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

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

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Corium International, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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Chief Executive Officer
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

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

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

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

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

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

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

SUBJECT TO COMPLETION, DATED MARCH 3, 2014

PRELIMINARY PROSPECTUS

Shares

Corium International, Inc.

Common Stock

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

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

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

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

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

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

Joint Book-Running Managers

Jefferies **Leerink Partners**

Co-Managers

Needham & Company **FBR**

Prospectus dated , 2014

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

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

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

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PROSPECTUS SUMMARY

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

CORIUM INTERNATIONAL, INC.

Overview

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

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

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

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

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

Transdermal Drug Delivery Industry

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

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

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

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

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

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

Our Solution

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

Corplex Technology

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

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

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

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

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

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

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

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MicroCor Technology

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

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

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

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

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

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

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

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

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Our Products and Partners

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

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

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

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

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

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

Our Strategy

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

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

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

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

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

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

Risks Related to Our Business

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

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

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

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

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

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

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

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

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

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

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

We face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate; to date we have settled 18 product liability claims, and we currently have one suit pending;

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

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

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

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

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

Our Corporate Information

We were incorporated in Michigan in 1995 as Corium Corporation and in 1996 as Converting Systems, Inc. In 2002, these companies were merged and re-named Corium International, Inc. and our place of incorporation changed to Delaware. Our principal executive offices are located at 235 Constitution Drive, Menlo Park, CA 94025, and our telephone number is (650) 298-8255. We have research and development operations and corporate offices in Menlo Park, California and pilot-scale and commercial-scale manufacturing facilities in Grand Rapids, Michigan. Our website address is www.coriumgroup.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

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

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

Emerging Growth Company

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

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

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

reduced disclosure about our executive compensation arrangements;

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

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

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

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THE OFFERING

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

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

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

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

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

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

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

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

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

the recapitalization as discussed in greater detail below;

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

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

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

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

Recapitalization

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

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

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SUMMARY FINANCIAL DATA

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

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

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

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

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

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

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

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

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RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

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

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

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

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

At any time, we or our partners may decide to discontinue the development of a marketed product or drug product candidate or not to continue commercializing a marketed product or a drug product candidate for a variety of reasons, including the appearance of new technologies that make our product obsolete, the position of our partner in the market, competition from a competing product, or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. If one of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The commercial use of our products and clinical use of our product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with Fentanyl TDS and Clonidine TDS, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in injury to a patient or even death. We have had 19 past legal proceedings related to Fentanyl TDS. Eighteen of the cases have been settled and dismissed with prejudice, and one case is pending. The complaint for the one pending product liability suit did not state a specified amount of compensatory or exemplary damages. We have insurance coverage up to $10 million dollars with a maximum liability of $50,000 of out-of-pocket expense for this claim. We cannot offer any assurance that we will not face other product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

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

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liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $10 million per occurrence and a $10 million annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of our products, approval of other product candidates, or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of our products and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, results of operations, financial condition and prospects.

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

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

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

For our products that are available only by prescription, successful sales by our partners depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If our products do not demonstrate superior efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

In addition, our MicroCor product candidates have been manufactured in small quantities for preclinical studies and early stage clinical trials. As we prepare for later stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our MicroCor product candidates. In order to conduct larger or late-stage scale clinical trials for a MicroCor product candidate and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to increase successfully the manufacturing capacity for any of such product candidates in a timely or cost-effective manner or at all. Significant scale-up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up the manufacture of any of our MicroCor product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting drug products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business.

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If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, although we have initiated Phase I clinical trials through self-funding, we will need to find a partner or partners for the commercialization of MicroCor hPTH(1-34) if we are to effectively compete in the target primary care market against generic medicines and drug delivery systems.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and experience, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

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

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern without additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for fiscal 2013 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

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

Our management, personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. As a public company, we will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures, including the implementation of new enterprise resource management software;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities for our products and product candidates effectively and in a cost-effective manner;
- manage our relationship with our partners related to the commercialization of our products and product candidates;
- manage our clinical trials effectively;
- manage our internal manufacturing operations effectively and in a cost-effective manner while increasing production capabilities for our current product candidates to commercial levels;
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

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

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

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on our management and scientific personnel, including our President and Chief Executive Officer, Peter Staple, our Chief Financial Officer, Robert Breuil, and our Chief Technology Officer and Vice President, Research and Development, Parminder Singh. The loss of the services of any of these individuals could impede, delay or prevent the continuing commercialization of our products and the development of our product candidates and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value

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

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. We do not currently have a chief medical officer, and we cannot assure you that, if we require such a position to be filled, we will be able to hire a qualified candidate for this position. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher-than-expected acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and

inability to retain key employees of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, results of operations, financial condition and prospects. We have no current plan, commitment or obligation to enter into any transaction described above.

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

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

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

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations, or CROs, may engage in fraudulent or other illegal activity. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have dismissed employees in the past for improper handling and theft of our product components, and although we reported their actions to all relevant authorities, any similar incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. In connection with the consummation of this offering, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

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

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

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

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

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Risks Related to Our Financial Position and Capital Requirements

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

Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. As a result, our independent re