 2,191	$ 55,856
Debt, current and long-term portions	65,903	40,021	40,021
Recall liability, current and long-term portions	4,552	4,552	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, 347,945 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; 5,000,000 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 1,884,370 shares issued and outstanding, actual; 150,000,000 shares authorized, pro forma and pro forma as adjusted; 11,207,765 shares issued and outstanding, pro forma; 16,707,765 shares issued and outstanding, pro forma as adjusted	2	11	17
Additional paid-in capital	(30,101)	69,558	123,217
Accumulated deficit	(94,521)	(94,521)	(94,521)
Total stockholders' equity (deficit)	(124,620)	(24,952)	28,713
Total capitalization	$ 13,261	$ 19,621	$ 73,286

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by $5.1 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 $10.2 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 $8.4 million, after deducting estimated underwriting discounts and commissions, and we would have 17,532,765 shares of our common stock issued and outstanding, pro forma as adjusted.

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The table above excludes the following shares:

- 1,530,075 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013, with a weighted-average exercise price of $2.18 per share;
- 467,089 shares of common stock issuable upon the exercise of options granted subsequent to January 1, 2014, with an exercise price of $4.14 per share;
- 120,464 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 $9.26 per share, that do not expire upon the completion of this offering;
- 8,118 shares of common stock issuable upon the exercise of a warrant to purchase common stock that was outstanding as of December 31, 2013, with an exercise price of $0.10 per share, that does not expire upon the completion of this offering;
- 1,000,000 shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan that will become effective in connection with this offering;
- 310,000 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
- 55,867 shares of common stock available for future issuance as of March 21, 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 $(31.6) million, or $(2.82) 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 5,423,701 shares of common stock and the related reclassification of the subordinated note embedded derivative liability to additional paid-in capital, (iv) the repurchase of 1,077,809 shares from our founders and the related reclassification of our redeemable common stock to additional paid-in capital, and (v) the issuance of 1,061,777 shares of common stock upon the automatic net exercise of certain outstanding warrants, based on the assumed initial offering price of $11.00 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 5,500,000 shares of common stock at an assumed initial public offering price of the common stock of $11.00 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 $22.1 million, or $1.32 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $4.14 per share to our existing stockholders and an immediate dilution of $9.68 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			$	11.00
Pro forma net tangible book value per share as of December 31, 2013	$	(2.82)		
Increase in pro forma net tangible book value per share attributable to investors purchasing shares in our initial public offering		4.14		
Pro forma as adjusted net tangible book value per share after our initial public offering				1.32
Dilution in pro forma net tangible book value per share to investors in this offering			$	9.68

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) our pro forma as adjusted net tangible book value per share after our initial public offering by $0.31, 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 $0.48 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 $0.48 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 $2.12 per share, and the dilution in pro forma net tangible book value per share to investors in our initial public offering would be $8.88 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 $11.00 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
	Number	Percent	Amount (In thousands)	Percent	Per Share
Existing stockholders	11,207,765	67%	$ 53,386	47%	$ 4.76
New investors	5,500,000	33	60,500	53%	11.00
Total	16,707,765	100%	$ 113,886	100%	

A $1.00 increase (decrease) in the assumed initial public offering price of $11.00 per share would increase (decrease) total consideration paid by new investors by $5.1 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 63.3% and our new investors would own 36.7% of the total number of shares of our common stock outstanding after our initial public offering.

The above table and discussions are based on 16,707,765 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:

- 1,530,075 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2013, with a weighted-average exercise price of $2.18 per share;
- 467,089 shares of common stock issuable upon the exercise of options granted subsequent to January 1, 2014, with an exercise price of $4.14 per share;
- 120,464 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 $9.26 per share, that do not expire upon the completion of this offering;
- 8,118 shares of common stock issuable upon the exercise of a warrant to purchase common stock that was outstanding as of December 31, 2013, with an exercise price of $0.10 per share, that does not expire upon the completion of this offering;
- 1,000,000 shares of our common stock reserved for future issuance under our 2014 Equity Incentive Plan that will become effective in connection with this offering;

- 310,000 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

- 55,867 shares of common stock available for future issuance as of March 21, 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	(1,062)
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)	$	(2.47)	$	(6.24)	$	(0.65)	$	(0.94)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted(1)		2,200,727		2,222,981		2,212,035		2,229,852